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

FORM S-1
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)

2836
(Primary Standard Industrial
Classification Code Number)

94-3171943
(I.R.S. Employer
Identification Number)

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
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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, 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 post-effective amendment filed pursuant to Rule 462(d) 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.

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 the 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 which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the 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. We 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 it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 23, 2024

PRELIMINARY PROSPECTUS



Up to 10,679,758 Shares of Common Stock

This prospectus relates to the potential resale from time to time by Seven Knots, LLC, or Seven Knots or the Selling Stockholder, of up to 10,679,758 shares of common stock, par value \$0.001 per share, or common stock. The shares of common stock to which this prospectus relates consists of shares that have been or may be issued by us to the Selling Stockholder pursuant to a Common Stock Purchase Agreement, dated as of June 26, 2024, by and between us and the Selling Stockholder, or the Purchase Agreement, establishing an equity line of credit, or the Equity Financing. Such shares of our common stock include (i) up to 10,574,018 shares of common stock, or the Purchase Shares, that we may elect, in our sole discretion, to issue and sell to Seven Knots, from time to time from and after the Commencement Date (as defined below) under the Purchase Agreement, and subject to applicable stock exchange rules (assuming the shares to be issued and sold at a price of \$3.31 per share) and (ii) up to 105,740 shares of common stock, or the Note Shares, issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the convertible promissory note, or the Commitment Note, issued to Seven Knots as consideration for it entering into the Purchase Agreement.

The actual number of shares of our common stock issuable will vary depending on the then-current market price of shares of our common stock sold to the Selling Stockholder under the Purchase Agreement, but will not exceed the number set forth in the preceding sentences unless we file an additional registration statement under the Securities Act of 1933, as amended, or the Securities Act, with the Securities Exchange Commission, or the SEC, and we obtain the approval of the issuance of shares of common stock by our stockholders in accordance with the applicable stock exchange rules. Under the applicable rules of The Nasdaq Stock Market LLC, or Nasdaq, in no event may we issue to the Selling Stockholder shares of our common stock representing more than 19.99% of the total number of shares of common stock outstanding as of the date of the Purchase Agreement, unless (i) we obtain the approval of the issuance of such shares by our stockholders in accordance with the applicable stock exchange rules or (ii) sales of common stock are made at an average price equal to or in excess of the lower of (A) the closing price on the Nasdaq Capital Market on June 26, 2024 and (B) the average of the closing prices of the common stock for the five business days immediately preceding June 26, 2024 (in each case plus an incremental amount to take into account the Note Shares), such that the sales of such common stock to the Selling Stockholder would not count toward such limit because they are “at market” under applicable stock exchange rules. See “*The Committed Equity Financing*” for a description of the Purchase Agreement and “*Selling Stockholder*” for additional information regarding the Selling Stockholder.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of the shares of our common stock by the Selling Stockholder. Additionally, we will not receive any proceeds from the issuance or sale of the Note Shares. However, we may receive up to \$35.0 million in aggregate gross proceeds from the sale of the shares of common stock to the Selling Stockholder under the Purchase Agreement, from time to time in our discretion after the date the registration statement that includes this prospectus is declared effective and after satisfaction of other conditions in the Purchase Agreement. The actual proceeds from the Selling Stockholder may be less than this amount depending on the number of shares of our common stock sold and the price at which the shares of our common stock are sold.

This prospectus provides you with a general description of such securities and the general manner in which the Selling Stockholder may offer or sell the securities. More specific terms of any securities that the Selling Stockholder may offer or sell may be provided in a prospectus supplement that describes, among other things, the specific amounts and prices of the securities being offered and the terms of the offering. The prospectus supplement may also add, update or change information contained in this prospectus.

The Selling Stockholder may offer, sell or distribute all or a portion of the shares of our common stock acquired under the Purchase Agreement and hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will bear all costs, expenses and fees in connection with the registration of the shares of our common stock, including with regard to compliance with state securities or “blue sky” laws. The timing and amount of any sales are within the sole discretion of the Selling Stockholder. The Selling Stockholder is an underwriter under the Securities Act with respect to the resale of shares held by it. Although the Selling Stockholder is obligated to purchase shares of our common stock under the terms and subject to the conditions and limitations of the Purchase Agreement to the extent we choose to sell such shares of our common stock to it (subject to certain conditions), there can be no assurances that we will choose to sell any shares of our common stock to the Selling Stockholder, or that the Selling Stockholder will sell any or all of the shares of our common stock, if any, purchased under the Purchase Agreement pursuant to this prospectus. The Selling Stockholder will bear all commissions and discounts, if any, attributable to its sale of shares of our common stock. See “*Plan of Distribution*.”

You should read this prospectus and any prospectus supplement or amendment carefully before you invest in our securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol “WINT.” On August 22, 2024, the last reported sale price of our common stock on the Nasdaq Capital Market was \$11.03 per share.

We are a “smaller reporting company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and the documents incorporated by reference herein and may elect to comply with reduced public company reporting requirements in future filings. See “*Prospectus Summary — Implications of Being a Smaller Reporting Company*.”

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described beginning on page 6 of this prospectus under the caption “*Risk Factors*”, and under similar headings in any amendment or supplement to this prospectus or in any other documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus dated _____, 2024

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission, or the SEC, includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto.

You should not assume that the information contained in this prospectus or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference herein or therein is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date. This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been or will be filed or have been or will be incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading “*Where You Can Find More Information.*”

You should rely only on the information that we have included or incorporated by reference in this prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not, and the underwriters have not, authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus or any related 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 or any related free writing prospectus. This prospectus and any related 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 or any related 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.

In addition, while we believe the industry, market and competitive position data included in this prospectus, including the information incorporated by reference herein is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors. These factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

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.

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 biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Our portfolio of product candidates includes istaroxime, a Phase 2 candidate that inhibits the sodium-potassium ATPase and also activates sarco endoplasmic reticulum Ca²⁺-ATPase 2a, or SERCA2a, for acute heart failure and associated cardiogenic shock; preclinical SERCA2a activators for heart failure; rostaduroxin for the treatment of hypertension in patients with a specific genetic profile; and a preclinical atypical protein kinase C iota, or aPKC ι , inhibitor (topical and oral formulations), being developed for potential application in rare and broad oncology indications. We also have a licensing business model with partnership out-licenses currently in place.

Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. Istaroxime demonstrated significant improvement in both systolic and diastolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure in acute decompensated heart failure patients and had a favorable renal profile, we initiated a Phase 2 global clinical study, or the SEISMic Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. In April 2022, we announced our observations in the SEISMic Study that istaroxime rapidly and significantly increased systolic blood pressure while also improving cardiac function and preserving renal function. We believe that istaroxime has the potential to fulfill an unmet need in early and potentially more severe cardiogenic shock. We further believe that the data from the SEISMic Study supports continued development in both cardiogenic shock and AHF. In the fourth quarter of 2023, we initiated an extension to the SEISMic Study, or the SEISMic Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of SERCA2a. The SEISMic Extension study is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in the second half of 2024. Additionally, we have recently initiated a small study in more severe SCAI Stage C cardiogenic shock, or the SEISMic C Study, to evaluate the safety and efficacy of istaroxime in cardiogenic shock patients who are also receiving standard of care rescue therapy for shock. The SEISMic C Study is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock with enrollment anticipated to be completed in late 2024. Our ability to complete both of these studies with their intended sample size is dependent upon our ability to secure adequate resourcing for the program through financing efforts or business development activities.

Our heart failure cardiovascular portfolio also includes other SERCA2a activators. One family of compounds has the dual mechanism of action that includes inhibition of the sodium-potassium ATPase as well as activation of SERCA2a. The other family of compounds are considered selective SERCA2a activators and are devoid of activity against the sodium-potassium ATPase. 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 rostaduroxin, 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 the development of rostaduroxin without securing such an arrangement or partnership.

Our cardiovascular assets and programs are associated with a regional licensed partnership with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), for the development and commercialization of our product candidate, istaroxime, in Greater China. In addition to istaroxime, the agreement also licenses our preclinical next-generation dual mechanism SERCA2a activators, and rostafuroxin. In addition, we are supporting the efforts of Lee's (HK) in starting a Phase 3 trial in AHF with istaroxime.

On April 2, 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with a license agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. The Transferred Assets include a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations (topical and oral) of an aPKCi inhibitor. We plan to advance investigational new drug enabling activities and are in the process of determining the expected clinical development plan for the platform.

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, 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, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations.

Corporate Information

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

Implications of Being a Smaller Reporting Company

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

THE OFFERING

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus.

