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): September 25, 2024

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39290**	**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 September 25, 2024, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing positive topline results from the Company's Phase 2b SEISMiC Extension Study of istaroxime in treating early cardiogenic shock due to heart failure. A copy of the press release is attached 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 September 25, 2024, announcing positive topline results from the Company's Phase 2b SEISMiC Extension Study of istaroxime
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Dated: September 25, 2024

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

Exhibit 99.1

Windtree Announces Positive Topline Results from Its Phase 2b SEISMiC Extension Study of Istaroxime in Early Cardiogenic Shock

Istaroxime significantly improved primary endpoint of the systolic blood pressure profile over six hours and showed significant improvements in many secondary endpoint assessments

Study results to be presented at the Heart Failure Society of America Medical Conference on September 30, 2024

WARRINGTON, PA – September 25, 2024 – Windtree Therapeutics, Inc. ("Windtree" or the "Company") (NasdaqCM: WINT), a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases, today announced positive topline results from its Phase 2b SEISMiC Extension Study of istaroxime in significantly increasing systolic blood pressure over six hours, a critical clinical objective in treating patients in early cardiogenic shock due to heart failure.

The SEISMiC Extension Study in early cardiogenic shock (SCAI Stage B) is being conducted in the United States, Europe and Latin America. The study is focused on the effects of istaroxime on blood pressure, cardiac function and other parameters over 96 hours of close monitoring with the final visit at 30 days. The results build upon the positive results reported previously in the Phase 2 SEISMiC trial. The SEISMiC Extension Study focused on improving low blood pressure and heart function and providing other potential benefits in early cardiogenic shock patients. It also provided information to help further inform dose optimization and the characterization of istaroxime's mechanism of action including potential benefits of SERCA2a activation. The study included hospitalized patients with SCAI Stage B cardiogenic shock with persistent hypotension due to acute heart failure and evaluated two different dose regimens of istaroxime compared to placebo. Patients received infusions of istaroxime for up to 60 hours, with one group receiving a decreasing istaroxime dose over time and the second group receiving a constant istaroxime dose. The study tested an extended dosing duration of istaroxime compared to previous studies where treatment was limited to 24 hours to determine the potential for additional benefit and, along with dose titration, is an important factor in determining the optimal dosing regimen to utilize in a late-stage trial. Importantly, the study collected detailed information related to both cardiac and renal function and additional safety information on cardiac arrhythmias. Istaroxime has not been associated with an increase in cardiac arrhythmias, which the Company believes is a potentially important differentiating characteristic compared to commonly used current drug therapies.

Topline study results:

- The study met its primary endpoint in significantly improving systolic blood pressure over six hours, with the combined istaroxime group performing significantly better compared to the placebo group. Significant benefits were seen in many secondary endpoints as well.

- The safety profile was favorable and generally consistent with what has been previously reported in other clinical trials.

- Further details of study results, including other measures of efficacy and safety and by individual istaroxime dosing groups, are planned to be presented at the Heart Failure Society of America Meeting on September 30, 2024.

- Following the clinical presentation at the conference, the Company plans to issue a press release with more detailed results as well as conduct an investor call (details of which to follow in the coming days).

Dr. Steve Simonson, Senior Vice President and Chief Medical Officer at Windtree said, “We are very pleased with the results of the study and the potential for istaroxime to positively impact patients in acute heart failure with early cardiogenic shock. The study collected a large amount of data related to blood pressure profiles, cardiac function and safety measures for two istaroxime dosing regimens. We look forward to sharing more details at the Heart Failure Society of America Meeting and through a presentation of the data.”

Craig Fraser, Chairman and CEO of Windtree stated, “Cardiogenic shock is a critical condition with high morbidity and mortality where clinicians note a high need for new drug innovation. Across four Phase 2 studies to date, istaroxime has demonstrated a highly unique and attractive profile as a potential therapy for cardiogenic shock and acute heart failure patients. We are excited to share the details of study results next week and to continuing to progress istaroxime towards Phase 3 readiness for cardiogenic shock.”

About Istaroxime
Istaroxime is a first-in-class dual-mechanism therapy designed to improve both systolic and diastolic cardiac function. Istaroxime is designed as 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 early cardiogenic shock or acute decompensated heart failure have demonstrated that istaroxime infused intravenously significantly improved cardiac function and blood pressure without increasing heart rate or the incidence of cardiac rhythm disturbances.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Windtree’s portfolio of product candidates includes istaroxime, a Phase 2 candidate with SERCA2a activating properties for acute heart failure and associated cardiogenic shock, preclinical SERCA2a activators for heart failure and preclinical precision aPKCi inhibitors that are being developed for potential in rare and broad oncology applications. Windtree also has a licensing business model with partnership out-licenses currently in place.

Forward Looking Statements

This press release contains statements related to the potential clinical effects of istaroxime; the potential benefits and safety of istaroxime; the clinical development of istaroxime; our research and development program for treating patients in early cardiogenic shock due to heart failure. Such statements constitute 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, among other things: the Company’s ability to secure significant additional capital as and when needed; the Company’s ability to achieve the intended benefits of the aPKCi asset acquisition with Varian Biopharmaceuticals, Inc.; the Company’s risks and uncertainties associated with the success and advancement of the clinical development programs for istaroxime and the Company’s other product candidates, including preclinical oncology candidates; 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, and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the U.S. Food and Drug Administration 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 that the Company may never realize the value of its intangible assets and have to incur future impairment charges; 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; the rate and degree of market acceptance of the Company’s product candidates, if approved; the economic and social consequences of the COVID-19 pandemic and the impacts of political unrest, including as a result of geopolitical tension, including the conflict between Russia and Ukraine, the People’s Republic of China and the Republic of China (Taiwan), and the evolving events in Israel and Gaza, and any sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries which could have an adverse impact on the Company’s operations, including through disruption in supply chain or access to potential international clinical trial sites, and through disruption, instability and volatility in the global markets, which could have an adverse impact on the Company’s ability to access the capital markets. These and other risks are described in the Company’s periodic reports, including its 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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