
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.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300
(Name, address including zip code, and telephone number, including area code, of agent for service)

Copies to:

Rachael M. Bushey
Jennifer L. Porter
Goodwin Procter LLP
2929 Arch Street Suite #1700
Philadelphia, Pennsylvania 19104
(445) 207-7800

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.

[Table of Contents](#)

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 MAY 19, 2023

PRELIMINARY PROSPECTUS



236,836 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 236,836 shares of our common stock, par value \$0.001, issuable upon exercise of (i) warrants to purchase 192,344 shares of our common stock issued in January 2023, or the January 2023 Warrants, and (ii) warrants to purchase 44,492 shares of our common stock issued in February 2023, or the February 2023 Warrants (and together with the January 2023 Warrants, the Warrants). We issued the January 2023 Warrants and the February 2023 Warrants to the selling stockholders in exchange for their exercise of certain of their then outstanding warrants, collectively, the Exchange Warrants, to purchase our common stock on January 24, 2023 and February 21, 2023, respectively. The January 2023 Warrants will become exercisable on July 24, 2023, expire on July 24, 2028, and have an exercise price of \$10.76 per share. The February 2023 Warrants will become exercisable on August 21, 2023, expire on August 21, 2028, and have an exercise price of \$10.76 per share. We are registering the shares issuable upon exercise of the Warrants 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 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 17 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 May 18, 2023 was \$1.51 per share.

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 _____, 2023.

TABLE OF CONTENTS

| | <u>Page</u> |
|---|--------------------|
| ABOUT THIS PROSPECTUS | 1 |
| PROSPECTUS SUMMARY | 2 |
| RISK FACTORS | 5 |
| SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS | 6 |
| USE OF PROCEEDS | 8 |
| SELLING STOCKHOLDERS | 9 |
| DESCRIPTION OF CAPITAL STOCK | 12 |
| PLAN OF DISTRIBUTION | 16 |
| LEGAL MATTERS | 18 |
| EXPERTS | 19 |
| WHERE YOU CAN FIND MORE INFORMATION | 20 |
| INCORPORATION OF DOCUMENTS BY REFERENCE | 21 |

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 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 our 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 improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic 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 to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions 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 this Phase 2 global clinical 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 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. 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 our recently completed Phase 2 global clinical study in early cardiogenic shock not only supports that program’s continued development but also supports the continued development of our AHF program as well.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca²⁺-ATPase 2a, or 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 rostafuloxin, 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 this product candidate without securing such an arrangement or partnership.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business, financial condition, and results of operations.

January 2023 Warrant Exercise Inducement Offer Letters

On January 20, 2023, we entered into warrant exercise inducement offer letters, with certain holders of certain of our: (i) warrants issued in December 2019 to purchase 1,573 shares of common stock with an exercise price of \$604.50 per share; (ii) warrants issued in May 2020 to purchase 5,598 shares of common stock with an exercise price of \$398.75 per share, and (iii) warrants issued in March 2021 to purchase 89,001 shares of common stock with an exercise price of \$180.00 per share (collectively, the January 2023 Existing Warrants).

Pursuant to the terms of the inducement letters, we agreed to amend the January 2023 Existing Warrants by lowering the exercise price of the January 2023 Existing Warrants to \$10.00 per share. Additionally, the exercising holders agreed to exercise for cash all of their January 2023 Existing Warrants to purchase an aggregate of 96,172 shares of common stock in exchange for our agreement to issue to such exercising holders the January 2023 Warrants to purchase up to an aggregate of 192,344 shares of common stock. We received aggregate net proceeds of approximately \$0.7 million from the exercise of the January 2023 Existing Warrants by the exercising holders.

Each January 2023 Warrant is exercisable into shares of common stock at a price per share of \$10.76, will initially be exercisable six months following its date of issuance, or the January 2023 Initial Exercise Date, and will expire on the fifth anniversary of the January 2023 Initial Exercise Date. Subject to limited exceptions, a holder of January 2023 Warrants will not have the right to exercise any portion of its January 2023 Warrants if the holder (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, upon election by a holder prior to the issuance of any Warrants, 9.99%) of the shares of common stock then outstanding. At the holder’s option, upon notice to us, the holder may increase or decrease this beneficial ownership limitation not to exceed 9.99% of the shares of common stock then outstanding, with any such increase becoming effective upon 61 days’ prior notice to us.