Shares of common stock offering by the Selling Stockholder	Up to 10,679,758 shares of common stock, consisting of (i) up to 10,574,018 Purchase Shares that have been or may be issued by us to the Selling Stockholder, from time to time at our sole discretion, pursuant to the Purchase Agreement, and (ii) up to 105,740 Note Shares.
Shares of common stock outstanding immediately prior to this offering	591,909 shares (as of August 22, 2024).
Shares of common stock outstanding immediately following this offering	11,271,667 shares.
Terms of the offering	The Selling Stockholder will determine when and how it will dispose of any shares of our common stock that are registered under this prospectus for resale. See “Plan of Distribution.”
Use of proceeds	We will not receive any of the proceeds from the sale of shares of our common stock offered by Seven Knots. In addition, we will not receive any proceeds from the issuance or sale of the Note Shares. We may receive up to \$35.0 million in aggregate gross proceeds from Seven Knots under the Purchase Agreement in connection with sales of our shares of our common stock to Seven Knots pursuant to the Purchase Agreement after the date of this prospectus. However, the actual proceeds may be less than this amount depending on the number of shares of our common stock sold and the price at which the shares of our common stock are sold. We intend to use any net proceeds that we receive under the Purchase Agreement for working capital and other general corporate purposes. However, as of the date of this prospectus, we cannot specify with certainty all of the particular uses, and the respective amounts we may allocate to those uses, for any net proceeds we receive. See “ <i>Use of Proceeds</i> ” on page 20 of this prospectus.
Nasdaq Capital Market symbol	Our shares of common stock are traded on The Nasdaq Capital Market under the symbol “WINT”.
Transfer Agent and Registrar	Continental Stock Transfer and Trust Company

The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of August 22, 2024, and excludes:

- 16,331,331 shares of common stock issuable upon conversion of our outstanding shares of Series C Convertible Preferred Stock, par value \$0.001 per share;
- 11,336,775 shares of common stock issuable upon exercise of warrants issued pursuant to the Securities Purchase Agreement, dated July 18, 2024 and dated July 26, 2024, in each case by and among us and the investor party thereto;
- 258,130 shares of our common stock issuable upon the exercise of outstanding warrants as of June 30, 2024, with a weighted-average exercise price of \$274.18 per share;

- 15,361 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2024, with a weighted-average exercise price of \$1,518.83 per share;
- 8,107 shares of our common stock issuable upon the exercise of outstanding restricted stock units as of June 30, 2024, with a weighted-average grant date fair value of \$37.22 per share; and
- 19,112 shares of our common stock reserved for future issuance under our Amended and Restated Windtree Therapeutics 2020 Equity Incentive Plan, or A&R 2020 Plan, plus any future increases in the number of shares of common stock reserved for issuance.

Except otherwise indicated, the information in this prospectus assumes no exercise of the outstanding options or warrants described above.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, and those discussed under the section entitled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2023, which is incorporated by reference in this prospectus, 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. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Risks Related to the Committed Equity Financing

It is not possible to predict the actual number of shares of our common stock, if any, we will sell under the Purchase Agreement, or the actual gross proceeds resulting from those sales or the dilution to you from those sales. Further, we may not have access to the full amount available under the Purchase Agreement.

Pursuant to the Purchase Agreement, Seven Knots shall purchase from us up to the lesser of (a) \$35.0 million of shares of common stock and (b) 19.99% of the total number of shares of common stock outstanding as of the date of the Purchase Agreement, or the Exchange Cap, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, or the Commitment Amount; provided, however, that such limitations will not apply if we obtain stockholder approval to issue additional shares of common stock and, accordingly, we have registered 10,574,018 shares for issuance under the Purchase Agreement and resale pursuant to this prospectus, assuming that such stockholder approval is obtained and that \$35.0 million of shares are issued and sold at a price of \$3.31 per share. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Seven Knots at our discretion from time to time from the Commencement Date (as defined below) until the earliest to occur of (i) the first day of the month next following the 24-month anniversary of the Commencement Date, (ii) the date on which Seven Knots shall have purchased the Commitment Amount, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any Eligible Market (as defined in the Purchase Agreement), (iv) the thirtieth trading day next following the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person commences a proceeding against us, in each case that is not discharged or dismissed prior to such thirtieth trading day, and (v) the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors, or each, a Termination Event.

We do not have a right to commence any sales of common stock to Seven Knots under the Purchase Agreement until the time when all of the conditions to our right to commence sales of common stock to Seven Knots set forth in the Purchase Agreement have been satisfied, or the Commencement Date, including the effectiveness of the registration statement of which this prospectus forms a part. Over the 36-month period from and after the Commencement Date, we will generally have the right to control the timing and amount of any sales of our common stock to Seven Knots under the Purchase Agreement. Sales of our common stock, if any, to Seven Knots under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Seven Knots all, some or none of the common stock that may be available for us to sell to Seven Knots pursuant to the Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell all of the Commitment Amount or how much in proceeds we may obtain under the Purchase Agreement. If we cannot sell securities under the Committed Equity Financing, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could have a material adverse effect on our liquidity and cash position.

Because the purchase price per share of common stock to be paid by Seven Knots for the common stock that we may elect to sell to Seven Knots under the Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we make such election, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of common stock that we will sell to Seven Knots under the Purchase Agreement, the purchase price per share that Seven Knots will pay for shares of common stock purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Seven Knots under the Purchase Agreement.

We are registering 10,679,758 shares of our common stock under this prospectus, including 105,740 Note Shares issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the convertible promissory note, or the Commitment Note, issued to Seven Knots as consideration for its execution and delivery of the Purchase Agreement. As of August 22, 2024, there were 591,909 shares of common stock outstanding. If all of the 10,679,758 shares of our common stock offered for resale by the Selling Stockholder under this prospectus were issued and outstanding as of August 22, 2024, such shares would represent approximately 95% of total number of shares of our common stock outstanding.

The actual number of shares of our common stock issuable will vary depending on the then current market price of shares of our common stock sold to Seven Knots in this offering and the number of shares of our common stock we ultimately elect to sell to Seven Knots under the Purchase Agreement. If it becomes necessary for us to issue and sell to Seven Knots under the Purchase Agreement more than the 10,574,018 shares of our common stock being registered for resale under this prospectus in order to receive aggregate gross proceeds equal to \$35.0 million under the Purchase Agreement, we must file with the SEC one or more additional registration statements to register under the Securities Act the resale by Seven Knots of any such additional shares of our common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock under the Purchase Agreement. Under applicable Nasdaq rules, in no event may we issue to Seven Knots shares of our common stock representing more than 19.99% of the total number of shares of common stock outstanding immediately prior to the execution of the Purchase Agreement, or 118,322 shares of common stock, unless (i) we obtain the approval of the issuance of additional shares by our stockholders in accordance with the applicable stock exchange rules or (ii) sales of common stock are made at an average price equal to or in excess of the lower of (A) the closing price on the Nasdaq Capital Market on June 26, 2024 and (B) the average of the closing prices of the common stock for the five business days immediately preceding June 26, 2024 (in each case plus an incremental amount to take into account the Note Shares), such that the sales of such common stock to Seven Knots would not count toward such limit because they are “at market” under applicable stock exchange rules. In addition, Seven Knots is not obligated to buy any common stock under the Purchase Agreement if such shares, when aggregated with all other common stock then beneficially owned by Seven Knots and its affiliates (as calculated pursuant to Section 13(d) of the Securities Exchange Act, and Rule 13d-3 promulgated thereunder), would result in Seven Knots beneficially owning common stock in excess of 4.99% of the then-outstanding shares of common stock. Our inability to access a portion or the full amount available under the Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business or results of operation.

Seven Knots will pay less than the then-prevailing market price for our common stock, which could cause the price of our common stock to decline.

The purchase price of our common stock to be sold to Seven Knots under the Purchase Agreement is derived from the market price of our common stock on Nasdaq. Shares to be sold to Seven Knots pursuant to the Purchase Agreement will be purchased at a discounted price.

For example, we may effect sales to Seven Knots pursuant to a Fixed Purchase Notice (as defined below) at a purchase price equal to the lesser of 95% of (i) the daily volume weighted average price of the common stock for the five trading days immediately preceding the applicable Fixed Purchase Date (as defined below) and (ii) the lowest trading price of a share of common stock during the full trading day on the trading day immediately following the applicable Fixed Purchase Date. See “*The Committed Equity Financing*” for more information.

As a result of this pricing structure, Seven Knots may sell the shares they receive immediately after receipt of such shares, which could cause the price of our common stock to decrease.

