

**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): January 8, 2025

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

**Delaware
(State or other jurisdiction of
incorporation or organization)**

**001-39290
(Commission
File Number)**

**94-3171943
(I.R.S. Employer
Identification No.)**

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

**18976
(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 January 8, 2025, Windtree Therapeutics, Inc. (the “Company”) issued a press release announcing that the Company has a new corporate strategy. 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 January 8, 2025.
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.

Windtree Therapeutics, Inc.

By: /s/ Jed Latkin

Name: Jed Latkin

Title: President and Chief Executive Officer

Date: January 8, 2025

Windtree Therapeutics Announces New Corporate Strategy Seeking to Identify and Acquire FDA-Approved Revenue Assets While Advancing Its Cardiovascular and Oncology Pipeline

All-Stock Acquisition Strategy Targets Multiple Small Companies with FDA-Approved Products to Drive Growth and Shareholder Value

WARRINGTON, PA – January 8, 2025 – 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 it has launched a new corporate strategy to become a revenue generating biotech company through acquisitions of small companies and their FDA-approved products while the Company continues to progress its cardiovascular and oncology development pipeline. The Company will seek acquisition targets to achieve the Company’s new corporate strategy.

Windtree believes there is an opportunity in the market: the acquisition of small companies with FDA-approved products from the many small biotech companies that struggle to maximize their commercialization potential. To capitalize on this opportunity, Windtree plans to become a parent company acquiring strategic subsidiaries with FDA-approved products. The Company's management team has commercialization expertise in both large pharmaceutical and small biotech companies across multiple therapeutic areas, potentially enabling them to leverage synergies and optimize commercial performance across future subsidiaries.

The Company will seek to use equity to acquire subsidiaries. The number of deals, if any, over time will depend upon the valuation and growth potential of the subsidiary companies.

"We believe that Windtree becoming a revenue generating company would be a significantly positive transformation and would mark a new chapter in our growth story," said Jed Latkin, CEO of Windtree. "By pursuing this strategy, we maintain our commitment to advance our promising cardiovascular and oncology pipeline while simultaneously leveraging our deep commercialization expertise to accelerate revenue growth through strategic acquisitions. This approach allows us to create near-term value through acquired commercial operations while preserving the potential of our development programs."

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 aPKC α inhibitor 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

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 acquire revenue generating subsidiaries; the market’s reaction to potential acquisitions by the Company; 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 secure and successfully complete an out-licensing or asset acquisition transaction; 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 the Middle East, 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.

Contact Information:

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