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

January 3, 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))

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.

Reference is made to the Current Report on Form 8-K filed by Windtree Therapeutics, Inc. (the "Company") on December 21, 2018 with respect to execution of (i) an Agreement and Plan of Merger with CVie Investments Limited, an exempted company with limited liability incorporated under the laws of the Cayman Islands ("CVie"), pursuant to which WT Acquisition Corp., a wholly-owned subsidiary of the Company, merged with and into CVie (the "Merger"), with CVie surviving the merger as a wholly owned subsidiary of the Company, and (ii) a Securities Purchase Agreement and a Registration Rights Agreement with select institutional investors, whereby the Company agreed to issue and sell to the Investors an aggregate of 11,785,540 shares of Common Stock at a price per share of $3.3132, for an aggregate cash purchase price of approximately $39.0 million (the "Financing").

The Company will host a conference call and webcast for investors on Thursday, January 3, 2019 at 8:00 a.m. EST to discuss the Merger and the Financing and introduce its new products (including sharing topline phase 2b data in heart failure). The call will also cover the Company's plans and objectives for 2019. The live webcast, including a slide presentation, can be accessed at http://windtreetx.investorroom.com/events. To participate in the live call, dial (844) 802-2436 (domestic) or (412) 317-5129 (international). A replay of the conference call will be accessible one hour after completion through January 10, 2019 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference number 10127199. An archive of the webcast will be available on the Company's website at http://windtreetx.investorroom.com/events and a copy of the presentation can found at http://windtreetx.investorroom.com/corporate_presentation

A copy of the presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

The furnishing of the attached presentation is not an admission as to the materiality of any information contained therein. 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 (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise.

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 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, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Windtree Therapeutics, Inc. Corporate Presentation dated January 3, 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, potential strategic transactions and collaboration agreements, the success of the Company's product development activities, the timing of planned clinical trials, cash flows, future revenues, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement made by us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

SIGNATURES

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

Windtree Therapeutics, Inc.

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

Date: January 3, 2019

WINDTREE THERAPEUTICS™

Investor Conference Call
January 3, 2019

OTCQB:WINT

Forward-looking Statement

To the extent that statements in this presentation are not strictly historical, including statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this presentation are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made 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 Focused on Addressing the Company Needs While Creating an Opportunity to Strengthen Our Company

- Mid-2017: After completing the AEROSURF® Phase 2b, we needed to:
  - Develop a new, phase 3 Aerosol Delivery System (ADS) and execute an AEROSURF bridge study with the phase 3 ADS
  - Address the capital structure and non-program related cash burn

- In 2H 2017, we executed a financial restructuring initiative that resulted in:
  - Retirement of $25MM of debt
  - Lower non-program related cash burn
  - Additional but limited operating capital
- Development to complete Phase 2 required significant time and money

- In 2018, the Company successfully completed device validation of the phase 3 ADS and has been ready to go back into the clinic, but needed to address the following:

Intermediate Needs
- Funding for AEROSURF bridge study, ongoing operations and addressing existing obligations

Strategic Opportunities
- Diversify the portfolio beyond just AEROSURF
- Position the Company for a potential return to NASDAQ

- Throughout 2017 and into 2018, the company conducted extensive, formal business development and financing initiatives and explored numerous options to satisfy the above needs and opportunities. One particular opportunity presented itself as a very attractive option that we believe will significantly enhance the trajectory of the company

CVie Therapeutics

- Headquartered in Taipei, Taiwan with additional preclinical operations in Milan, Italy
- Privately held - investors included Kleiner Perkins Caufield Byers (KPCB), Bioengine, Lee's Pharm, Lilly Asia Ventures, Yuanta Securities and China Development Industrial Bank (CDIB)
- Early and late stage development focused primarily in the acute cardiovascular therapeutic area with four product and program assets