Investors who buy shares of common stock from Seven Knots at different times will likely pay different prices.

Pursuant to the Purchase Agreement, we have discretion, to vary the timing, price and number of shares of common stock we sell to Seven Knots. If and when we elect to sell shares of common stock to Seven Knots pursuant to the Purchase Agreement, after Seven Knots has acquired such shares, Seven Knots may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from Seven Knots in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Seven Knots in this offering as a result of future sales made by us to Seven Knots at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares to Seven Knots under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangements with Seven Knots may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Future resales and/or issuances of shares of common stock, including pursuant to this prospectus, or the perception that such sales may occur, may cause the market price of our shares to drop significantly.

In June 2024, we entered into the Purchase Agreement, pursuant to which Seven Knots shall purchase from us up to an aggregate of \$35.0 million of shares of common stock, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement. Additionally, we issued a convertible promissory note in the amount of \$350,000 to Seven Knots as consideration for its execution and delivery of the Purchase Agreement.

The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Seven Knots at our discretion from time to time from the date of effectiveness of the registration statement of which this prospectus forms a part until the earliest to occur of (i) the first day of the month next following the 24-month anniversary of the Commencement Date, (ii) the date on which Seven Knots shall have purchased the Commitment Amount, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any Eligible Market (as defined in the Purchase Agreement), (iv) the thirtieth trading day next following the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person commences a proceeding against us, in each case that is not discharged or dismissed prior to such thirtieth trading day, and (v) the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

The purchase price for shares of our common stock that we may sell to Seven Knots under the Purchase Agreement will fluctuate based on the trading price of shares of our common stock. Depending on market liquidity at the time, sales of shares of our common stock may cause the trading price of shares of our common stock to decrease. We generally have the right to control the timing and amount of any future sales of shares of our common stock to Seven Knots. Additional sales of shares of our common stock, if any, to Seven Knots will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Seven Knots all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares of our common stock to Seven Knots, after Seven Knots has acquired shares of our common stock, Seven Knots may resell all, some or none of such shares of our common stock at any time or from time to time in its discretion and at different prices. Therefore, sales to Seven Knots by us could result in substantial dilution to the interests of other holders of shares of our common stock. In addition, if we sell a substantial number of shares of our common stock to Seven Knots under the Purchase Agreement, or if investors expect that we will do so, the shares held by Seven Knots will represent a significant portion of our public float and may result in substantial decreases to the price of our common stock. The actual sales of shares of our common stock or the mere existence of our arrangement with Seven Knots may also make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

In addition, shares of our common stock issuable upon exercise or vesting of incentive awards under our incentive plans are, once issued, eligible for sale in the public market, subject to any lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144. Furthermore, shares of our common stock reserved for future issuance under our incentive plan may become available for sale in future.

As of June 30, 2024, there were approximately 42,580 shares subject to outstanding options or subject to certain outstanding inducement grants, shares subject to outstanding restricted stock units, and shares reserved for future issuance or otherwise issuable under our equity compensation plans. We have registered or will register the shares of common stock available for issuance under the Company's 2011 Long-Term Incentive Plan and A&R 2020 Plan under the Securities Act on Registration Statements on Form S-8. The registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above, to the extent applicable.

As of June 30, 2024, we had 258,130 outstanding warrants exercisable for shares with a weighted-average exercise price of \$274.18 per share. The shares of our common stock underlying such warrants will, upon issuance, be freely tradeable without restriction or further registration under the Securities Act.

The market price of shares of our common stock could drop significantly if the holders described above sell or are perceived by the market as intending to sell. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our common stock or other securities.

We may use proceeds from sales of our common stock made pursuant to the Purchase Agreement in ways with which you may not agree or in ways which may not yield a significant return.

We will have broad discretion over the use of proceeds from sales of our common stock made pursuant to the Purchase Agreement, including for any of the purposes described in the section entitled “*Use of Proceeds*,” and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may vary substantially from their currently intended use. While we expect to use the net proceeds from this offering as set forth in “*Use of Proceeds*,” we are not obligated to do so. The failure by us to apply these funds effectively could harm our business, and the net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock.

Risks Related to Our Financial Condition and Capital Requirements

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

The auditor’s opinion on our audited financial statements for the year ended December 31, 2023 includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. Management has also concluded that substantial doubt exists about our ability to continue as a going concern. As of June 30, 2024, we had cash and cash equivalents of \$1.8 million and current liabilities of \$8.8 million. In July 2024, we entered into the (i) Securities Purchase Agreement dated July 18, 2024, or the Tranche I Purchase Agreement, with the investors party thereto, pursuant to which we agreed to the private placement of 16,099 shares of Series C Convertible Preferred Stock, \$0.001 par value, or the Series C Preferred Stock, or the Tranche I Preferred Shares, and warrants to acquire up to the aggregate number of 3,440,631 additional shares of common stock, or the Tranche I Warrants, for aggregate gross proceeds of approximately \$12.9 million of which \$9.5 million was paid through the cancellation and extinguishment of certain holders’ (i) outstanding principal amount, conversion/exchange premiums and all accrued interest and dividends thereon under certain of our notes, and (ii) 5,500 shares of our Series B Convertible Preferred Stock, par value \$0.001 per share. and (ii) Securities Purchase Agreement dated July 26, 2024, or the Tranche II Purchase Agreement, and together with the Tranche I Purchase Agreement, the July Purchase Agreements, with the investor party thereto pursuant to which we agreed to the private placement of 1,250 shares of Series C Preferred Stock, or the Tranche II Preferred Shares, and together with the Tranche I Preferred Shares, the Preferred Shares, and warrants to acquire up to the aggregate number of 267,380 additional shares of common stock, or the Tranche II Warrants, and together with the Tranche I Warrants, the Warrants, for aggregate gross proceeds of approximately \$1.0 million. In addition, we issued 191 Preferred Shares and 70,914 Warrants in connection with certain placement agent and other advisory fees and expenses. As a result, we believe that we have sufficient resources available to fund our business operations into October 2024. We do not have sufficient cash and cash equivalents as of the date hereof to support our operations for at least the 12 months following the date of this prospectus. These conditions raise substantial doubt about our ability to continue as a going concern.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to secure additional capital, potentially through a combination of public or private securities offerings; convertible debt financings; and/or strategic transactions, including potential licensing arrangements, alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next 12 months following the date that the financial statements are issued. In addition, we may be unable to pay our vendors and other service partners on time, or at all. If any of our key vendors and service providers were to cease working with us or subject the delivery of products or services to timing or payment preconditions, our development activities may be adversely affected, which could have a material adverse effect on our business and operations. The failure to obtain sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. Further, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “*Risk Factors*” section and Part I, Item 1A “*Risk Factors*” of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on April 16, 2024 and any of our subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. We have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.

We have incurred operating losses since our incorporation on November 6, 1992. For the year ended December 31, 2023, we had operating losses of \$20.6 million. As of June 30, 2024, we had an accumulated deficit of \$846.6 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock and borrowings from investors and financial institutions. As of June 30, 2024, we had cash and cash equivalents of \$1.8 million and current liabilities of \$8.8 million. In July 2024, we entered into the July Purchase Agreements, pursuant to which we agreed to sell the Preferred Shares and Warrants for an aggregate of \$13.9 million in gross proceeds, of which \$9.5 million was paid through the cancellation and extinguishment of certain of our securities held by certain holders. As a result, we believe that we have sufficient resources available to fund our business operations into October 2024.

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

Risks Related to the Ownership of Our Securities

The market price of our common stock may be highly volatile, and investors may not be able to resell their shares at or above the price at which they purchase them.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- our ability to execute our planned clinical trials on a timely basis consistent with timelines established;
- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the U.S. and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, along with any product modifications and improvements;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates;
- the implementation of our business model and strategic plans for our business and technology;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry and market conditions other events or factors, including as a result of inflation, liquidity constraints or banking stability, many of which are beyond our control;
- our commercialization, marketing and manufacturing prospects and capabilities;

- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, the stock markets in general, and the markets for biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the market price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

The sale and issuance of our common stock or rights to purchase our common stock, stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

We will require additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of preferred stock or common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. The issuance of shares of our common stock in connection with a public or private financing, in connection with our compensation programs, and upon exercise of outstanding warrants will have a dilutive impact on our other stockholders and the issuance, or even potential issuance, of such shares could have a negative effect on the market price of our common stock.

