
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**FORM S-3
REGISTRATION STATEMENT**
UNDER
THE SECURITIES ACT OF 1933

WINDTREE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Craig E. Fraser
President and Chief Executive Officer
Windtree Therapeutics, Inc.
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(215) 488-9300
(Name, address including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time, after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7(a)(2)(B) of Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and the selling stockholders are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 14, 2024

PRELIMINARY PROSPECTUS



Up to 608,272 Shares of Common Stock

This prospectus relates to the offer and resale by the selling stockholders identified in this prospectus of up to an aggregate of 608,272 shares of our common stock, par value \$0.001, issued to the selling stockholders in a private placement transaction pursuant to that certain Exchange and Termination Agreement, or the Exchange and Termination Agreement, by and between us and the selling stockholders, dated as of January 24, 2024. We are registering the shares on behalf of the selling stockholders, to be offered and sold by them from time to time.

We are not selling any shares of common stock under this prospectus and will not receive any proceeds from the sale by the selling stockholders of such shares.

Sales of the shares by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices, at negotiated prices and/or at varying prices determined at the time of sale. The selling stockholders may sell the shares directly or to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both. The selling stockholders may sell any, all or none of the securities offered by this prospectus and we do not know when or in what amount the selling stockholders may sell their shares of common stock hereunder following the effective date of the registration statement of which this prospectus forms a part. The registration of the shares on behalf of the selling stockholders, however, does not necessarily mean that any of the selling stockholders will offer or sell their shares under this registration statement or at any time in the near future. We cannot predict when, or in what amounts, the selling stockholders may sell any of the shares. We provide more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock in the section titled “*Plan of Distribution*” beginning on page 15 of this prospectus.

We are paying the cost of registering the shares of common stock covered by this prospectus as well as various related expenses. The selling stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares.

Investing in our common stock involves a high degree of risk. You should consider carefully the “*Risk Factors*” beginning on page 6 of this prospectus, and in the documents incorporated by reference herein, before purchasing any of the shares offered by this prospectus.

Our common stock is traded on the Nasdaq Capital Market, or Nasdaq, under the symbol “WINT”. The last reported sale price of our common stock on Nasdaq on February 13, 2024 was \$0.36 per share. On January 22, 2024, we received a deficiency letter from the Nasdaq Listing Qualifications Department indicating that we are not in compliance with Nasdaq’s minimum bid price requirement of at least \$1.00 per share. To maintain listing on Nasdaq, we must demonstrate compliance with the Nasdaq minimum bid price requirement by or before July 22, 2024 (subject to a second 180 calendar day period to regain compliance that may be granted by Nasdaq), or our common stock will become subject to delisting. For more information, see “*Prospectus Summary—Recent Developments—Nasdaq Continued Listing Standards*” and “*Risk Factors—If we are unable to meet the listing standards of Nasdaq by July 22, 2024, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.*”

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 under the Securities Act of 1933, as amended, or the Securities Act, that we filed with the Securities and Exchange Commission, or the SEC, using the “shelf” registration process. Under this shelf registration process, the selling stockholders named in this prospectus may offer and sell the common stock described in this prospectus in one or more offerings. Any accompanying prospectus supplement or any related free writing prospectus may also add, update or change information contained in this prospectus or in any documents incorporated by reference into this prospectus. If the information varies between this prospectus and any accompanying prospectus supplement, you should rely on the information in the accompanying prospectus supplement. You should read this prospectus, any accompanying prospectus supplement and any related free writing prospectus, together with the information incorporated herein by reference as described under the heading “*Where You Can Find More Information*,” before investing in the common stock offered hereby.

You should rely only on the information that we have included or incorporated by reference into this prospectus, any accompanying prospectus supplement and any applicable free writing prospectus. We have not, and the selling stockholders have not, authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement or any applicable free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus, any accompanying prospectus supplement or any applicable free writing prospectus. This prospectus, any accompanying prospectus supplement and any applicable free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus, any accompanying prospectus supplement or any applicable free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. Since the respective dates of this prospectus and the documents incorporated by reference into this prospectus, our business, financial condition, results of operations and prospects may have changed.

