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): October 1, 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 8.01 Other Events.

On October 1, 2020, Windtree Therapeutics, Inc. issued a press release announcing that it has dosed the first patient in its Phase 2 study of istaroxime in patients experiencing early cardiogenic shock. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Press Release of Windtree Therapeutics, Inc., dated October 1, 2020.

SIGNATURES

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

Windtree Therapeutics, Inc.

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

Date: October 1, 2020

Exhibit 99.1

Windtree Announces First Patient Dosed in Phase 2 Study of Istaroxime for the Acute Treatment of Early Cardiogenic Shock in Heart Failure Patients

Study Opens a New, Additional Area of Development for Istaroxime

WARRINGTON, PA – October 1, 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 announced that it has dosed the first patient in its Phase 2 study of istaroxime in patients experiencing early cardiogenic shock. Early cardiogenic shock is one of two developmental programs for istaroxime. The second is acute heart failure, which is supported by positive phase 2a and phase 2b trial results and a FDA Fast Track designation

“Cardiogenic shock is a life-threatening state of lack of heart function and blood flow to vital organs that is associated with high risk of mortality, despite intensive montoring and current treatments,” said Craig Fraser, Chief Executive Officer of Windtree. “We believe istaroxime's dual mechanism of action, improving both systolic contraction of the heart as well as diastolic function, along with positive effects on blood pressure, could be a key approach in effectively bringing severe acute heart failure patients out of this critical condition. Additionally, because of the unmet need in cardiogenic shock and the regulatory precedent in this area, we believe positive data could lead to an opportunity for breakthrough therapy designation, which may provide for an expedited development program.”

The istaroxime 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. Regulatory precedent exists for an approval in shock settings based upon improvements in blood pressure with an acceptable safety profile. Based on positive data from the acute heart failure studies, the Company is starting its program in the patients experiencing early cardiogenic shock due to severe heart failure and, if the data is positive, the Company would plan to expand the study population in future development.

Steve Simonson, M.D., Chief Medical Officer of Windtree, added, “Patients in early cardiogenic shock due to heart failure have decreased cardiac output with very low blood pressure resulting in a critical reduction of blood flow. Data from the istaroxime Phase 2 program in acute heart failure showed that istaroxime significantly improved cardiac function and increased systolic blood pressure. Importantly, istaroxime produced these changes without an increase in clinically significant arrythmias or increases in cardiac troponins. Istaroxime may represent a novel treatment strategy for acute treatment of early cardiogenic shock due to progression of heart failure.”

About Istaroxime

Istaroxime is a first-in-class dual mechanism therapy designed to improve both systolic diastolic cardiac function. Istaroxime is a positive inotropic agent that increases myocardial contractility through inhibition of Na+/K+-ATPase with a complimentary mechanism that facilitates myocardial relaxation through activation of the SERCA2a calcium pump on the sarcoplasmic reticulum enhancing calcium reuptake from the cytoplasm. Data from multiple Phase 2 studies in patients with acute heart failure (AHF) demonstrate that istaroxime infused intravenously significantly improves cardiac function and blood pressure without causing heart rate increases or rhythm disturbances.

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 is also developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, as well as evaluating 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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