February 2023 Warrant Exercise Inducement Offer Letter

On February 21, 2023, we entered into a warrant exercise inducement offer letter with Panacea Venture Healthcare Fund I, L.P., a holder of certain of our: (i) warrants issued in July 2018 to purchase 1,250 shares of common stock with an exercise price of \$600.00 per share; (ii) warrants issued in December 2018 to purchase 9,960 shares of common stock with an exercise price of \$607.50 per share; (iii) warrants issued in December 2019 to purchase 5,519 shares of common stock with an exercise price of \$604.50 per share; and (iv) warrants issued in May 2020 to purchase 5,517 shares of common stock with an exercise price of \$398.75 per share (collectively, the February 2023 Existing Warrants).

Pursuant to the terms of the inducement letter, we agreed to amend the February 2023 Existing Warrants by lowering the exercise price of the February 2023 Existing Warrants to \$7.06 per share. Additionally, Panacea agreed to exercise for cash all of their February 2023 Existing Warrants to purchase an aggregate of 22,246 shares of common stock in exchange for our agreement to issue to Panacea the February 2023 Warrants to purchase up to an aggregate of 44,492 shares of common stock. We received aggregate net proceeds of approximately \$0.1 million from the exercise of the February 2023 Existing Warrants by Panacea.

Each February 2023 Warrant is exercisable into shares of common stock at a price per share of \$10.76, will initially be exercisable six months following its date of issuance, or the February 2023 Initial Exercise Date, and will expire on the fifth anniversary the February 2023 Initial Exercise Date. Subject to limited exceptions, Panacea will not have the right to exercise any portion of its February 2023 Warrants if Panacea (together with Panacea's affiliates, and any persons acting as a group together with Panacea or any of Panacea's affiliates) would beneficially own a number of shares of our common stock in excess of 19.99% of our total shares of common stock outstanding.

April 2023 Public Offering

On April 20, 2023, we entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, as the sole underwriter relating to a public offering, or the April 2023 Offering, of an aggregate of 3,686,006 units with each unit consisting of one share of common stock and a warrant, or the April 2023 Warrants. The April 2023 Warrants are immediately exercisable for shares of common stock at a price of \$2.93 per share and expire five years from the date of issuance. The shares of common stock and the April 2023 Warrants were immediately separable and were issued separately in the April 2023 Offering.

In addition, Ladenburg exercised in full a 45-day option, or the Overallotment Option, to purchase up to 552,900 additional shares of common stock and warrants to purchase up to 552,900 additional shares of common stock.

The closing of the April 2023 Offering occurred on April 24, 2023, inclusive of the Overallotment Option. The offering price to the public was \$2.93 per unit. After deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the April 2023 Warrants issued pursuant to this April 2023 Offering, the net proceeds to us were approximately \$10.8 million.

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.windtreetworks.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 236,836 shares

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 “*Plan of Distribution*” on page 16.

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 “*Risk Factors*” beginning on page 5, 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 or issuable to the selling stockholders upon exercise of the Warrants issued in the Exchange as described above. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, their 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 risks discussed 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. If any of the events or developments described below or in our Annual Report on Form 10-K or subsequent filings occurs, our business, financial condition, results of operations and prospects could be materially and adversely affected. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

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.

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;
- 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 and goodwill 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 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, or U.S., 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., and its 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 commercialize the 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 U.S. 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
- 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®, **AFFECTAIR®**, **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 236,836 shares of our common stock issuable upon the exercise of the Warrants 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 names 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, none of the selling stockholders are a broker-dealer or an affiliate of a broker-dealer.

The total number of shares of common stock saleable pursuant to this prospectus is 236,836.