For investors outside the United States, neither we nor the selling stockholders have done anything that would permit this offering, or possession or distribution of this prospectus, any prospectus supplement or free writing prospectus, in any jurisdiction where action for that purpose is required other than in the United States. Persons outside the United States who come into possession of this prospectus, any applicable prospectus supplement or free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Unless the context otherwise requires, references in this prospectus to “Windtree,” “Windtree Therapeutics,” “the Company,” “we,” “our,” and “us” refer to Windtree Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries.

We use “Windtree Therapeutics,” as our trademark, and we have been granted a trademark or have a trademark application on file with the United States Patent and Trademark Office. All trademarks or trade names referred to in this prospectus and the documents incorporated by reference herein are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus and the documents incorporated by reference herein are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us, by any other companies.

All references to “this prospectus” refer to this prospectus and any applicable prospectus supplement, including the documents incorporated by reference herein and therein, unless the context otherwise requires.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. We also plan to demonstrate that istaroxime can produce a therapeutic benefit in these settings with a differentiated safety profile compared to drugs currently used in these patients. Istaroxime demonstrated significant improvement in both systolic and diastolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure, or SBP, in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study, or the SEISMiC Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. We completed the SEISMiC Study and, in April 2022, announced positive topline results. Istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. In May 2022, we presented the SEISMiC Study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. A second manuscript comparing the two doses used in the trial was published in the Journal of Cardiac Failure in April 2023. We believe that istaroxime has the potential to fulfill an unmet need in early and potentially more severe cardiogenic shock. We further believe that the data from the SEISMiC Study supports continued development in both cardiogenic shock and AHF. We are currently initiating an extension to the SEISMiC Study, or the SEISMiC Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of sarco endoplasmic reticulum Ca²⁺-ATPase 2a, or SERCA2a. The SEISMiC Extension trial is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in mid-2024. Additionally, we are engaged in start-up procedures and exploring the possibility of commencing a small study in more severe SCAI Stage C cardiogenic shock.

Our heart failure cardiovascular portfolio also includes SERCA2a activators. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. These candidates would potentially be developed for both acute decompensated and chronic out-patient heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance rostafuroxin without securing such an arrangement or partnership.

Recent Developments

Exchange and Termination Agreement

We and the selling stockholders previously entered into an Exchange and Termination Agreement on October 27, 2017, or the Milestone Agreement. Pursuant to the Milestone Agreement, among other things, the selling stockholders had the right to receive certain milestone payments, or the Milestone Payments) based on achievement of specified development and commercial milestones related to our AEROSURF® development program, which, if achieved, could potentially total up to \$15,000,000.

On January 24, 2024, we and the selling stockholders entered into an Exchange and Termination Agreement, or the Exchange and Termination Agreement, pursuant to which the selling stockholders agreed to terminate its rights to receive the Milestone Payments and all related rights and obligations in respect of such Milestone Payments in exchange for (i) cash in the aggregate amount of \$200,000, \$100,000 of which was paid on January 24, 2024 and \$100,000 of which will be paid no later than the earlier to occur of (a) January 24, 2025 and (b) our receipt of a specified amount of gross proceeds from debt or equity financings occurring on or after January 24, 2024, and (ii) an aggregate of 608,272 shares of our common stock, par value \$0.001 per share. The shares of our common stock were issued to the selling stockholders in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended.

Contemporaneously with the execution of the Exchange and Termination Agreement, we and the selling stockholders entered into a Registration Rights Agreement pursuant to which we have agreed to, among other matters, register for resale with the Securities and Exchange Commission, or the SEC, the shares of our common stock issued to the selling stockholders pursuant to the Exchange and Termination Agreement.

Nasdaq Continued Listing Standards

On January 22, 2024, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market LLC notifying us that, for 31 consecutive business days (from December 5, 2023 to January 19, 2024), the closing bid price for our common stock was below the minimum \$1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on Nasdaq under the symbol “WINT” at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been given an initial 180 calendar days, or until July 22, 2024, to regain compliance with Rule 5550(a)(2). If at any time before July 22, 2024, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, the Staff will provide us written confirmation that we have regained compliance with Rule 5550(a)(2).