Merger with CVie Therapeutics

- The merger followed nearly a year of extensive and comprehensive diligence, governance, negotiation and other good practices.
- Windtree's direct wholly-owned subsidiary merged with and into CVie, with CVie surviving as a wholly-owned sub of Windtree in an all-stock transaction effective December 21, 2018
- Windtree issued shares of its common stock to CVie's former shareholders, at a rate of .3512 share of Windtree's common stock, for each share of CVie outstanding common stock prior to the Merger resulting in the issuance of 16.3 million shares of Windtree common stock.
- On December 20, 2018, Windtree declared a dividend to the holders of Windtree's common stock and certain warrants immediately prior to the merger of Series H AEROSURF Warrants, which will be exercisable without any exercise price for .5731 additional share of Windtree common stock for each share of common stock outstanding on the record date (the AEROSURF Warrants).
  - The AEROSURF Warrants will be automatically exercised upon Windtree's public announcement of the first dosing of the first human subject enrolled in the Company's Phase 3 clinical trial for AEROSURF®.

Merger with CVie Therapeutics *(cont'd)*

- In connection with the Merger, Lee's Pharmaceutical Holdings Limited (Lee's), which owned 49.58% of the outstanding shares of CVie prior to the Merger, agreed to indemnify the Windtree shareholders of record on December 20, 2018 for losses resulting from any potential material inaccuracy in any representation or warranty made by CVie in the Merger Agreement and placed in escrow 984,000 shares (an amount equal to the total number of shares held by Windtree minority holders just prior to the merger) for one year to satisfy any such claims.
- Windtree plans to operate CVie as a business division focused on early development of drug product candidates in cardiovascular diseases

$39.0 Million Private Placement

- Concurrent with the closing of the merger, Windtree completed a private placement of 11.8 million common stock shares at a per share purchase price equal to $3.3132 (10% discount from the 15-day average closing price as of December 17, 2018) for gross proceeds of $39.0 million
  - Proceeds include $7.0 million in non-cash consideration in the form of a reduction in existing debt obligations with Lee's ($6.0 million) and Battelle Memorial Institute ($1.0 million)
  - Net proceeds, after deducting estimated fees and expenses related to the offering and merger, are expected to be approximately $36 million.
- For each share purchased, the purchaser received an 18-month Series F warrant to purchase .17 shares of common stock at an exercise price of $3.68 per share and a five-year Series G warrant to purchase .33 shares of common stock at an exercise price of $4.05 per share
- Both existing and new investors from across the globe participated in the private placement

Rationale for Merger and Financing -

Creating a Stronger Company with More Opportunity

- CVie and Windtree each have attractive product assets addressing significant unmet medical needs and valuable market opportunities.
- Windtree's management team has extensive experience in: developing and commercializing drugs, global regulatory strategy, operating in public markets and executing business development. The team also has extensive cardiovascular experience.
- The merger and financing result in a series of important near to mid-term value-creating milestone opportunities including the merger and financing, phase 2b data and advancement in heart failure, an ability to potentially relist on NASDAQ, AEROSURF bridge study, etc.
- The new company formed from the merger results in a global business that already has attracted investment to provide needed capital.

WINDTREE THERAPEUTICS

Windtree Post-Merger Global Company

- Public, biopharmaceutical / medical device company with a current market cap of approximately $160MM
- Headquarters in Pennsylvania, USA with operations in Taipei, Taiwan and research in Milan, Italy

- Late-stage development company primarily focused on acute care markets
- Lead programs expected to address significant needs in the Acute Heart Failure, Respiratory Distress Syndrome (RDS) and Resistant Hypertension markets
- Pulmonary and Cardiac pre-clinical pipeline

WINDTREE THERAPEUTICS

Diversified, Late-Stage Development with Robust Pipeline

Istaroxime
for the Treatment of Acute Heart Failure

AEROSURF®
for non-invasive treatment of RDS

WINDTREE THERAPEUTICS™

Rostafuroxin
for genetically associated hypertension and renal impairment

Lucinactant LS
for RDS treatment

+ Pre-Clinical Candidates and Programs:

SERCA2a	Oral Heart Failure	Eleison	KL4 Platform
	chronic heart failure	Aerosol Oncology collaboration	for lung protection and drug delivery