The exercise of stock options and other securities could also cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

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 on our condensed consolidated balance sheet, which could lead to material impairment charges in the future;
- our ability to repay indebtedness;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the COVID-19 pandemic and the evolving events in Israel and Gaza on our clinical trial operations;
- the costs, timing, and results, of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States, 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 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 regulatory activities in a timely manner, if at all, to support development and commercialization of 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 the evolving events in Israel and Gaza; and
- other risks and uncertainties, including those described or incorporated by reference under the caption “Risk Factors” in this prospectus.

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).

THE COMMITTED EQUITY FINANCING

Overview

In July 2024, we entered into Purchase Agreement with Seven Knots. Sales of our common stock to Seven Knots under the Purchase Agreement, and the timing of any sales, will be determined by us from time to time in our sole discretion and will depend on a variety of factors, including, among other things, market conditions, the trading price of our common stock and determinations by us regarding the use of proceeds from any sale of such common stock. The net proceeds from any sales under the Committed Equity Financing will depend on the frequency with, and prices at, which the common stock are sold to Seven Knots. To the extent we sell shares under the Purchase Agreement, we currently plan to use the net proceeds for working capital and other general corporate purposes. We cannot predict whether the net proceeds invested will yield a favorable return.

In accordance with our obligations under the Purchase Agreement and the Registration Rights Agreement, dated as of June 26, 2024, between us and Seven Knots, or the Registration Rights Agreement, pursuant to which we agreed to provide Seven Knots with customary registration rights related to the shares issued under the Purchase Agreement, we have filed a registration statement of which this prospectus forms a part in order to register the resale of up to: (i) 10,574,018 Purchase Shares that we may elect, in our sole discretion, to issue and sell to Seven Knots, from time to time from and after the Commencement Date upon the terms and subject to the conditions and limitations of the Purchase Agreement, subject to applicable stock exchange rules (assuming the shares are sold at a price of \$3.31 per share); and (ii) 105,740 Note Shares are issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the Commitment Note issued to Seven Knots as consideration for its execution and delivery of the Purchase Agreement.

Under applicable Nasdaq rules, in no event may we issue to Seven Knots shares of our common stock representing more than 19.99% of the total number of shares of common stock outstanding immediately prior to the date of the Purchase Agreement, unless we obtain prior stockholder approval or if such approval is not required in accordance with the applicable Nasdaq rules, or the Exchange Cap. In addition, Seven Knots is not obligated to buy any common stock under the Purchase Agreement if such shares, when aggregated with all other common stock then beneficially owned by Seven Knots and its respective affiliates (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder), would result in Seven Knots beneficially owning common stock in excess of 4.99% of the then-outstanding shares of common stock, or the Beneficial Ownership Limitation.

The Purchase Agreement and Registration Rights Agreement contain customary registration rights, representations, warranties, conditions and indemnification obligations by each party. The representations, warranties and covenants contained in such agreements were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements and are subject to certain important limitations.

Purchase Agreement

Pursuant to the Purchase Agreement, Seven Knots shall purchase from us up to the lesser of (i) \$35.0 million of shares of our common stock and (ii) the Exchange Cap, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, or the Commitment Amount; provided, however, that such limitations will not apply if we obtain stockholder approval to issue additional shares of common stock and, accordingly, we have registered 10,574,018 shares for issuance under the Purchase Agreement and resale pursuant to this prospectus, assuming that such stockholder approval is obtained and that \$35.0 million of shares are issued and sold at a price of \$3.31 per share. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Seven Knots at our discretion from time to time from the Commencement Date until the earliest to occur of (i) the first day of the month next following the 24-month anniversary of the Commencement Date, (ii) the date on which Seven Knots shall have purchased the Commitment Amount, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any Eligible Market (as defined in the Purchase Agreement), (iv) the thirtieth trading day next following the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person commences a proceeding against us, in each case that is not discharged or dismissed prior to such thirtieth trading day, and (v) the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

Purchases of Shares of our Common Stock Under the Purchase Agreement

During the term described above, on any business day on which the closing sale price of the common stock is equal to or greater than \$0.50, or the Fixed Purchase Date, we will have the right, but not the obligation, from time to time at our sole discretion, to direct Seven Knots, by delivery of an irrevocable written notice, or a Fixed Purchase Notice, to purchase a number of shares of our common stock, or the Fixed Purchase, up to the lesser of 10,000 shares of common stock or \$50,000, or the Fixed Purchase Maximum Amount, at a purchase price equal to the lesser of 95% of (i) the daily VWAP (as defined below) of the common stock for the five trading days immediately preceding the applicable Fixed Purchase Date and (ii) the lowest trading price of a share of common stock during the full trading day on the trading day immediately following the applicable Fixed Purchase Date, or the Fixed Purchase Price.

In addition, at any time from and after the Commencement Date, on any business day on which the closing sale price of the common stock is equal to or greater than \$0.50 and such business day is also the Fixed Purchase Date for a Fixed Purchase of an amount of shares of common stock not less than the applicable Fixed Purchase Maximum Amount, we may also direct Seven Knots, by delivery of an irrevocable written notice, or a VWAP Purchase Notice, to purchase, on the immediately following business day, or the VWAP Purchase Date, an additional number of shares of common stock in an amount equal to the lesser of (i) 300% of the number of shares of common stock directed by us to be purchased by Seven Knots for the applicable Fixed Purchase and (ii) 30% of the trading volume in our common stock on Nasdaq during the applicable VWAP Purchase Period (as defined in the Purchase Agreement) on the applicable VWAP Purchase Date, or the VWAP Purchase, at a purchase price equal to the lesser of 90% of (i) the closing sale price of the common stock on the applicable VWAP Purchase Date and (ii) the VWAP during the applicable VWAP Purchase Period, or the VWAP Purchase Price.

At any time from and after the Commencement Date, on any business day that is also the VWAP Purchase Date for a VWAP Purchase, we may also direct Seven Knots, by delivery of an irrevocable written notice, or an Additional VWAP Purchase Notice and, together with a Fixed Purchase Notice and a VWAP Purchase Notice, a Purchase Notice, to purchase, on the same business day, or the Additional VWAP Purchase Date and, together with a Fixed Purchase Date and a VWAP Purchase Date, the Purchase Dates, an additional number of shares of common stock in an amount equal to the lesser of (i) 300% of the number of shares of common stock directed by us to be purchased by Seven Knots for the applicable Fixed Purchase and (ii) 30% of the trading volume in our common stock on Nasdaq during the applicable Additional VWAP Purchase Period (as defined in the Purchase Agreement) on the applicable VWAP Purchase Date, or an Additional VWAP Purchase, and together with a Fixed Purchase and a VWAP Purchase, the Purchases, at a purchase price equal to the lesser of 90% of (i) the closing sale price of the common stock on the applicable Additional VWAP Purchase Date and (ii) the VWAP during the Additional VWAP Purchase Period (as defined in the Purchase Agreement).

For purposes of the Purchase Agreement, "VWAP" is, for the common stock for a specified period, the dollar volume-weighted average price for the common stock on Nasdaq, for such period, as reported by Bloomberg through its "AQR" function. All such determinations shall be appropriately adjusted for any sales of shares of common stock through block transactions, any reorganization, non-cash dividend, stock split, reverse stock split, stock combination, recapitalization or other similar transaction during such period.

Note Shares and Fees

As consideration for its irrevocable commitment to purchase our common stock under the Purchase Agreement, 105,740 shares of common stock are issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the Commitment Note issued to Seven Knots as consideration for its execution and delivery of the Purchase Agreement. We have registered the resale of 105,740 Note Shares hereunder.

We have also agreed to pay to Seven Knots \$25,000 in cash as reimbursement for the reasonable, out-of-pocket expenses incurred by Seven Knots, including the legal fees and disbursements of Seven Knots' legal counsel, in connection with its due diligence investigation of our company and in connection with the preparation, negotiation and execution of the Purchase Agreement.

Conditions Precedent to Commencement

Our right to commence delivering Purchase Notices under the Purchase Agreement and Seven Knots' obligation to accept such Purchase Notices, are subject to the initial satisfaction, at the Commencement Date, of the conditions precedent thereto set forth in the Purchase Agreement, which conditions include, among others, the following:

- the accuracy in all material respects of our representations and warranties included in the Purchase Agreement;
- us having performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the Purchase Agreement and the Registration Rights Agreement to be performed, satisfied or complied with by us;
- the absence of any material misstatement or omission in the registration statement that includes this prospectus;
- this prospectus, in final form, and all reports, schedules, registrations, forms, statements, information and other documents required to have been filed by us with the SEC pursuant to the reporting requirements of the Exchange Act having been so filed;
- the common stock not having been suspended by the SEC, Nasdaq or FINRA and there not having been imposed any suspension of, or restriction on, accepting additional deposits of common stock by The Depository Trust Company;
- no condition, occurrence, state of facts or event constituting a Material Adverse Effect (as defined in the Purchase Agreement) shall have occurred and be continuing;
- customary compliance with laws and bankruptcy-related conditions; and
- the receipt by Seven Knots of customary legal opinions, as required under the Purchase Agreement.