If we do not regain compliance with Rule 5550(a)(2) by July 22, 2024, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement, by effecting a reverse stock split, if necessary. In addition, we would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period.

If we do not qualify for, or fail to regain compliance during, a second compliance period, then the Staff will provide us written notification that our common stock will be subject to delisting. At that time, we may appeal the Staff’s delisting determination to the Nasdaq Listing Qualifications Panel. However, there can be no assurance that, if we receive a delisting notice and appeals the delisting determination, such an appeal would be successful.

We intend to actively monitor the closing bid price of our common stock and will consider all available options to resolve the deficiency and regain compliance with Rule 5550(a)(2). There can be no assurance that we will be able to regain compliance with Rule 5550(a)(2) or will otherwise be in compliance with other applicable Nasdaq listing rules.

For more information, see “*Risk Factors—If we are unable to meet the listing standards of Nasdaq by July 22, 2024, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.*”

Corporate Information

We were incorporated in Delaware on November 6, 1992. Our principal executive offices are located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, and our telephone number is (215) 488-9300. Our website address is *www.windtreetx.com*. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein and you should not consider it part of this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being a Smaller Reporting Company

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, as long as we are a smaller reporting company with less than \$100 million in annual revenue, we are not required to obtain an attestation report on internal control over financial reporting from our independent registered public accounting firm.

The Offering

Common stock offered by the selling stockholders	Up to 608,272 shares of common stock
Terms of the offering	The selling stockholders, including their transferees, donees, pledgees, assignees or successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The shares of common stock may be sold at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at negotiated prices and/or at varying prices determined at the time of sale. See “ <i>Plan of Distribution</i> ” on page 15.
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus.
Risk factors	See “ <i>Risk Factors</i> ” beginning on page 6, for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol	WINT

Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders for offer and resale, we are referring to the shares of common stock issued. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, its transferees, donees, pledgees, distributes and other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before you decide to invest in our securities, you should carefully consider the following risks and uncertainties as well as the risks and uncertainties described under the section entitled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2022 and our subsequent Quarterly Reports, together with other information in this prospectus, the information and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not currently known to us, or that we currently view as immaterial, may also impair our business, operating results, prospects or financial condition. If any of the risks or uncertainties described in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to this Offering

A sale of a substantial number of shares of common stock by the selling stockholders could cause the price of our common stock to decline.

The shares of common stock covered by this prospectus represent a large number of shares of our common stock, and, following the effectiveness of the Registration Statement of which this prospectus forms a part, such shares of common stock may be sold by the selling stockholders in the public market without restriction. If the selling stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of the shares of common stock in the public market, the price of our common stock may decline. Additionally, such conditions may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Risks Related to Our Finances and Capital Requirements

Our losses, negative cash flows from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.

Management has concluded that substantial doubt exists about our ability to continue as a going concern for the next twelve months from the date hereof. As of September 30, 2023, we had an accumulated deficit of \$839.7 million, cash and cash equivalents of \$7.4 million and current liabilities of \$3.7 million. To date, we have financed our operations primarily through private placements and public offerings of our common stock and warrants to purchase common stock. Based on available resources, we believe that we have sufficient resources available to support our development activities and fund our business operations through the first quarter of 2024, however, our current capital resources are not sufficient to support our planned operations for the next twelve months from the date hereof.

We expect to continue to incur significant research and clinical development, regulatory and other expenses as we (i) develop product candidates; (ii) seek regulatory clearances or approvals for our planned or future product candidates; (iii) conduct clinical trials on our planned or future product candidates; and (iv) manufacture, market, and sell any product candidates for which we may obtain regulatory approval. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and may cause the market price of our common stock to decline.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. Additionally, if we are unable to regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise funding. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “*Risk Factors*” section and Part I, Item 1A “*Risk Factors*” of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023, as amended by our Annual Report on Form 10-K/A filed with the SEC on May 1, 2023, and in our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, June 30, 2023, and September 30, 2023 filed with the SEC on May 15, 2023, August 7, 2023, and November 9, 2023, respectively. We have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

If we are unable to meet the initial listing standards of Nasdaq by July 22, 2024, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.