WINDTREE THERAPEUTICS™

Istaroxime

for the Treatment of Acute Heart Failure

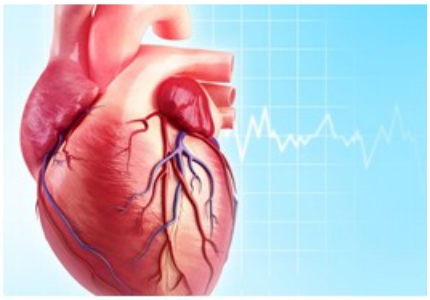
WINDTREE THERAPEUTICS

Heart Failure is a Significant Healthcare Issue

- There are more than 6 million patients with heart failure in the U.S. and over 18 million worldwide
- Heart Failure is the #1 reason for hospitalizations in patients >60 years old
  - > 1 million hospitalizations per year
  - 50% of patients will readmit within 6 months
- Mortality within 3 months of hospital admission approaches 30%
- Over $35B in U.S. costs annually (and increasing)

Heart Failure

- Impaired myocardial contractility is characteristic of heart failure; pulmonary congestion and edema are typical features
- Inadequate forward flow of blood contributes to other organs failing in these patients
- Mainstays of *chronic* therapy include diuretics, inhibitors of neurohumoral imbalances (angiotensin / renin / aldosterone) and beta blockers
- Effective treatments to improve cardiac pumping function in acute decompensated heart failure are lacking



Significant Unmet Medical Need Exists

- Patients presenting with acute decompensated heart failure are often complex and difficult to manage

- Current approaches to acutely improve cardiac function (inotropes) are associated with potential 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

- Treatment is needed to improve cardiac function without causing other adverse clinical outcomes

Istaroxime

- Novel intravenous agent designed to improve systolic and diastolic function of the heart
- Dual mechanism of effect—***luso-inotropic***
  - Inhibition of the sodium-potassium pump and effects on the sodium-calcium exchanger results in more calcium available for contraction
    Inotropic effect (systole)
  - Stimulation of SERCA2a activity enhances calcium reuptake improving the relaxation-contraction cycle
    lusitropic effect (diastole)

Istaroxime is being developed to improve cardiac function without the unwanted side effects of existing inotropes

WINDTREE THERAPEUTICS

Istaroxime Phase 2a Study

- This study of 120 patients evaluated 3 doses of istaroxime over a 6 hour infusion in hospitalized patients with heart failure and LVEF (Left Ventricular Ejection Fraction) ≤ 35%
- Results:
  - The primary endpoint, lowering of PCWP (pulmonary capillary wedge pressure), was significantly ($p<0.05$) improved by all 3 doses of istaroxime
  - Secondary hemodynamic endpoints were also improved
    - increased systolic blood pressure
    - decreased heart rate
  - The main side effects were vomiting (7.9%) and pain at the infusion site when a short catheter was used (5.6%); one severe adverse event of ventricular tachycardia was observed
- The favorable effects on PCWP, blood pressure and heart rate with potential lusointropic effects provided the basis for the program to move forward into a Phase 2b trial

Istaroxime Phase 2b Study Topline Results

- A phase 2b study of 2 doses of istaroxime compared to placebo has recently been completed in 120 patients hospitalized for acute decompensated heart failure. Key trial characteristics included:
  - LVEF ≤ 40%, elevated BNP (a marker of worsening heart failure)
  - 24 hour infusion of istaroxime (0.5 or 1.0 µg/kg/min) or placebo
  - Cardiac function was assessed non-invasively with tissue doppler echocardiography utilizing a single, central reader
  - The primary endpoint was change from baseline to 24 hours in E/Ea ratio reflecting changes in PCWP or left ventricular filing pressure

Results:

- **The primary endpoint, E/Ea, was significantly ($p<0.05$) improved by both doses of istaroxime in the ITT and PP populations**
- **Stroke volume (volume of blood ejected with each beat) was substantially increased**

- This study confirmed the physiologic improvements seen in the Phase 2a study and is consistent with the earlier effects observed of istaroxime in acute decompensated heart failure