Termination of the Purchase Agreement

Unless earlier terminated as provided in the Purchase Agreement, the Purchase Agreement will terminate automatically on the earliest to occur of:

- the first day of the month next following the 24-month anniversary of the Commencement Date;
- the date on which Seven Knots shall have purchased the Commitment Amount;
- the date on which our common stock fails to be listed or quoted on Nasdaq or any Eligible Market (as defined in the Purchase Agreement);
- the thirtieth trading day next following the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person commences a proceeding against us, in each case that is not discharged or dismissed prior to such thirtieth trading day; and
- the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

We have the right to terminate the Purchase Agreement at any time after Commencement Date, at no cost or penalty, upon one trading days' prior written notice to Seven Knots, provided that we shall have issued all Note Shares to Seven Knots prior to such termination. We and Seven Knots may also terminate the Purchase Agreement at any time by mutual written consent. Seven Knots also has the right to terminate the Purchase Agreement upon 10 trading days' prior written notice to us, but only upon the occurrence of certain customary events as listed in the Purchase Agreement. No termination of the Purchase Agreement by us or by Seven Knots will become effective prior to the first trading day immediately following the date on which any pending Purchase has been fully settled in accordance with the terms and conditions of the Purchase Agreement, and will not affect any of our respective rights and obligations under the Purchase Agreement with respect to any pending Purchase, and both we and Seven Knots have agreed to complete our respective obligations with respect to any such pending Purchase under the Purchase Agreement.

Prohibition of “Dilutive Issuances” During Pending Purchases

Subject to certain exceptions, during any Reference Period (as defined in the Purchase Agreement) with respect to a Purchase, we are limited in our ability to issue any common stock, or any securities convertible into common stock, at an effective price per share of common stock less than the applicable Purchase Price to be sold to Seven Knots in the applicable Purchase to which such Reference Period relates.

No Short-Selling or Hedging

The Selling Stockholder has agreed that neither it nor any entity managed or controlled by it, will engage in, directly or indirectly, any (i) “short sale” (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of the common stock or (ii) hedging transaction, which, with respect to items (i) and (ii), establishes a net short position with respect to the common stock, during the term of the applicable Purchase Agreement.

Effect of Sales of our Common Stock under the Purchase Agreement on our Stockholders

The common stock being registered for resale in this offering may be issued and sold by us to the Selling Stockholder from time to time at our discretion, during the terms described above. The resale by the Selling Stockholder of a significant quantity of shares registered for resale in this offering at any given time, or the perception that these sales may occur, could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock, if any, to Seven Knots under the Purchase Agreement will be determined by us in our sole discretion, subject to the satisfaction of certain conditions in the Purchase Agreement, and will depend upon market conditions and other factors. We may ultimately decide to sell to Seven Knots all, some or none of the common stock that may be available for us to sell to Seven Knots pursuant to the Purchase Agreement. If we elect to sell common stock to Seven Knots pursuant to the Purchase Agreement, after Seven Knots has acquired such shares, Seven Knots may resell all, some or none of such common stock at any time or from time to time in its discretion and at different prices. As a result, investors who purchase common stock from Seven Knots in this offering at different times will likely pay different prices for those shares of common stock, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. See *“Risk Factors—Risks Related to the Committed Equity Financings—Investors who buy shares of common stock from Seven Knots at different times will likely pay different prices.”*

Investors may experience a decline in the value of the common stock they purchase from Seven Knots in this offering as a result of future sales made by us to Seven Knots at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares of common stock to Seven Knots under the Purchase Agreement, or if investors expect that we will do so, the actual sales of common stock or the mere existence of our arrangement with Seven Knots may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Because the purchase price per share to be paid by Seven Knots for the common stock that we may elect to sell to Seven Knots under the Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we make such election, as of the date of this prospectus, it is not possible for us to predict the number of shares of common stock that we will sell to Seven Knots under the Purchase Agreement, the actual purchase price per share to be paid by Seven Knots for those shares of common stock, or the actual gross proceeds to be raised by us from those sales, if any. As of August 22, 2024, there were 591,909 shares of common stock outstanding. If all of the 10,679,758 shares of our common stock offered for resale by the Selling Stockholders under this prospectus were issued and outstanding as of August 22, 2024, such shares would represent approximately 95% of total number of shares of our common stock outstanding. The actual number of shares of our common stock issuable will vary depending on the then current market price of shares of our common stock sold to the Selling Stockholders in this offering.

The number of shares of common stock ultimately offered for sale by the Selling Stockholders for resale under this prospectus is dependent upon the number of shares of common stock, if any, we ultimately sell to Seven Knots under the Purchase Agreement. Further, if and when we elect to sell shares of common stock to Seven Knots pursuant to the Purchase Agreement, after Seven Knots has acquired such shares, Seven Knots may resell all, some or none of such shares of common stock at any time or from time to time in its discretion and at different prices.

The issuance of our shares of common stock to the Selling Stockholders pursuant to the Purchase Agreement will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares of common stock owned by our existing stockholders will represent a smaller percentage of our total outstanding shares of common stock after any such issuance.

The following table sets forth the number of Purchase Shares to be issued to Seven Knots under the Purchase Agreement registered hereunder at varying purchase prices:

Assumed Purchase Price Per Share⁽¹⁾	Total Number of Seven Knots Purchase Shares to be Issued	Percentage of Outstanding Common Stock After Giving Effect to the Issuance of Seven Knots Purchase Shares to Seven Knots⁽²⁾	Proceeds from the Sale of Seven Knots Purchase Shares to Seven Knots ⁽³⁾
\$ 3.00	118,322	17%	\$ 354,966
\$ 3.31	10,574,018	95%	\$ 35,000,000
\$ 8.50	4,117,647	87%	\$ 35,000,000
\$ 9.00	3,888,889	87%	\$ 35,000,000
\$ 9.50	3,684,211	86%	\$ 35,000,000
\$ 10.48 ⁽⁴⁾	3,339,694	85%	\$ 35,000,000

(1) The purchase prices assume a discount to the market price of our shares, in accordance with the terms of the Purchase Agreement.

(2) The denominator is based on 591,909 shares of our common stock outstanding on a fully diluted basis as of August 22, 2024, adjusted to include the issuance of the number of Purchase Shares set forth in the adjacent column which we would have issued to Seven Knots based on the applicable assumed purchase price per share.

(3) The Company will not receive any proceeds from the issuance of the Note Shares. As noted above, the exact number of Note Shares to be issued cannot yet be determined. The proceeds reflected in this column would be reduced by an amount equal to the product of the final Note Shares multiplied by the assumed purchase price per share of common stock.

(4) Represents the last reported sales price of our common stock on August 22, 2024, as reported by Nasdaq, less a 5% discount.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock offered by Seven Knots. In addition, we will not receive any proceeds from the issuance or sale of the Note Shares. We may receive up to \$35.0 million in aggregate gross proceeds from Seven Knots under the Purchase Agreement in connection with sales of our shares of our common stock to Seven Knots pursuant to the Purchase Agreement after the date of this prospectus. However, the actual proceeds may be less than this amount depending on the number of shares of our common stock sold and the price at which the shares of our common stock are sold.

We intend to use any net proceeds that we receive under the Purchase Agreement for working capital and other general corporate purposes. We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in complementary businesses, technologies, products or assets. Although we currently have no agreements, commitments or obligations to do so, we evaluate such opportunities and engage in related discussions with third parties from time to time.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our planned clinical trials, our ability to take advantage of expedited programs or to obtain regulatory approval for product candidates, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments or other securities.

DIVIDEND POLICY

We have not paid any cash dividends and we do not anticipate paying any cash dividends in the foreseeable future and we intend to retain all of our earnings, if any, to finance our growth and operations and to fund the expansion of our business. Payment of any dividends, if any, will be made in the discretion of our board of directors, or Board, after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

SELLING STOCKHOLDER

This prospectus relates to the possible resale from time to time by the Selling Stockholder of any or all of the common stock that may be issued by us to the Selling Stockholder under the Purchase Agreement. Such shares of our common stock include (i) 10,574,018 Purchase Shares that we may elect, in our sole discretion, to issue and sell to Seven Knots, from time to time from and after the Commencement Date under the Purchase Agreement; and (ii) 105,740 Note Shares are issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the Commitment Note issued to Seven Knots as consideration for its execution and delivery of the Purchase Agreement.