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.

| Name of Selling Stockholder ⁽¹⁾ | Beneficial Ownership of Common Stock Prior to the Offering | | Common Stock Saleable Pursuant to this Prospectus | Beneficial Ownership of Common Stock After the Offering ⁽²⁾ | |
|---|--|---------------------------------|---|--|---------------------------------|
| | Number of Shares | Percent of Class ⁽³⁾ | | Number of Shares | Percent of Class ⁽³⁾ |
| Panacea Venture Healthcare Fund I, L.P. ⁽⁴⁾ | 113,475 | 2.11% | 44,492 | 68,983 | 1.28% |
| Armistice Capital Master Fund, Ltd. ⁽⁵⁾ | 39,800 | * | 39,800 | — | — |
| Lincoln Park Capital Fund, LLC ⁽⁶⁾ | 32,000 | * | 32,000 | — | — |
| Lind Global Macro Fund LP ⁽⁷⁾ | 22,044 | * | 22,000 | 44 | * |
| Bigger Capital Fund, LP ⁽⁸⁾ | 19,900 | * | 19,900 | — | — |
| District 2 Capital Fund LP ⁽⁹⁾ | 19,900 | * | 19,900 | — | — |
| Cavalry Fund I LP ⁽¹⁰⁾ | 10,800 | * | 10,800 | — | — |
| Cavalry Special Ops Fund LLC ⁽¹¹⁾ | 10,800 | * | 10,800 | — | — |
| 3i, LP ⁽¹²⁾ | 8,115 | * | 8,115 | — | — |
| Kepos Alpha Master Fund LP ⁽¹³⁾ | 6,600 | * | 6,600 | — | — |
| NongHyup Bank as Trustee of Pacific Bridge Global Inner Circle Fund 1 ⁽¹⁴⁾ | 5,960 | * | 5,960 | — | — |
| Hudson Bay Master Fund Ltd. ⁽¹⁵⁾ | 4,480 | * | 4,480 | — | — |
| Intracoastal Capital LLC ⁽¹⁶⁾ | 4,478 | * | 4,478 | — | — |
| Warberg WF X LP ⁽¹⁷⁾ | 3,127 | * | 3,127 | — | — |
| BoothBay Absolute Return Strategies LP ⁽¹⁸⁾ | 1,955 | * | 1,955 | — | — |
| BoothBay Diversified Alpha Master Fund LP ⁽¹⁹⁾ | 997 | * | 997 | — | — |
| Tyrus Industries ⁽²⁰⁾ | 1,324 | * | 662 | 662 | * |
| Tyrus Holdings ⁽²¹⁾ | 884 | * | 442 | 442 | * |
| Kingsbrook Opportunities Master Fund LP ⁽²²⁾ | 328 | * | 328 | — | — |
| TOTAL | 306,967 | 5.70% | 236,836 ⁽²⁾ | 70,131 | 1.30% |

* Less than 1%.

- (1) This table and information in the notes below are based upon information supplied to us by the selling stockholders.
- (2) The total number of shares of our common stock saleable pursuant to this prospectus is 236,836. For purposes of this table, we have assumed the exercise in full of all Warrants held by such selling stockholder without giving effect to any limits on beneficial ownership included in the terms thereof and that the selling stockholders will not acquire any additional shares of common stock before the completion of this offering. However, as 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 that the selling stockholders will ultimately offer or sell under this prospectus and the number of shares that will be held by the selling stockholders upon the termination of this offering.
- (3) Calculated based on 5,384,755 shares to be issued and outstanding as of May 19, 2023 (assuming the issuance of the shares of common stock upon exercise of the January 2023 Warrants and February 2023 Warrants on that date and 5,147,919 shares of common stock outstanding as of May 19, 2023).
- (4) The number of shares of common stock beneficially owned prior to this offering consists of (i) 68,983 shares of common stock held by Panacea Venture Healthcare Fund I, L.P. and (ii) 44,492 shares of common stock issuable upon the exercise of the February 2023 Warrants, which become exercisable on August 21, 2023. Panacea Venture Management Company Ltd. is the management company of Panacea Venture Healthcare Fund GP Company, Ltd., which is the general partner of Panacea Venture Healthcare Fund GP I, L.P., which is the general partner of Panacea Venture Healthcare Fund I, L.P. By virtue of his control of Panacea Venture Management Company Ltd., James Huang, a founding and managing partner of Panacea Venture Healthcare Fund I, L.P., may be deemed to share beneficial ownership of the securities held by Panacea Venture Healthcare Fund I, L.P. Mr. Huang is a former director and the former Chairman of our Board of Directors. The address for Panacea Venture Healthcare Fund I, L.P. is No. 5, Lane 1350, Fuxing Middle Road, Xuhui District, Shanghai, China 200031.
- (5) The number of shares of common stock beneficially owned prior to this offering consists of 39,800 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Armistice Capital Master Fund, Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.
- (6) The number of shares of common stock beneficially owned prior to this offering consists of 32,000 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Lincoln Park Capital Fund, LLC is 440 N. Wells St., Suite 410, Chicago, IL 60654.