The listing standards of Nasdaq provide, among other things, that a company, in order to qualify for continued listing, must maintain a minimum bid price of at least \$1.00 per share pursuant to Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2).

On January 22, 2024, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market LLC notifying us that, for 31 consecutive business days (from December 5, 2023 to January 19, 2024), the closing bid price for our common stock was below the minimum \$1.00 per share required for continued listing on Nasdaq pursuant to Rule 5550(a)(2). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on Nasdaq under the symbol “WINT” at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been given an initial 180 calendar days, or until July 22, 2024, to regain compliance with Rule 5550(a)(2). If at any time before July 22, 2024, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, the Staff will provide us written confirmation that we have regained compliance with Rule 5550(a)(2).

If we do not regain compliance with Rule 5550(a)(2) by July 22, 2024, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement, by effecting a reverse stock split, if necessary. In addition, we would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period.

If we do not qualify for, or fail to regain compliance during, a second compliance period, then the Staff will provide us written notification that our common stock will be subject to delisting. At that time, we may appeal the Staff’s delisting determination to the Nasdaq Listing Qualifications Panel. However, there can be no assurance that, if we receive a delisting notice and appeals the delisting determination, such an appeal would be successful.

There is no assurance that we will be able to meet Nasdaq’s listing requirements or comply with the requisite Nasdaq requirements to maintain our listing of common stock on Nasdaq. If Nasdaq delists our securities from trading on its exchange and we are not able to list our securities on Nasdaq or any other national securities exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;

- a determination that our common stock is a “penny stock,” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for its securities;
- a limited amount of news and analyst coverage for us;
- a decreased ability to issue additional securities or obtain additional financing in the future; and
- the incurring of additional costs under state blue sky laws in connection with any sales of our securities.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. In the event our common stock is delisted from Nasdaq, we may not be able to list our common stock on another national securities exchange or obtain quotation on an over-the counter quotation system.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- our estimates regarding future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- how long we can continue to fund our operations with our existing cash and cash equivalents;
- our ability to meet and regain compliance with the listing requirements of Nasdaq;
- changes in market conditions, general economic conditions, and the banking sector, and potential constraints in accessing capital or credit if and when needed with favorable terms, if at all;
- the potential impairment of our intangible assets on our consolidated balance sheet, which could lead to material impairment charges in the future;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the coronavirus pandemic and the evolving events in Israel and Gaza on our clinical trial operations;
- the costs, timing, and results, of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- risks related to manufacturing active pharmaceutical ingredients, drug product, and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the plans of our AEROSURF and KL4 licensee, Lee’s Pharmaceutical (HK) Ltd., or Lee’s, and Lee’s affiliate, Zhaoke Pharmaceutical (Hefei) Co. Ltd., and their ability to successfully source materials, execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialization of the licensed product candidates;
- the plans for our istaroxime, dual mechanism SERCA2a activators and rosfuroxin licensee, Lee’s, and Lee’s ability to successfully source materials, execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialization of the regional licensed product candidates;

- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contract laboratories, and independent contractors;
- the size and growth of the potential markets for our product candidates, the regulatory requirements in such markets, the rate and degree of market acceptance of our product candidates, and our ability to serve those markets;
- the success of competing therapies and products that are or may become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- recently enacted and future legislation, including but not limited to, the Inflation Reduction Act of 2022, regarding the healthcare system in the United States or the healthcare systems in foreign jurisdictions;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to secure electronically stored work product, including clinical data, analyses, research, communications, and other materials necessary to gain regulatory approval of our product candidates, including those acquired from third parties, and assure the integrity, proper functionality, and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, security incidents, data privacy violations, or other significant disruption;
- economic uncertainty resulting from inflation and the rapid increase in interest rates, including concerns involving liquidity, defaults or other non-performance by financial institutions;
- economic uncertainty resulting from geopolitical instability, including the ongoing military conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan), and the conflict in Gaza and Israel; and
- other risks and uncertainties, including those described under the caption "*Risk Factors*" in this prospectus or in the documents incorporated by reference herein.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts, and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section entitled "*Risk Factors*" in this prospectus and the risk factors set forth in the documents incorporated by reference in this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents incorporated by reference in this prospectus completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Trademark Notice

AEROSURF®, **AFECTAIR®**, **SURFAXIN®**, **SURFAXIN LS™**, **WINDTREE THERAPEUTICS® (logo)**, **WINDTREE THERAPEUTICS™**, and **WINDTREE™** are registered and common law trademarks of Windtree Therapeutics, Inc. (Warrington, PA).