As used in this prospectus, the term “*Selling Stockholder*” includes the Selling Stockholder listed in the table below, and its permitted pledgees, donees, transferees, assignees, successors, designees, successors-in-interest and others who later come to hold any of the Selling Stockholder’s interest in the shares of common stock in accordance with the terms of the applicable agreements governing their respective registration rights, other than through a public sale. This prospectus also covers any additional securities that may become issuable by reason of stock splits, stock dividends or other similar transactions.

For additional information regarding the issuance of common stock covered by this prospectus, see the section entitled “*Committed Equity Financing*” above. We are registering the shares of common stock pursuant to the provisions of the Purchase Agreement and the Registration Rights Agreement in order to permit the Selling Stockholder to offer the shares for resale from time to time. Except for the transactions contemplated by the Purchase Agreement and the Registration Rights Agreement, the Selling Stockholder has not had any material relationship with us within the past three years.

The table below presents information regarding the selling stockholder and the shares of common stock that it may offer from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of August 22, 2024. The number of shares in the column “Maximum Number of Shares of Common Stock to be Offered Pursuant to this Prospectus” represents all of the shares of common stock that the Selling Stockholder may offer under this prospectus. The Selling Stockholder may sell some, all or none of its shares in this offering. We do not know how long the Selling Stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the Selling Stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, and includes shares of common stock with respect to which the Selling Stockholder have voting and investment power. The percentage of common stock beneficially owned by the Selling Stockholder prior to the offering shown in the table below is based on an aggregate of 591,909 shares of our common stock outstanding on August 22, 2024. Because the purchase price of the common stock issuable under the Purchase Agreement is determined on each Fixed Purchase Date, with respect to a Fixed Purchase, on the applicable VWAP Purchase Date, with respect to a VWAP Purchase, and on the applicable Additional VWAP Purchase Date, with respect to an Additional VWAP Purchase, the number of shares that may actually be sold by us to the Selling Stockholder under the Purchase Agreement may be fewer than the number of shares being offered by this prospectus. The fourth column assumes the sale of all of the shares offered by the Selling Stockholder pursuant to this prospectus.

We may amend or supplement this prospectus from time to time in the future to update or change the Selling Stockholder list and the securities that may be resold.

Please see the section titled “*Plan of Distribution*” for further information regarding the Selling Stockholder’s method of distributing these securities.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering		Maximum Number of Shares of Common Stock to be Offered Pursuant to this Prospectus	Number of Shares of Common Stock Owned After Offering	
	Number(1)	Percent(2)		Number(3)	Percent(2)
	Seven Knots, LLC(4)	31,088		4.99%	10,679,758

- (1) In accordance with Rule 13d-3(d) under the Exchange Act, we have excluded from the number of shares beneficially owned prior to the offering all of the shares that Seven Knots may be required to purchase under the Purchase Agreement, because the issuance of such shares is solely at our discretion and is subject to conditions contained in the Purchase Agreement, the satisfaction of which are entirely outside of Seven Knots’ control, including the registration statement that includes this prospectus becoming and remaining effective. Furthermore, the Fixed Purchases, VWAP Purchase, or Additional VWAP Purchase, as applicable, of common stock is subject to certain agreed upon maximum amount limitations set forth in the Purchase Agreement. Also, the Purchase Agreement prohibits us from issuing and selling any of our common stock to Seven Knots to the extent such shares, when aggregated with all other common stock then beneficially owned by Seven Knots, would cause Seven Knots beneficial ownership of our common stock to exceed the 4.99% Beneficial Ownership Limitation.
- (2) Applicable percentage ownership is based on 591,909 shares of our common stock outstanding as of August 22, 2024.
- (3) Assumes the sale of all shares being offered pursuant to this prospectus.
- (4) Column two consists of 105,740 Note Shares issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the Commitment Note. The business address of Seven Knots, LLC is 400 E 66th Street, New York, NY 10065. Seven Knots, LLC’s principal business is that of a private investor. Marissa J. Welner is the beneficial owner of 50% of the membership interests in Seven Knots LLC. Marissa J. Welner has sole voting control and investment discretion over securities beneficially owned directly by Seven Knots, LLC. We have been advised that neither Ms. Welner nor Seven Knots LLC is a member of the Financial Industry Regulatory Authority, or FINRA, or an independent broker- dealer, or an affiliate or associated person of a FINRA member or independent broker-dealer. The foregoing should not be construed in and of itself as an admission by Ms. Welner as to beneficial ownership of the securities beneficially owned directly by Seven Knots, LLC.

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 42 holders of our common stock as of August 22, 2024.

Reverse Split

On April 28, 2020, we filed an amendment to our Charter in order to effect a 1-for-3 reverse stock split of our common stock effective for trading purposes on May 29, 2020. The number of authorized stock remained unchanged at 120,000,000 shares.

On February 22, 2023, we filed an amendment to our Charter in order to effect a 1-for-50 reverse stock split of our common stock effective for trading purposes on February 24, 2023. The number of authorized stock remained unchanged at 120,000,000 shares.

On April 19, 2024, we filed an amendment to our Charter in order to effect a 1-for-18 reverse stock split of our common stock effective for trading purposes on April 22, 2024. The number of authorized stock remained unchanged at 120,000,000 shares.

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.

Of the 5,000,000 authorized shares of preferred stock, 40,000 shares are designated as Series A Preferred Stock, 5,500 shares are designated as Series B Convertible Preferred Stock and 18,820 shares are designated as Series C Preferred Stock. As of August 22, 2024, there are no shares of Series A Preferred Stock outstanding, no shares of Series B Convertible Preferred Stock outstanding and 17,540 shares of Series C Preferred Stock outstanding. We have no present plans to issue any additional shares of preferred stock.

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 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

The common stock offered by this prospectus are being offered by the Selling Stockholder. The shares may be sold or distributed from time to time by the Selling Stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of our common stock offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for our common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

The Selling Stockholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

The Selling Stockholder has informed us that it intends to use one or more registered broker-dealers to effectuate all sales, if any, of our common stock that it has acquired and may in the future acquire from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such registered broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. The Selling Stockholder has informed us that each such broker-dealer will receive commissions from the Selling Stockholder that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of our common stock offered by this prospectus may receive compensation in the form of commissions, discounts, or concessions from the purchasers, for whom the broker-dealers may act as agent, of the shares sold by the Selling Stockholder through this prospectus. The compensation paid to any such particular broker-dealer by any such purchasers of our common stock sold by the selling stockholder may be less than or in excess of customary commissions. Neither we nor the Selling Stockholder can presently estimate the amount of compensation that any agent will receive from any purchasers of our common stock sold by the Selling Stockholder.

We know of no existing arrangements between the Selling Stockholder or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of our common stock offered by this prospectus.

We may from time to time file with the SEC one or more supplements to this prospectus or amendments to the registration statement of which this prospectus forms a part to amend, supplement or update information contained in this prospectus, including, if and when required under the Securities Act, to disclose certain information relating to a particular sale of shares offered by this prospectus by the Selling Stockholder, including the names of any brokers, dealers, underwriters or agents participating in the distribution of such shares by the Selling Stockholder, any compensation paid by the Selling Stockholder to any such brokers, dealers, underwriters or agents, and any other required information.

We will pay the expenses incident to the registration under the Securities Act of the offer and sale of our common stock covered by this prospectus by the Selling Stockholder. As consideration for its irrevocable commitment to purchase our common stock under the Purchase Agreement, we have agreed to issue to Seven Knots 105,740 shares of common stock as Note Shares in accordance with the Purchase Agreement. We have also agreed to pay to Seven Knots \$25,000 in cash as reimbursement for the reasonable, out-of-pocket expenses incurred by Seven Knots, including the legal fees and disbursements of Seven Knots' legal counsel, in connection with its due diligence investigation of the Company and in connection with the preparation, negotiation and execution of the Purchase Agreement. See "*The Committed Equity Financing*" for more information.

We also have agreed to indemnify the Selling Stockholder and certain other persons against certain liabilities in connection with the offering of our common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. The Selling Stockholder has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by the Selling Stockholder specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

We estimate that the total expenses for the offering will be approximately \$52,772.18.

The Selling Stockholder has represented to us that at no time prior to the date of the Purchase Agreement has the Selling Stockholder or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. The Selling Stockholder has agreed that during the term of the Purchase Agreement, neither the Selling Stockholder, nor any of its agents, representatives or affiliates will enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised the Selling Stockholder that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the Selling Stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all of our common stock offered by this prospectus have been sold by the Selling Stockholder.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "WINT."