[Table of Contents](#)

- (7) The number of shares of common stock beneficially owned prior to this offering consists of (i) 44 shares of common stock held by Lind Global Macro Fund LP and (ii) 22,000 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Lind Global Macro Fund LP is 444 Madison Ave., 41st Floor, New York, NY 10022.
- (8) The number of shares of common stock beneficially owned prior to this offering consists of 19,900 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Bigger Capital Fund, LP is 11700 W. Charleston Blvd. 170-659, Las Vegas, NV 89135.
- (9) The number of shares of common stock beneficially owned prior to this offering consists of 19,900 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for District 2 Capital Fund LP is 14 Wall Street, 2nd Floor, Huntington, NY 11743.
- (10) The number of shares of common stock beneficially owned prior to this offering consists of 10,800 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Cavalry Fund I LP is 82 E. Allendale Rd., Ste. 5B, Salle River, NJ 07458.
- (11) The number of shares of common stock beneficially owned prior to this offering consists of 10,800 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Cavalry Special Ops Fund LLC is 82 E. Allendale Rd., Ste. 5B, Salle River, NJ 07458.
- (12) The number of shares of common stock beneficially owned prior to this offering consists of 8,115 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for 3i, LP is 2 Wooster Street, Fl. 2, New York, NY 10013.
- (13) The number of shares of common stock beneficially owned prior to this offering consists of 6,600 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Kepos Capital LP is the investment manager of Kepos Alpha Master Fund LP and Kepos Partners LLC is the General Partner of Kepos Alpha Master Fund LP and each may be deemed to have voting and dispositive power with respect to the shares. The general partner of Kepos Capital LP is Kepos Capital GP LLC, or Kepos GP, and the Managing Member of Kepos Partners LLC is Kepos Partners MM LLC, or Kepos MM. Mark Carhart controls Kepos GP and Kepos MM and, accordingly, may be deemed to have voting and dispositive power with respect to the shares held by this selling securityholder. Mr. Carhart disclaims beneficial ownership of the shares held by Kepos Alpha Master Fund LP. The address for Kepos Capital LP and Mr. Carhart is 11 Times Square, 35th Floor, New York NY 10036.
- (14) The number of shares of common stock beneficially owned prior to this offering consists of 5,960 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for NongHyup Bank as Trustee of Pacific Bridge Global Inner Circle Fund 1 is NH Bank Bldg 13F, 120 Tongli-ro Jung-gu, Seoul, Korea.
- (15) The number of shares of common stock beneficially owned prior to this offering consists of 4,480 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities. The address for Hudson Bay Master Fund Ltd. is c/o Hudson Bay Capital Management LP, 28 Havemeyer Pl, 2nd Floor, Greenwich CT 06830.
- (16) The number of shares of common stock beneficially owned prior to this offering consists of 4,478 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Mitchell P. Kopin and Daniel B. Asher, each of whom are managers of Intracoastal Capital LLC, have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal Capital LLC. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership of the securities reported herein that are held by Intracoastal Capital LLC. The address for Intracoastal Capital LLC is 245 Palm Trail, Delray Beach, FL 33483.
- (17) The number of shares of common stock beneficially owned prior to this offering consists of 3,127 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Warberg WF X LP is 716 Oak St., Winnetka, IL 60093.
- (18) The number of shares of common stock beneficially owned prior to this offering consists of 1,955 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Boothbay Absolute Return Strategies LP, a Delaware limited partnership, is managed by Boothbay Fund Management, LLC, a Delaware limited liability company. Boothbay Fund Management, LLC, in its capacity as the investment manager, has the power to vote and the power to direct the disposition of all securities held by Boothbay Absolute Return Strategies LP. Ari Glass is the Managing Member of Boothbay Fund Management, LLC. Each of Boothbay Absolute Return Strategies LP, Boothbay Fund Management, LLC and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein. The address for BoothBay Absolute Return Strategies LP is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.
- (19) The number of shares of common stock beneficially owned prior to this offering consists of 997 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Boothbay Diversified Alpha Master Fund LP, a Cayman Islands limited partnership, is managed by Boothbay Fund Management, LLC, a Delaware limited liability company. Boothbay Fund Management, LLC, in its capacity as the investment manager, has the power to vote and the power to direct the disposition of all securities held by Boothbay Diversified Alpha Master Fund LP. Ari Glass is the Managing Member of the Boothbay Fund Management, LLC. Each of Boothbay Diversified Alpha Master Fund LP, Boothbay Fund Management, LLC and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein. The address for BoothBay Diversified Alpha Master Fund LP is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.
- (20) The number of shares of common stock beneficially owned prior to this offering consists of (i) 662 shares of common stock held by Tyrus Industries and (ii) 662 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24,