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of our common stock held by the selling stockholders.

The selling stockholders will receive all of the net proceeds from the sale of shares of our common stock under this prospectus. The selling stockholders will pay any underwriting, broker-dealer or agent discounts, concessions and commissions and expenses incurred by the selling stockholders for accounting, tax, and legal services and any other expenses incurred by the selling stockholders in disposing of the shares of common stock, unless otherwise agreed to by us. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares of our common stock covered by this prospectus.

SELLING STOCKHOLDERS

This prospectus relates to the resale of up to 608,272 shares of our common stock held by the selling stockholders named herein. The term “selling stockholders” includes the stockholders listed below and their transferees, pledges, donees or other successors-in-interest who may acquire shares from a selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer after the date of this prospectus. Information concerning the selling stockholders may change after the date of this prospectus and changed information will be presented in a supplement to this prospectus if and when required.

Certain Information Concerning the Selling Stockholders

The following table sets forth, based on information provided to us by or on behalf of the selling stockholders or known to us, the name of the selling stockholders, the nature of any position, office or other material relationship, if any, which the selling stockholders have had, within the past three years, with us or with any of our predecessors or affiliates, and the number of shares of our common stock beneficially owned by the selling stockholders before and after this offering. The number of shares owned are those beneficially owned, as determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock that the person has the right to acquire within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. Except as otherwise set forth herein, the selling stockholders are not a broker-dealer or an affiliate of a broker-dealer.

The total number of shares of common stock saleable pursuant to this prospectus is 608,272.

For purposes of calculating the number of shares of common stock saleable pursuant to this prospectus, we have assumed that all of the shares of common stock issuable to the selling stockholders covered by this prospectus are sold and that the selling stockholders acquire no additional shares of common stock before the completion of this offering. However, because the selling stockholders can offer all, some, or none of their shares of common stock, no definitive estimate can be given as to the number of shares of common stock that the selling stockholders will ultimately offer or sell under this prospectus or the number of shares of common stock that will be held by the selling stockholders upon termination of this offering.

The information set forth below is based upon information obtained from the selling stockholders and upon information in our possession regarding the issuance of shares of common stock to the selling stockholders in connection with the Exchange and Termination Agreement. The percentages of shares owned after the offering are based on 8,501,864 shares of our common stock outstanding as of February 1, 2024, including the shares of common stock registered for resale hereby.

Name of Selling Stockholder	Beneficial Ownership of Common Stock Prior to the Offering		Common Stock Saleable Pursuant to this Prospectus	Beneficial Ownership of Common Stock After the Offering	
	Number of Shares	Percent of Class		Number of Shares	Percent of Class
Deerfield PDI Financing II, L.P.(1)	324,817	3.82%	324,817	—	—%
Deerfield Private Design Fund II, L.P.(2)	283,455	2.80%	283,455	—	—%
TOTAL	608,272	7.15%	608,272	—	—%

- (1) Deerfield Mgmt, L.P. is the general partner of Deerfield PDI Financing II, L.P. Deerfield Management Company, L.P. is the investment manager of Deerfield PDI Financing II, L.P. James E. Flynn is the sole member of the general partner of each of Deerfield Mgmt, L.P. and Deerfield Management Company, L.P. Each of Deerfield Mgmt, L.P., Deerfield Management Company, L.P. and Mr. James E. Flynn may be deemed to beneficially own the shares of common stock of the Company beneficially owned by Deerfield PDI Financing II, L.P. The selling stockholder’s address is c/o Deerfield Management Company, L.P., 345 Park Avenue South, 12th Floor, New York, NY 10010.