LEGAL MATTERS

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

EXPERTS

The consolidated balance sheets of Windtree Therapeutics, Inc. and Subsidiaries as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in mezzanine equity and stockholders' equity, and cash flows for each of the years 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.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus forms part of a registration statement on Form S-1 that we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement or the documents incorporated by reference herein and therein. For further information with respect to us and the securities that we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement and the documents incorporated by reference herein and therein. You should rely only on the information contained in this prospectus or incorporated by reference herein or therein. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered hereby. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Windtree. The address of the SEC website is www.sec.gov.

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

INCORPORATION OF CERTAIN INFORMATION 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, 2023, filed with the SEC on [April 16, 2024](#);
- our Quarterly Reports on Form 10-Q for the quarters ended March 30, 2024 and June 30, 2024, filed with the SEC on [May 15, 2024](#) and [August 19, 2024](#), respectively;
- our Current Reports on Form 8-K, filed with the SEC on [January 17, 2024](#), [January 22, 2024](#), [January 25, 2024](#), [January 31, 2024](#), [February 16, 2024](#), [April 8, 2024](#), [April 10, 2024](#), [April 19, 2024](#), [April 23, 2024](#), [July 1, 2024](#), [July 10, 2024](#), [July 22, 2024](#), [July 29, 2024](#) and [August 14, 2024](#); and
- the description of our common stock contained in [Exhibit 4.18](#) our 2023 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.



Up to 10,679,758 Shares of Common Stock

Preliminary Prospectus

, 2024

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses in connection with the issuance and distribution of the securities being registered (excluding the underwriting discount and management fee). Except for the SEC registration fee and the FINRA filing fee, all amounts are estimates.

Item	Amount
SEC registration fee	\$ 16,772.18
Legal fees and expenses	25,000
Accounting fees and expenses	10,000
Miscellaneous expenses	1,000
Total	\$ 52,772.18

Item 14. Indemnification of Directors and Officers.

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

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

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

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

- we may indemnify any and all persons whom it shall have power to indemnify to the fullest extent permitted by the DGCL, subject to limited exceptions;
- 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 15. Recent Sales of Unregistered Securities.

On April 2, 2024, we issued 5,500 shares, or the Series B Preferred Shares, of our Series B Convertible Preferred Stock, par value \$0.001 per share, or the Series B Preferred Stock, to certain creditors of Varian Biopharmaceuticals, Inc. pursuant to an Asset Purchase Agreement that we entered into with Varian Biopharmaceuticals, Inc. on April 2, 2024. We filed a Series B Certificate of Designation with the Secretary of State of the State of Delaware on April 2, 2024, which became effective on April 3, 2024, authorizing the Series B Preferred Shares with an initial conversion price of \$6.4854, or the Preferred Conversion Price, which is subject to adjustment as provided in the Series B Certificate of Designation to no lower than \$1.2978. The Series B Preferred Shares have a stated value of \$1,000 per share, or the Stated Value, which equal to an aggregate Stated Value of \$5,500,000 as of April 2, 2024. Each share of Series B Preferred Stock is initially convertible into 155 shares of our common stock, subject to adjustment as provided in the Series B Certificate of Designation. No fractional shares will be issued upon conversion; rather any fractional share will be rounded up to the nearest whole share.

On April 2, 2024, we agreed to sell 10% senior convertible notes due January 2025 in an aggregate principal amount of \$1.5 million, or the 10% Senior Convertible Notes due 2025, for \$1.5 million of gross proceeds, or the Notes Offering, pursuant to a Securities Purchase Agreement that we entered into with the buyers named therein on April 2, 2024. The Notes have an initial conversion price of \$6.4854, which is subject to adjustment upon the occurrence of specified events to no lower than \$1.2978, subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock. We intend to use the net proceeds from the Notes Offering for general corporate purposes. We agreed to seek stockholder approval for the issuance of all of the shares of common stock issuable upon conversion of the Notes and the Series B Preferred Shares in accordance with the rules and regulations of the Nasdaq Stock Market.

We agreed to issue and sell to an institutional investor (i) on June 25, 2024 an aggregate principal amount of \$287,500 in senior secured notes due 2025, and (ii) on June 28, 2024 an aggregate principal amount of \$117,647 in senior secured notes due 2025, for aggregate gross proceeds of \$350,000. The senior secured notes due 2025 include 15% original issue discount.

On July 3, 2024, we agreed to issue and sell to (i) an institutional investor an aggregate principal amount of \$117,647.05 in senior secured notes due 2025, and (ii) an additional institutional investor an aggregate principal amount of \$117,647.06 in senior unsecured promissory notes due 2025, for aggregate gross proceeds of \$200,000. Both the Secured Note and Promissory Note include a 15% original issue discount.

On July 18, 2024, we agreed to the private placement of (i) 16,099 shares, or the Series C Preferred Shares, of our Series C Convertible Preferred Stock, \$0.001 par value, or the Series C Preferred Stock, and (ii) warrants to acquire up to the aggregate number of 3,440,631 additional shares of common stock for aggregate gross proceeds of approximately \$12.9 million, of which \$9.5 million was paid through the cancellation and extinguishment of certain holders' (x) outstanding principal amount, conversion/exchange premiums and all accrued interest and dividends thereon under our (i) 10% Senior Convertible Notes due 2025, (ii) senior secured notes due June 2025, (iii) senior unsecured promissory notes due July 2025, and/or (iv) senior secured notes due July 2025, and (y) 5,500 shares of our Series B Preferred Stock. Additionally, we issued 161 shares of Series C Preferred Stock and 62,892 warrants as compensation for certain placement agent fees and expenses. We intend to use the gross proceeds from the private placement described above for working capital and general corporate purposes.

On July 26, 2024, we agreed to the private placement of (i) 1,250 shares of Series C Preferred Stock and (ii) warrants to acquire up to the aggregate number of 267,380 additional shares of common stock for aggregate gross proceeds of approximately \$1.0 million pursuant the Securities Purchase Agreement that we entered into with each of the investors listed on the Schedule of Buyers attached thereto. Additionally, we issued 30 shares of Series C Preferred Stock and 8,022 warrants as compensation for certain placement agent fees and expenses. We intend to use the gross proceeds from the private placement described above for working capital and general corporate purposes.

The issuances of these securities were exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, in that the transactions were by an issuer not involving any public offering.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this registration statement.

Exhibit No.	Description
2.1+	Form of Asset Purchase Agreement by and between Windtree Therapeutics, Inc. and Varian Biopharmaceuticals, Inc., dated April 2, 2024 (incorporated by reference to Exhibit 2.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Windtree's Registration Statement on Form S-1, as filed with the SEC on May 9, 2024).
3.2	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on August 11, 2022).
3.3	Certificate of Designations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024).
3.4	Certificate of Designations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 22, 2024).
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 Warrant dated July 22, 2015 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015).
4.3	Form of Series B Warrant dated July 22, 2015 (incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	Form of Series F Warrant dated December 24, 2018 (incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
4.9	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).