2023. The address for Tyrus Industries is #1904 Trade Tower, Yeongdongdaero 511, Gangnam-gu, Seoul, Korea.

- (21) The number of shares of common stock beneficially owned prior to this offering consists of (i) 442 shares of common stock held by Tyrus Holdings and (ii) 442 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. The address for Tyrus Holdings is #1904 Trade Tower, Yeongdongdaero 511, Gangnam-gu, Seoul, Korea.
- (22) The number of shares of common stock beneficially owned prior to this offering consists of 328 shares of common stock issuable upon the exercise of the January 2023 Warrants, which become exercisable on July 24, 2023. Kingsbrook Partners LP, or Kingsbrook Partners, is the investment manager of Kingsbrook Opportunities Master Fund LP, or Kingsbrook Opportunities, and consequently has voting control and investment discretion over securities held by Kingsbrook Opportunities. Kingsbrook Opportunities GP LLC, or Opportunities GP, is the general partner of Kingsbrook Opportunities and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Opportunities. KB GP LLC, GP LLC, is the general partner of Kingsbrook Partners and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Partners. Ari J. Storch, Adam J. Chill and Scott M. Wallace are the sole managing members of Opportunities GP and GP LLC and as a result may be considered beneficial owners of any securities deemed beneficially owned by Opportunities GP and GP LLC. Each of Kingsbrook Partners, Opportunities GP, GP LLC and Messrs. Storch, Chill and Wallace disclaim beneficial ownership of these securities. The address for Kingsbrook Opportunities Master Fund LP is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12

Material Relationship Between the Selling Stockholders and Windtree

James Huang, a former director and the former Chairman of our Board of Directors, is a founding and managing partner of Panacea Venture Healthcare Fund I, L.P. Panacea Venture Management Company Ltd. is the management company of Panacea Venture Healthcare Fund GP Company, Ltd., which is the general partner of Panacea Venture Healthcare Fund GP I, L.P., which is the general partner of Panacea Venture Healthcare Fund I, L.P. By virtue of his control of Panacea Venture Management Company Ltd., Mr. Huang, a founding and managing partner of Panacea Venture Healthcare Fund I, L.P., may be deemed to share beneficial ownership of the securities held by Panacea Venture Healthcare Fund I, L.P.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation, which has been publicly filed with the SEC. See “Where You Can Find Additional Information and Incorporation of Certain Information by Reference.”

Capital Stock

Our authorized capital stock consists of 120,000,000 shares of common stock, par value \$0.001 per share and 5,000,000 shares of preferred stock, par value \$0.001 per share.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. The affirmative vote of the voting power of the outstanding shares of capital stock entitled to vote, voting as a single class, will be required to amend certain provisions of our Amended and Restated Certificate of Incorporation, including the provisions relating to amending our By-Laws, procedures for our stockholder meetings, director liability, and exclusive forum for proceedings.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our Board out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. In the event of a liquidation, dissolution or winding up of us, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Number of Holders

There are approximately 38 holders of our common stock as of May 1, 2023.