Istaroxime Phase 2b Study Topline Results

- Importantly, there was a relative absence of common complications associated with currently available inotropes.
  - Istaroxime infusion did not appear to:
    - Increase arrhythmias
    - Increase troponin (no heart muscle damage)
  - Additionally
    - Heart rate was decreased
    - Blood pressure increased during the infusion
- Common side effects included infusion site reactions and nausea and vomiting similar to the Phase 2a trial
- These safety assessments confirmed the profile from the Phase 2a trial and suggest that istaroxime may be able to provide the improved cardiac performance needed in acutely decompensated heart failure patients without the untoward effects seen with current inotropes

Istaroxime Next Steps

- Having just completed a Phase 2b study and with the post-merger data integration, we will be conducting a detailed analysis of the complete Phase 2b results beyond the topline data
- Our goal is to transition Ista to Phase 3. We will be utilizing heart failure experts and engaging with regulators globally:
  - We are assembling an advisory panel of US and EU heart failure experts to review the program data and assist us in identifying the potential clinical benefits that should be assessed in the istaroxime clinical program going forward
  - We plan to update the istaroxime US IND and quickly prepare for a Type C Meeting with the FDA and Scientific Advice from the EMA
- We plan to return to present more complete and detailed information to you later this quarter / early Q2

More Opportunity Provided By -

Two Additional Preclinical Heart Failure Programs

Selective SERCA2a Candidates

- SERCA2a with pure stimulatory activity, but devoid of any Na^+/K^+ ATPase inhibitory activity.
- Directed by scientists with years of experience in SERCA2a activators

Oral AHF Candidate

- Oral, dual-mechanism Na^+/K^+ pump and SERCA2a drug candidate
- Would serve as a follow-on or complementary, chronic heart failure drug to acute, i.v. Istaroxime

WINDTREE THERAPEUTICS

Rostafuroxin

for genetically associated hypertension and renal impairment

WINDTREE THERAPEUTICS

Hypertension Market

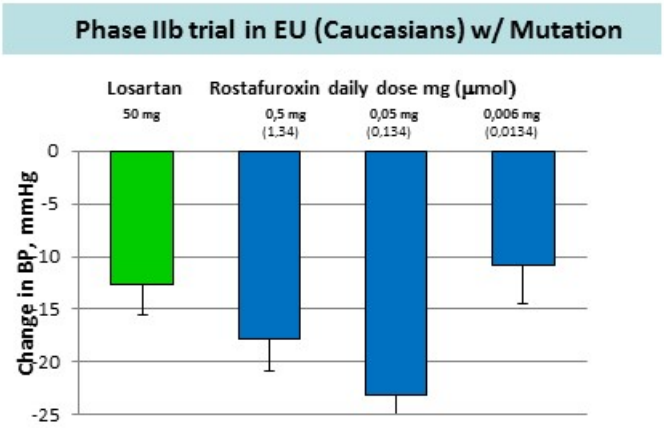
- Hypertension is a very large market with high unmet need
- Over 1/3 of the adult population in the U.S. has hypertension and the incidence is increasing
- Hypertension is a very heterogeneous disease and it is well known that ethnicity can impact response to different classes of agents
- The majority of treated patients (50-85% globally) do not reach their therapeutic target for blood pressure control
- There remains substantial unmet medical need in the treatment of hypertension

Rostafuroxin

- Uncontrolled hypertension has been associated with certain genetic makeup
  - 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
  - It may offer the possibility to reduce or normalize blood pressure in a *genetically identified subset of patients* and reduce the risk of cardiovascular events beyond the level expected by the absolute reduction of blood pressure, per se, because the molecular mechanism blocked by rostafuroxin is also involved in organ damage.