- (2) Deerfield Mgmt, L.P. is the general partner of Deerfield Private Design Fund II, L.P. Deerfield Management Company, L.P. is the investment manager of Deerfield Private Design Fund II, L.P. James E. Flynn is the sole member of the general partner of each of Deerfield Mgmt, L.P. and Deerfield Management Company, L.P. Each of Deerfield Mgmt, L.P., Deerfield Management Company, L.P. and Mr. James E. Flynn may be deemed to beneficially own the shares of common stock of the Company beneficially owned by Deerfield Private Design Fund II, L.P. The selling stockholder's address is c/o Deerfield Management Company, L.P., 345 Park Avenue South, 12th Floor, New York, NY 10010.

Material Relationship Between the Selling stockholders and Windtree

We and the selling stockholders previously entered into the Milestone Agreement as described in "*Prospectus Summary—Recent Developments—Exchange and Termination Agreement*". Pursuant to the Milestone Agreement, among other things, the selling stockholders had the right to receive Milestone Payments based on achievement of specified development and commercial milestones related to our AEROSURF® development program, which, if achieved, could potentially total up to \$15,000,000. Pursuant to the Exchange and Termination Agreement, the selling stockholders agreed to terminate its rights to receive the Milestone Payments and all related rights and obligations in respect of such Milestone Payments.

PLAN OF DISTRIBUTION

We are registering the resale of shares of common stock held by the selling stockholders from time to time after the date of this prospectus.

The selling stockholders may sell all or a portion of the shares of our common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may also decide not to sell all of the shares of common stock they are permitted to sell under this prospectus. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale.

Sales of the shares of common stock by the selling stockholders may occur from time to time in one or more of the following types of transactions (which may include block transactions):

- disposition on any national securities exchange on which our common stock may be listed at the time of the sale;
- disposition in the over-the-counter markets;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- disposition in one or more underwritten offerings in a best efforts basis or firm commitment basis;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- distribution to employees, members, limited partners or stockholders of the selling securityholders;
- by pledge to secured debts and other obligations;
- in “at the market” offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- under Rule 144, or any other exemption from registration under the Securities Act, if available, rather than under this prospectus;
- a combination of any such methods of sale; or
- any other method permitted by applicable law.

We do not know of specific arrangements by the selling stockholders for the sale of their shares of common stock. The aggregate proceeds to the selling stockholders from any sale of the shares of common stock offered by them will be the purchase price of the shares of common stock less discounts or commissions, if any. The selling stockholders reserve the right to accept and, together with their respective agents from time to time, to reject, in whole or in part, any proposed purchase of the shares of common stock to be made directly or through agents. We will not receive any of the proceeds from any such sale.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We have agreed to pay certain expenses incurred in connection with the registration and sale of the shares of common stock covered by this prospectus, including, among other things, all registration and filing fees (including SEC, Nasdaq and state blue sky registration and filing fees), printing expenses, and the fees and disbursements of our outside counsel and independent accountants, but excluding underwriting discounts and commissions.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be immediately resold by the selling stockholders to the public without registration and without regard to any restriction or limitation pursuant to Rule 144, without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The shares of common stock will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares of our common stock covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares of our common stock may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act). Once sold under the registration statement of which this prospectus forms a part, the shares of our common stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

The validity of the issuance of the common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Philadelphia, Pennsylvania.

EXPERTS

The consolidated balance sheet of Windtree Therapeutics, Inc. and Subsidiaries as of December 31, 2022, and the related consolidated statements of operations, changes in mezzanine equity and stockholders' equity, and cash flows for the year then ended have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference, which report includes an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Windtree Therapeutics, Inc. at December 31, 2021, and for the year then ended, appearing in Windtree Therapeutics, Inc.'s 2022 Annual Report (Form 10-K) for the year ended December 31, 2022 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 3 to the consolidated financial statements), included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus forms part of a registration statement on Form S-3 that we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement or the documents incorporated by reference herein and therein. For further information with respect to us and the securities that we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement and the documents incorporated by reference herein and therein. You should rely only on the information contained in this prospectus or incorporated by reference herein or therein. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered hereby. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Windtree. The address of the SEC website is www.sec.gov.