Preferred Stock

Our Board currently has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock by us could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon a liquidation of us. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of us or other corporate action.

Anti-takeover provisions

Amended and Restated Certificate of Incorporation and By-Laws

Among other things, our Amended and Restated Certificate of Incorporation and By-Laws:

- permit our Board to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed for cause or without cause, which removal may be effected, by the affirmative vote of a majority of the votes of the issued and outstanding shares of stock entitled to vote for the election of the stockholders called and held for that purpose, or by a majority vote of the Board at a meeting called for such purpose, and the vacancy in the Board caused by any such removal may be filled by such stockholders or directors, as the case may be, at such meeting, and if the stockholders shall fail to fill such vacancy, such vacancy shall be filled in the manner as provided by the By-Laws;
- provide that all vacancies, including newly created directorships, may be filled by the decision of majority of the directors then in office, including those who have so resigned, and shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section for the filling of other vacancies;
- provides that stockholders may act via a consent of stockholders in lieu of a meeting without prior notice and without a vote, if a consent or consents in writing, set forth the action so taken, and is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Company by delivery to its registered office in this State, its principal place of business, or an officer or agent of the Company having custody of the book in which proceedings of meetings of stockholders are recorded;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the Board, the Chairman of the Board, or the Chief Executive Officer; and
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require the affirmative vote of the majority of voting power of the outstanding shares of capital stock entitled to vote.

The combination of these provisions makes it more difficult for our stockholders to replace our Board as well as for another party to obtain control of us by replacing our Board. Because our Board has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the Board of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the Board and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

A Delaware corporation may “opt out” of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for the following claims or causes of action brought under Delaware statutory or common law: (1) any derivative claim or action brought on our behalf; (2) any claim or cause of action asserting a breach of fiduciary duty by any of our directors or officers; (3) any claim or cause of action asserting a claim against us arising out of, or pursuant to, the DGCL, our Amended and Restated Certificate of Incorporation or our By-Laws; or (4) any action asserting a claim against the Company governed by the internal affairs doctrine.

Limitations of Liability and Indemnification

Our Amended and Restated Certificate of Incorporation and our By-Laws limit our directors’ liability and may indemnify our directors and officers to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, 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 unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper benefit.

The DGCL and our By-Laws provide that we will, in certain situations, indemnify our directors and officers, to the fullest extent permitted by law.

We have entered into indemnification agreements with our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys’ fees, judgments, penalties, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We maintain a directors’ and officers’ insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our Amended and Restated Certificate of Incorporation, our By-Laws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our Amended and Restated Certificate of Incorporation and By-Laws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder’s investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no material pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened material litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act, and is therefore unenforceable.

Listing

Our common stock is listed on the Nasdaq Capital Market under the trading symbol “WINT”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

PLAN OF DISTRIBUTION

We are registering the resale of shares of common stock issuable upon exercise of the Warrants 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;
- 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;
- 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).

The selling stockholders and 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 resold by the selling stockholders 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.windtreetworks.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 Report on Form 10-Q for the quarter ended March 31, 2023 filed with the SEC on [May 15, 2023](#);
- 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](#) and [April 24, 2023](#); and
- the description of our common stock contained in [Exhibit 4.18](#) our 2022 Annual Report on Form 10-K, including any amendments or reports filed for the purposes of updating this 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.



236,836 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.

, 2023

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 | \$ | 37.59 |
| Legal fees and expenses | \$ | 30,000.00 |
| Accounting fees and expenses | \$ | 20,000.00 |
| Printing and miscellaneous fees and expenses | \$ | 5,000.00 |
| Total | \$ | <u>55,037.59</u> |

Item 15. Indemnification of Officers and Directors.