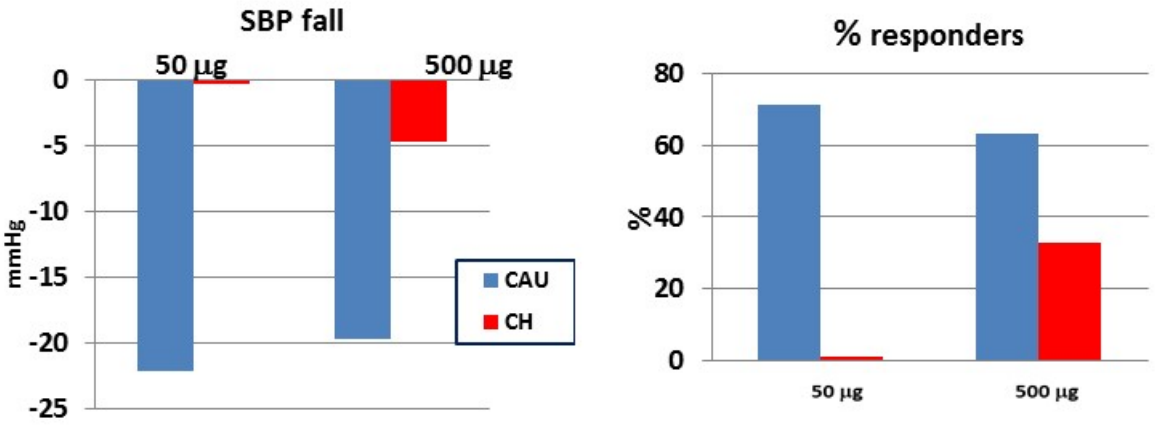
Rostafuroxin Reduced Blood Pressure in Caucasians with Select Mutation in Both Phase 2a and Phase 2b Trials

- **Clinical Objective of the Phase 2b Study:** Examine antihypertensive effect of different doses of ROSTAFUROXIN (6, 50 and 500 μg) in comparison with Losartan (50 mg), assessed by office and ambulatory blood pressure monitoring in a hypertensive population selected according to a specific genetic profile
- In an earlier Phase 2a trial, rostafuroxin demonstrated efficacy reducing blood pressure in a European population in the select mutations.
- For Phase 2b, CVie conducted as a two part study with the first part, n=160, conducted in Italy in Caucasian patients. The second part, n=120, was conducted in Chinese patients in Taiwan. Efficacy results for the Phase 2b in Italy:



Differential Response to Rostafuroxin in the PEARL 2b Study

While the BP reduction in Caucasians was notable in two trials, blood pressure response in Chinese patients was significantly less pronounced:



Potential reasons for the limited response in Chinese patients:

- Drug metabolism
- Oral bioavailability
- Drug Interaction with traditional Chinese medicines

WINDTREE THERAPEUTICS

Rostafuroxin Moving Forward

Strategy: *Large pharmaceutical companies have interest in this area as evidenced by recent hypertensive agents in licensing deals. These companies are well equipped to develop and commercialize these agents. Our strategy is to do the work necessary to position Rostafuroxin as an attractive asset for in licensing and conduct a formal business development process.*

1. Complete pharmaceutical development work for final formulation
2. Continue ongoing work to explain the ethnic differences seen in the Phase 2b trial
3. Engage hypertension experts in discussion on phase 3 options and evaluate development strategies
4. Create an asset that is attractive for partnering and conduct business development (starting with advancing discussions with interested parties)

AEROSURF®

Update

AEROSURF® Update

- The Company previously reported on multiple sets of safety and efficacy related data from our Phase 2 studies including the observations and clinical learnings:
  - ✓ meaningful nCPAP failure reduction at 80mg/kg across phase 2 clinical trials when dosed as intended
  - ✓ significantly improved key respiratory parameters seen with AEROSURF administration
  - ✓ potential for reduced respiratory support in patients who failed nCPAP when on AEROSURF
  - ✓ decreased incidence and severity of BPD
  - ✓ the need for device development to transition from the prototype ADS used in Phase 2 to a new phase 3 / commercial platform ADS - *which we successfully completed in mid-2018*
- Today we will provide an update on the latest data and our next steps for the clinic

AEROSURF® Phase 2 Program Latest Data -

Decreased BPD Incidence and Severity

Bronchopulmonary Dysplasia (BPD), a chronic lung disease of the newborn who have required intubation, mechanical ventilation and oxygen therapy. BPD is associated with ongoing pulmonary disease, neurodevelopmental impairment and increased healthcare utilization contributing to substantial patient morbidity and healthcare costs. Despite its importance, effective prevention and treatment strategies for BPD have been elusive and there is no approved treatment.

