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

May 30, 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)

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))

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	WINT	The OTCQB® Market

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

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

Item 8.01. Other Events

On May 30, 2019, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing new data from a phase 2b study of istaroxime. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Press Release of Windtree Therapeutics, Inc., dated May 30, 2019.

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.

Date: May 31, 2019

Windtree Therapeutics, Inc.
By: /s/ Craig Fraser
Craig Fraser
President and Chief Executive Officer

Exhibit 99.1

Istaroxime Phase 2b Study Results Presented in Late Breaker Clinical Trial Session at the ESC Heart Failure Congress

Istaroxime Demonstrated Significantly Improved Cardiac Function in Patients with Acute Heart Failure

WARRINGTON, PA – May 30, 2019 – Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology and medical device company focused on developing drug product candidates and medical device technologies to address acute cardiovascular and pulmonary diseases, today announced the presentation of new safety and efficacy data from a phase 2b study of istaroxime in patients hospitalized with acute heart failure (AHF) at a late-breaker session of the European Society of Cardiology (ESC) 2019 Heart Failure Congress. The study achieved its primary endpoint by demonstrating a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses. The study further showed that stroke volume, a key secondary endpoint, was substantially increased. Importantly, certain toxicities and complications experienced with many existing acute heart failure therapies were not observed in istaroxime-treated patients, including no signals of increased arrhythmias or increased troponin levels, a common marker of heart muscle damage. Istaroxime significantly increased or maintained systolic blood pressure during treatment which may have contributed to short term trend toward improvement in renal function.

“We are very encouraged by the results from this phase 2b study evaluating istaroxime, our novel, dual action agent that addresses both cardiac contractility and relaxation in patients with acute heart failure” said Steve Simonson, M.D., Chief Medical Officer at Windtree. “We achieved our primary objective of improved cardiac function, while maintaining or increasing blood pressure and decreasing heart rate during the infusion. We also did not observe other important safety signals in the patients studied. These positive results are consistent with the physiologic improvements seen in the phase 2a study in a similar population of patients with acute heart failure. Based on these promising results, we look forward to progressing the development of istaroxime.”

The phase 2b study in 120 patients was designed to assess the safety and efficacy of 24-hour infusions of two doses of istaroxime (0.5 and 1.0 µg/kg/min), compared to placebo, in the treatment of patients with acute heart failure. The primary endpoint of this study was a change from baseline to 24 hours after start of infusion (Day 1) in E/e’ with istaroxime 0.5 or 1.0 µg/kg/min vs. placebo. The E/e’ ratio is a marker of the function of the left ventricle (LV) of the heart and was measured using doppler echocardiography read by a central laboratory. Secondary endpoints included change in other parameters of cardiac function, such as diastolic function (E/A), stroke volume (SVI), left ventricle ejection fraction (LVEF), LV volumes, left atrial (LA) area, interior vena cava (IVC) diameter.

Investigators of this study concluded that a 24-hour infusion of istaroxime was associated with significant improvements in cardiac function, in both dosing groups, with a mean E/e’ of -4.55 for the 0.5 µg/kg/min group and -3.16 for the 1.0 µg/kg/min group, compared with mean placebo E/e’ ratios of -1.55 and -1.08, respectively.

Twenty-four-hour infusions of istaroxime were also associated with substantial increases in stroke volume in both dosing groups, with a mean SVI value of 5.33 ml/beat/m^2 for the 0.5 µg/kg/min group and 5.49 ml/beat/m^2 for the 1.0 µg/kg/min group, compared with the mean placebo SVI of 1.65 ml/beat/m^2 and 3.18 ml/beat/m^2, respectively. Importantly, subjects also maintained or increased systolic blood pressure (SBP), with a mean change in SBP of 2.82 mmHg for the 0.5 µg/kg/min group and 6.1 mmHg for the 1.0 µg/kg/min group, compared with the mean placebo SBP values of -2.47 mmHg and 2.7 mmHg, respectively.

Istaroxime was generally well tolerated. Istaroxime did not appear to be associated with an increase in risk for arrhythmias or increases in cardiac troponin T. Cardiovascular related adverse events were 23 percent for placebo, 10 percent for istaroxime low dose, and 18 percent for istaroxime high dose with cardiac failure occurring in 3 percent, 5 percent and 8 percent of placebo, low and high dose of istaroxime patients, respectively. The most common adverse drug reactions reported included pain at infusion site, generally associated with use of short catheters, and dose-related gastrointestinal adverse events in 5 percent, 10 percent and 35 percent of placebo, low and high dose istaroxime respectively.

About Istaroxime
Istaroxime is a first-in-class, dual action, luso-inotropic agent in clinical development for the treatment of acute heart failure. Istaroxime is an intravenously administered agent with a potent positive inotropic agent that increases myocardial contractility through inhibition of Na+/K+-ATPase. In addition, it facilitates myocardial relaxation through activation of the SERCA2a calcium pump on the sarcoplasmic reticulum and reduction in cytoplasmic calcium in order to increase fill and follow on stroke volume.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is a clinical-stage, biopharmaceutical and medical device company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Windtree has three lead clinical development programs and multiple pre-clinical programs spanning respiratory and cardiovascular disease states, including istaroxime, a novel, dual-acting agent being developed to improve cardiac function in patients with acute heart failure with a potentially improved side effect profile from existing treatments; AEROSURF®, an innovative combination drug/device product candidate that is designed to deliver the Company’s proprietary synthetic, peptide-containing surfactant non-invasively to premature infants with respiratory distress syndrome (RDS); and rostafuroxin, a novel precision drug product being developed to target hypertensive patients with certain genetic profiles in the important group of patients with resistant hypertension. Windtree also has multiple pre-clinical products including potential heart failure therapies delivered orally that are based on SERCA2a mechanism of action.

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

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties include: the risk that, as a development company with limited resources and no operating revenues, the Company's ability to continue as a going concern in the near term is highly dependent upon successful and timely advancement of its clinical development programs for istaroxime and AEROSURF®; risks that Windtree will be unable to secure significant additional capital as and when needed, or to access debt or equity financings, which could result in substantial equity dilution; risks related to Windtree's development programs, which may involve time-consuming and expensive pre-clinical studies and clinical trials and which may be subject to potentially significant delays or regulatory holds, or fail; risks related to technology transfers to contract manufacturers and manufacturing development, and problems or delays encountered by Windtree, 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 Windtree 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 Windtree's products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; risks related to Windtree's efforts to maintain and protect the patents and licenses related to its products; and other risks and uncertainties described in Windtree'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.

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