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 |
|------------------------|---|
| 1.1** | Form of Underwriting Agreement |
| 4.1 | Form of Warrant dated October 10, 2014 (incorporated by reference to Exhibit 4.11 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014). |
| 4.2 | Form of Series A-1 Warrant dated February 13, 2017 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017). |
| 4.3 | Form of Series C Warrant dated April 4, 2018 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018). |
| 4.4 | Form of Series D Warrant dated July 2, 2018 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 6, 2018). |
| 4.5 | Form of Series E Warrant dated December 11, 2018 (incorporated by reference to Exhibit 4.7 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019). |
| 4.6 | Form of Series G Warrant dated December 24, 2018 (incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018). |
| 4.7 | Form of Series H Warrant dated February 14, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018). |
| 4.8 | Form of Series I Warrant dated December 6, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019). |
| 4.9 | Form of Series I Warrant Amendment dated May 6, 2020, to the Series I Warrant dated December 6, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 7, 2020). |
| 4.10 | Form of Warrant issued in Windtree's May 2020 underwritten public offering of securities (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 22, 2020). |
| 4.11 | Form of Warrant issued in Windtree's March 2021 underwritten public offering of securities (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 24, 2021). |
| 4.12 | Form of Common Stock Purchase Warrant dated January 24, 2023 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 26, 2023). |
| 4.13 | Form of Common Stock Purchase Warrant dated February 21, 2023 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 22, 2023). |
| 4.14 | Form of Common Warrant (incorporated by reference to Exhibit 4.19 to Windtree's Registration Statement on Form S-1/A, as filed with the SEC on April 7, 2023). |
| 4.15 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.20 to Windtree's Registration Statement on Form S-1/A, as filed with the SEC on April 7, 2023). |
| 4.16 | Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.21 to Windtree's Registration Statement on Form S-1/A, as filed with the SEC on April 7, 2023). |

Table of Contents

| | |
|-------|---|
| 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.

** To be filed, if necessary, by amendment or as an exhibit to a document to be incorporated or deemed to be incorporated by reference in this registration statement, including a Current Report on Form 8-K.

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 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 May 19, 2023.

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.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|--------------|
| <u>/s/ Craig E. Fraser</u> Craig E. Fraser | Director, President, and Chief Executive Officer (Principal Executive Officer) | May 19, 2023 |
| <u>/s/ John Tattory</u> John Tattory | Interim Chief Financial Officer (Principal Financial and Accounting Officer) | May 19, 2023 |
| <u>/s/ Daniel E. Geffken</u> Daniel E. Geffken | Director | May 19, 2023 |
| <u>/s/ Robert A. Scott, M.D.</u> Robert A. Scott, M.D. | Director | May 19, 2023 |
| <u>/s/ Leslie J. Williams</u> Leslie J. Williams | Director | May 19, 2023 |



Goodwin Procter LLP
2929 Arch Street, Suite #1700
Philadelphia, PA 19104

goodwinlaw.com
+1 445 207 7800

May 19, 2023

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

Re: Securities 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 May 19, 2023 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 236,836 shares (the "Warrant Shares") of the Company's common stock, par value \$0.001 per share ("Common Stock"), issuable upon exercise of certain warrants issued by the Company (the "Warrants"), 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 Warrant 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 Warrant 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 Warrant Shares, when and if issued upon exercise of the Warrants in accordance with the terms of the Warrants, will have been duly authorized and will be validly issued, 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

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 May 19, 2023 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
May 19, 2023

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 236,836 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
May 19, 2023

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) | 236,836 | \$1.44 | \$341,043.84 | 0.0001102 | \$37.59 |
| Fees to Be Paid | Total Registration Fee: | | | | | | | \$37.59 |
| Carry Forward Securities | | | | | | | | |
| Carry Forward Securities | — | — | — | — | — | — | — | — |
| | Total Offering Amounts | | | | | \$341,043.84 | | \$37.59 |
| | Total Fees Previously Paid | | | | | | | — |
| | Total Fee Offsets | | | | | | | — |
| | Net Fee Due | | | | | | | \$37.59 |

(1) Consists of shares of common stock, issuable upon exercise of certain warrants of Windtree Therapeutics, Inc., registered for resale by the selling stockholders 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 May 16, 2023, such date being within five business days of the date that this Registration Statement was filed with the U.S. Securities and Exchange Commission.