Incidence for ALL Patients (n = 261)

	26-28 Weeks PMA		28-32 Weeks PMA	
Definition	**AEROSURF (N=24)**	**Control (N=24)**	**AEROSURF (N=142)**	**Control (n=71)**
O_2 at 36 Weeks	**0 (0%)**	**6 (25%)**	14 (10%)	10 (14%)
p-value	**0.02**		0.37	

Severity for Doses ≥75 mg/kg or Control

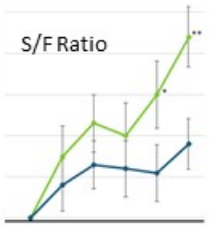
Definition		**AEROSURF (≥75 mg/kg) (N=88)**	**Control (N=95)**	**p-value**
O_2 at 36 Weeks	Incidence	**7 (8.0%)**	**16 (16.8%)**	**0.07**
NIH definition	Mild	3 (3.5%)	4 (4.2%)	
	Moderate	3 (3.4%)	4 (4.2%)	
	Severe	**1 (1.1%)**	**8 (8.4%)**	

AEROSURF® has the Potential to Impact the Clinical Course of RDS

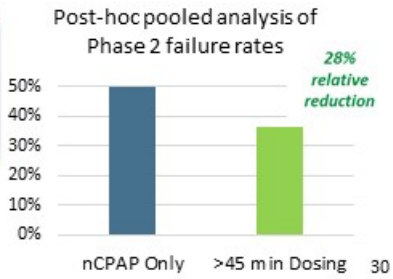
1 year Hospitalization Data Available in Q2 2019

Noninvasive RDS treatment

Improved Respiratory Parameters

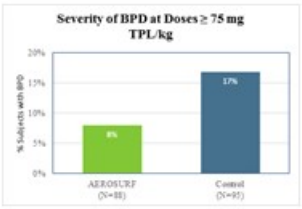


Decreased Rate of nCPAP Failures



Less Intubation and Respiratory Support Required

Reduced Rates and Severity of BPD



AEROSURF®

WINDTREE THERAPEUTICS

AEROSURF® Clinical Development Next Steps

Generate the strongest possible position for transition to Phase 3

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

1. Demonstrate adequate, consistent performance with the new ADS
   - Beyond Device Design Verification and bench performance study, Windtree confirms with actual "in-clinic" experience there are no issues
2. Sites gain experience with procedure and new device prior to use in Phase 3
3. Generate additional supportive data (with more intensive dosing)
   - Fourth data set at high dose is expected to provide data on safety of more intensive dosing and to augment phase 2b data

AEROSURF® Bridge Study Design

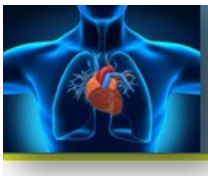
- Blinded study; nCPAP alone as control versus adding AEROSURF® treatment
- GA range: 26-32 weeks
- N=70 planned (35 per group) in a design similar to Phase 2b
- ~20-25 select sites
  - represent the best previous study sites for enrollment and execution in Phase 2 (predominate U.S. sites)
- Planned Timing: ~3 quarters study duration, plan is to start in 2H of 2019

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

Mitigating Risks and Strengthening Our Approach

AEROSURF® Program Evolution and Changes

- We have reproduced reductions in nCPAP failure in our phase 2a and 2b studies
- Utilize the new, phase 3 / intended commercial platform ADS, which is designed to mitigate the risk of treatment interruptions experienced with the prior, phase 2 porotype device
- Phase 3 ADS features may support better clinical outcomes:
  - Faster set up may decrease time to treatment (time is important)
  - Easier to use with enhanced user interface and operation
- Given AEROSURF safety profile, we are continually seeking to optimize dosing with more intensive dosing going forward:
  - Initial 100 min. dose for all
  - Decreasing interval between doses from 2 hours to 20 min. with additional repeat dosing possibilities
  - FiO_2 at 25% for inclusion, >21% for repeat allows more infants to receive clinically needed repeat dosing before RDS becomes severe
- Plan to execute the AEROSURF bridge study in our best sites