We also maintain a website at <https://ir.windtreetx.com/filings/sec-filings>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on [March 31, 2023](#), as amended by the Company’s Annual Report on Form 10-K/A filed with the Commission on [May 1, 2023](#);
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, June 30, 2023, and September 30, 2023 filed with the SEC on [May 15, 2023](#), [August 7, 2023](#), and [November 9, 2023](#), respectively;
- our Definitive Proxy Statement on Form DEF 14A filed with the SEC on [January 10, 2023](#);
- our Current Reports on Form 8-K, filed with the SEC on [January 19, 2023](#), [January 26, 2023](#), [February 8, 2023](#), [February 22, 2023](#), [February 23, 2023](#), [April 19, 2023](#), [April 24, 2023](#), [June 14, 2023](#), [June 27, 2023](#), [August 16, 2023](#), [August 28, 2023](#), [September 26, 2023](#), [November 9, 2023](#), [January 17, 2024](#), [January 22, 2024](#), [January 25, 2024](#) and [January 31, 2024](#); and
- the description of our common stock included in our Form 8-A filed with the SEC on [May 15, 2020](#), including any amendments or reports filed for the purpose of updating such description.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have “furnished” to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements on Schedule 14A.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100., Warrington, Pennsylvania 18976, Attn: Corporate Secretary.

You also may access these filings on our website at <https://ir.windtreetx.com/filings/sec-filings>. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus). You may also access these filings at the SEC’s website at www.sec.gov.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.



Up to 608,272 SHARES

COMMON STOCK

PROSPECTUS

Neither we nor the selling stockholders authorized any dealer, salesperson, or other person to give you written information other than this prospectus or to make representations as to matters not stated in this prospectus. You must not rely on unauthorized information. This prospectus is not an offer to sell these securities or our solicitation of your offer to buy these securities in any jurisdiction where that would not be permitted or legal. Neither the delivery of this prospectus nor any sales made hereunder after the date of this prospectus shall create an implication that the information contained herein or the affairs of the Company have not changed since the date of this prospectus.

, 2024

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following is an estimate of the expenses (all of which are to be paid by the registrant) that we may incur in connection with the securities being registered hereby, other than the SEC registration fee.

SEC registration fee	\$	33.22
Legal fees and expenses	\$	35,000.00
Accounting fees and expenses	\$	25,000.00
Printing and miscellaneous fees and expenses	\$	5,000.00
Total	\$	60,533.22

Item 15. Indemnification of Directors and Officers.

As permitted by Section 102 of the DGCL, we have adopted provisions in our Amended and Restated Certificate of Incorporation and By-Laws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our By-Laws also authorizes us to indemnify any and all persons whom it shall have power to indemnify to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the DGCL, our By-Laws provide that:

- we may indemnify any and all persons whom it shall have power to indemnify to the fullest extent permitted by the DGCL, subject to limited exceptions; and
- the rights provided in our By-Laws are not exclusive.

Our Amended and Restated Certificate of Incorporation and our By-Laws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of the Company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

Item 16. Exhibits.

a) Exhibits.

Exhibit Numbers	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, as filed with the SEC on March 31, 2023).
3.2	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC on August 11, 2022).
4.1**†	Exchange and Termination Agreement, by and between the Company and affiliates of Deerfield Management Company, L.P., effective upon January 24, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 25, 2024).
4.2	Registration Rights Agreement, by and between the Company and affiliates of Deerfield Management Company, L.P., effective upon January 24, 2024 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 25, 2024).
5.1*	Opinion of Goodwin Procter LLP
23.1*	Consent of EisnerAmper LLP, independent registered public accounting firm
23.2*	Consent of Ernst & Young LLP, independent registered public accounting firm
23.3*	Consent of Goodwin Procter LLP (included in exhibit 5.1)
24.1*	Power of Attorney (included in signature page hereto)
107*	Filing Fee Table

* Filed herewith.

**Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

† Certain portions of this exhibit have been omitted because they are not material and the registrant customarily and actually treats that information as private or confidential.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(a)

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) each prospectus filed pursuant to Rule 424(b)(3) as part of a registration statement as of the date the filed prospectus was deemed part of and included in the registration statement.

(ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter);

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(h) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Township of Warrington, Commonwealth of Pennsylvania, on February 14, 2024.

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig E. Fraser
 Name: Craig E. Fraser
 Title: President, and Chief Executive Officer
 (Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Craig E. Fraser as his or her true and lawful attorney-in-fact and agent, with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Craig E. Fraser</u> Craig E. Fraser	Chairman, President, and Chief Executive Officer (Principal Executive Officer)	February 14, 2024
<u>/s/ John Tattory</u> John Tattory	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	February 14, 2024
<u>/s/ Daniel E. Geffken</u> Daniel E. Geffken	Director	February 14, 2024
<u>/s/ Robert A. Scott, M.D.</u> Robert A. Scott, M.D.	Director	February 14, 2024
<u>/s/ Mark Strobeck, Ph.D.</u> Mark Strobeck, Ph.D.	Director	February 14, 2024
<u>/s/ Leslie J. Williams</u> Leslie J. Williams	Director	February 14, 2024



Goodwin Procter LLP
One Commerce Square
2005 Market Street, 32nd Floor
Philadelphia, PA 19103

goodwinlaw.com
+1 445 207 7800

February 14, 2024

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976

Re: Securities Being Registered under Registration Statement on Form S-3

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-3 (as amended or supplemented, the "Registration Statement") filed on February 14, 2024 with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration by Windtree Therapeutics, Inc., a Delaware corporation (the "Company"), of up to 608,272 (the "Shares") of the Company's common stock, par value \$0.001 per share ("Common Stock") to be sold by the selling stockholders listed in the Registration Statement under "Selling Stockholders" (the "Selling Stockholders").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company. For purposes of the opinion set forth below, we have assumed that before the Shares are issued the Company does not issue shares of Common Stock or reduce the total number of shares of Common Stock the Company is authorized to issue under its amended and restated certificate of incorporation such that the number of unissued shares of Common Stock authorized under the Company's amended and restated certificate of incorporation is less than the number of Shares.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and validly issued and are fully paid and non-assessable.

This opinion letter and the opinion it contains shall be interpreted in accordance with the Core Opinion Principles as published in *74 Business Lawyer* 815 (Summer 2019).

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of Windtree Therapeutics, Inc. on Form S-3 to be filed on or about February 14, 2024 of our report dated March 31, 2023, on our audit of the financial statements as of December 31, 2022 and for the year then ended, which report was included in the Annual Report on Form 10-K filed March 31, 2023. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to the reference to our firm under the caption "Experts" in this Registration Statement.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
February 14, 2024

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in the Registration Statement (Form S-3) and related Prospectus of Windtree Therapeutics, Inc. for the registration of 608,272 shares of its common stock and to the incorporation by reference therein of our report dated March 31, 2022 (except for the second paragraph of Note 2, as to which the date is March 31, 2023), with respect to the consolidated financial statements of Windtree Therapeutics, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
February 14, 2024

Calculation of Filing Fee Tables

Form S-3
(Form Type)

Windtree Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees to Be Paid	Equity	Common Stock, par value \$0.001 per share	457(c)	608,272	\$0.37	\$225,060.64	0.00014760	\$33.22
Fees to Be Paid	Total Registration Fee:							\$33.22
Carry Forward Securities								
Carry Forward Securities	-	-	-	-	-	-	-	-
	Total Offering Amounts					\$225,060.64		\$33.22
	Total Fees Previously Paid							-
	Total Fee Offsets							-
	Net Fee Due							\$33.22

- (1) Consists of shares of common stock Windtree Therapeutics, Inc., registered for resale by the selling stockholder named in this Registration Statement.
- (2) Pursuant to Rule 457(c) under the Securities Act, and solely for the purpose of calculating the registration fee, the proposed maximum offering price per share is the average of the high and low prices of shares of the Registrant's common stock on The Nasdaq Capital Market on February 9, 2024, such date being within five business days of the date that this Registration Statement was filed with the U.S. Securities and Exchange Commission.