Windtree Late and Early Stage Programs

Expanded Pipeline of Cardio / Pulmonary

	Pre-Clinical	Phase 1	Phase 2	Phase 3
Istaroxime *acute heart failure*				
Rostafuroxin *genetically associated HTN*				
AEROSURF *RDS (non-invasive)*				
Lucinactant LS *RDS*				
Eleison Oncology *ADS for inhaled cisplatin*				
CV-IST2 *oral for heart failure*				
SERCA2a *acute heart failure*				
KL4 Platform *acute lung injury*				

Value Creating Milestone Opportunities:

Robust Short and Mid Term Binary Events New Flow

Short-Term

1. Merger Transaction + Financing
2. Istaroxime Phase 2b data
3. Potential NASDAQ Up listing
4. Istaroxime Phase 3 start
5. Rostafuroxin other data and possible deal
6. AEROSURF® Bridge Study results (transition to Phase 3)

Mid-Term

7. AEROSURF and Lucinactant LS Phase 3 start
8. AEROSURF Phase 3 results
9. Istaroxime Phase 3 results
10. LS Phase 3 results

2019 Preliminary Objectives

1. **"Right from the Start"** - Post-merger integration and drive focus, alignment and execution with rigor
2. **Istaroxime: transition to Phase 3 readiness**
3. **AEROSURF®:** Solid execution of **Bridge Study start-up**
4. **Potential relisting on NASDAQ** to support increased price and volume and broader access to capital
5. **Rostafuroxin:** Create an **attractive asset for out licensing**, run process
6. **Lucinactant LS and KL4 Platform** – Execute LS program with focus in China (largest liquid surfactant market). Execute Eleison study of ASDS while exploiting platform potential in priority use areas
7. **Oral Heart Failure and SERCA2a** – Complete IND enabling preclinical work and advance toward proof of concept
8. Maintain a **financial healthy organization** with a focus on licensing opportunities and other non-dilutive initiatives

Financial Position Update

- Cash and cash equivalents (net of $3.0 million in estimated transaction related fees) of $29 million as of December 21, 2018
- Assumed $8.0 million of debt from CVie
  - $4.5 million in a bank credit facility currently due in March 2020
  - $3.5 million due to Lee's Pharmaceuticals; currently working with Lee's to finalize payment terms but expect payment in the first quarter of 2019
- Fully diluted outstanding shares of 46.4 million and 72.1 million available for future issuance.

Current Capital Summary

(in millions of shares)	
Common Stock	32.1
Warrants	
AEROSURF Warrants (merger warrants expiring December 2023)	3.0
December 2018 Private Placement ($3.68 exercise price ; expiring June 2020)	2.0
December 2018 Private Placement ($4.05 exercise price ; expiring December 2023)	3.9
Battelle December 2018 Warrants ($6.50 exercise price; expiring December 2023)	0.1
July 2018 Convertible Debt Warrants ($4.00 exercise price; expiring July 2023)	0.2
April 2018 Private Placement Warrants ($5.52 exercise price; expiring April 2025)	0.1
February 2017 Private Placement Warrants ($27.40 exercise price; expire February 2024)	0.4
All Other Warrants (exercise price >$196.00; expiring July 2022 to October 2024)	0.2
Employee Options and RSUs	
2018 Stock Options (exercise price of $4.22)	4.2
Other Stock Options (exercise prices > $24.60)	0.1
Restricted Stock Units	0.2
Fully Diluted Shares Outstanding	**46.4**

Potential Benefits of Transaction to Windtree Current and Future Shareholders - Enhanced Trajectory and Opportunity for Value Generation

1. Attractive product assets and diversification could yield **multiple short to mid term value-inflection and growth opportunities** as well as helping to **spread of risk** associated with drug development across multiple assets
2. The recent **financing provides needed funds** for operations and programs, including further development of **Ista and AEROSURF and advancement of other assets**
3. **If successful in achieving our objectives, being a company with a Phase 3 heart failure asset along with AEROSURF® potentially transitioning to Phase 3 has the potential to produce significant company valuation**
4. **Windtree provides access to public markets and is better positioned for a potential return to NASDAQ**
5. **Leveraging of a management team with extensive experience** and competencies in BD / licensing, drug development, global regulatory, financing and operating in public markets

WINDTREE THERAPEUTICS