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- 4.10 [Form of Series H Warrant dated February 14, 2019 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on December 21, 2018\).](#)
 - 4.11 [Form of Series I Warrant dated December 6, 2019 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on December 9, 2019\).](#)
 - 4.12 [Form of Series F Warrant Amendment No. 1 dated April 24, 2020 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on April 29, 2020\).](#)
 - 4.13 [Form of Series I Warrant Amendment dated May 6, 2020, to the Series I Warrant dated December 6, 2019 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on May 7, 2020\).](#)
 - 4.14 [Form of Warrant issued in the Company’s May 2020 underwritten public offering of securities \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on May 22, 2020\).](#)
 - 4.15 [Form of Warrant issued in the Company’s March 2021 underwritten public offering of securities \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on March 24, 2021\).](#)
 - 4.16 [Form of Common Stock Purchase Warrant dated January 24, 2023 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on January 26, 2023\).](#)
 - 4.17 [Form of Common Stock Purchase Warrant dated February 21, 2023 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on February 22, 2023\).](#)
 - 4.18 [Description of Securities \(incorporated by reference to Exhibit 4.18 to Windtree’s Annual Report on Form 10-K, as filed with the SEC on April 16, 2024\).](#)
 - 4.19 [Form of Common Warrant \(incorporated by reference to Exhibit 4.19 to Windtree’s Registration Statement on Form S-1/A \(File No. 333-269775\), as filed with the SEC on April 7, 2023\).](#)
 - 4.20 [Form of Pre-Funded Warrant \(incorporated by reference to Exhibit 4.20 to Windtree’s Registration Statement on Form S-1/A \(File No. 333-269775\), as filed with the SEC on April 7, 2023\).](#)
 - 4.21 [Form of Warrant Agency Agreement \(incorporated by reference to Exhibit 4.21 to Windtree’s Registration Statement on Form S-1/A \(File No. 333-269775\), as filed with the SEC on April 7, 2023\).](#)
 - 4.22 [Warrant Agency Agreement \(including form of global Common Warrant\), dated April 24, 2023, by and between Windtree and Continental Stock Transfer & Trust Company \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on April 24, 2023\).](#)
 - 4.23 [Form of Common Stock Warrant issued in the Company’s private placement on July 18, 2024 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on July 22, 2024\).](#)
 - 4.24 [Form of Common Stock Warrant issued in the Company’s July 2024 private placement on July 26, 2024 \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on July 29, 2024\).](#)
 - 4.25 [Form of 10% Convertible Note \(incorporated by reference to Exhibit 4.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on April 8, 2024\).](#)
 - 4.26 [Convertible Promissory Note, dated June 26, 2024, between Windtree and Seven Knots, LLC \(incorporated by reference to Exhibit 4.1 to Windtree’s Form 8-K, as filed with the SEC on July 1, 2024\).](#)
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- 4.27 [Form of Senior Unsecured Promissory Note due 2025 \(incorporated by reference to Exhibit 4.1 to Windtree’s Form 8-K, as filed with the SEC on July 10, 2024\).](#)
- 4.28 [Form of Senior Secured Note due 2025 \(incorporated by reference to Exhibit 4.2 to Windtree’s Form 8-K, as filed with the SEC on July 10, 2024\).](#)
- 5.1* [Opinion of Goodwin Procter LLP.](#)
- 10.1† [Sublicense Agreement dated October 28, 1996 between Johnson & Johnson, Ortho Pharmaceutical Corporation and Acute Therapeutics, Inc. \(incorporated by reference to Exhibit 10.6 to Windtree’s Registration Statement on Form SB-2/A, as filed with the SEC on April 18, 1997 \(Commission File Number 333-19375\)\).](#)
- 10.2† [Amended and Restated License Agreement dated March 28, 2008, between Windtree and Philip Morris USA Inc. \(incorporated by reference to Exhibit 10.4 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008\).](#)
- 10.3†† [Amendment No. 1, effective as of January 17, 2024, to the Amended and Restated License Agreement, between Windtree and Philip Morris USA Inc. dated March 28, 2008 \(incorporated by reference to Exhibit 10.3 to Windtree’s Annual Report on Form 10-K, as filed with the SEC on April 16, 2024\).](#)
- 10.4† [License Agreement dated March 28, 2008, between Windtree and Philip Morris Products S.A. \(incorporated by reference to Exhibit 10.5 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008\).](#)
- 10.5†† [Amendment No. 1, effective as of January 17, 2024, to the License Agreement, between Windtree and Philip Morris Products S.A. dated March 28, 2008 \(incorporated by reference to Exhibit 10.5 to Windtree’s Annual Report on Form 10-K, as filed with the SEC on April 16, 2024\).](#)
- 10.6†† [Amended and Restated Sublicense and Collaboration Agreement dated December 3, 2004, by and between Discovery Laboratories, Inc. \(predecessor-in-interest to Windtree\) and Laboratorios del Dr. Esteve, S.A. \(incorporated by reference to Exhibit 10.3 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020\).](#)
- 10.7†† [Amended and Restated Supply Agreement dated December 3, 2004, by and between Discovery Laboratories, Inc. \(predecessor-in-interest to Windtree\) and Laboratorios del Dr. Esteve, S.A. \(incorporated by reference to Exhibit 10.2 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020\).](#)
- 10.8† [License, Development and Commercialization Agreement dated June 12, 2017, between Windtree and Lee’s Pharmaceutical \(HK\) Ltd. \(incorporated by reference to Exhibit 10.1 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, as filed with the SEC on August 21, 2017\).](#)
- 10.9† [Amendment No. 1 dated August 14, 2017 to the License Development and Commercialization Agreement between Windtree and Lee’s Pharmaceutical \(HK\) Ltd. dated June 12, 2017 \(incorporated by reference to Exhibit 10.1 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the SEC on November 14, 2017\).](#)
- 10.10 [Amended and Restated License, Development and Commercialization Agreement, by and among Lee’s Pharmaceutical \(HK\) Ltd., Zhaoke Pharmaceutical \(Hefei\) Co. Ltd., and Windtree Therapeutics, Inc., effective as of August 9, 2022 \(incorporated by reference to Exhibit 10.1 to Windtree’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the SEC on November 14, 2022\).](#)
- 10.11# [Windtree’s 2011 Long-Term Incentive Plan, as amended \(incorporated by reference to Exhibit 10.1 to Windtree’s Current Report on Form 8-K, as filed with the SEC on December 31, 2018\).](#)
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- 10.12# [Windtree's 2020 Equity Incentive Plan \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 31, 2020\).](#)
- 10.13# [Amended and Restated Windtree Therapeutics, Inc. 2020 Equity Incentive Plan \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on August 16, 2023\).](#)
- 10.14# [Form of Restricted Stock Unit Grant for Employees under Windtree's 2020 Equity Incentive Plan \(incorporated by reference to Exhibit 4.5 to Windtree's Registration Statement on Form S-8, as filed with the SEC on February 12, 2021\).](#)
- 10.15# [Form of Stock Option Grant for Employees under Windtree's 2020 Equity Incentive Plan \(incorporated by reference to Exhibit 4.6 to Windtree's Registration Statement on Form S-8, as filed with the SEC on February 12, 2021\).](#)
- 10.16# [Form of Inducement Award Agreement \(incorporated by reference to Exhibit 4.4 to Windtree's Registration Statement on Form S-8 \(File No. 333-253067\), as filed with the SEC on February 12, 2021\).](#)
- 10.17# [Form of Employee Option Agreement under Windtree's 2011 Long-Term Incentive Plan \(incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012\).](#)
- 10.18# [Form of Non-Employee Director Option Agreement under Windtree's 2011 Long-Term Incentive Plan \(incorporated by reference to Exhibit 10.10 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020\).](#)
- 10.19# [Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Windtree's 2011 Long-Term Incentive Plan \(incorporated by reference to Exhibit 10.11 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015\).](#)
- 10.20# [Form of Restricted Stock Unit Award Agreement for Employees under Windtree's 2011 Long-Term Incentive Plan \(incorporated by reference to Exhibit 10.14 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on April 17, 2018\).](#)
- 10.21# [Employment Agreement dated February 1, 2016, between Windtree and Craig Fraser \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016\).](#)
- 10.22# [Inducement Stock Option Award Agreement dated February 1, 2016, between Windtree and Craig Fraser \(incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016\).](#)
- 10.23# [Amendment dated March 13, 2018, to Employment Agreement dated February 1, 2016, between Windtree and Craig Fraser \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018\).](#)
- 10.24# [Employment Agreement dated December 19, 2014, between Windtree and Steven G. Simonson, M.D. \(incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015\).](#)
- 10.25# [Amendment dated December 29, 2014 to Employment Agreement dated December 19, 2014, effective as of April 1, 2015, between Windtree and Steven G. Simonson, M.D. \(incorporated by reference to Exhibit 10.5 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015\).](#)
- 10.26# [Amendment dated March 13, 2018, to Employment Agreement dated December 19, 2014 between Windtree and Steven G. Simonson, M.D. \(incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018\).](#)
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- 10.27# [At The Market Offering Agreement, dated as of November 9, 2023, by and between Windtree Therapeutics, Inc. and Ladenburg Thalmann & Co. Inc. \(incorporated by reference to Exhibit 1.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 9, 2023\).](#)
- 10.28# [Form of Indemnification Agreement between Windtree and certain named executive officers and directors \(incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016\).](#)
- 10.29# [Form of Indemnification Agreement between Windtree and certain named directors \(incorporated by reference to Exhibit 10.23 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.30 Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, between TR Stone Manor Corp. and Windtree (incorporated by reference to Exhibits [10.1](#) and [10.2](#) to Windtree's Current Report on Form 8-K, as filed with the SEC on April 6, 2007).
- 10.31 [Second Amendment to Lease Agreement dated January 3, 2013 between TR Stone Manor Corp. and Windtree \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 8, 2013\).](#)
- 10.32 [Third Amendment to Lease Agreement dated November 24, 2014 between TR Stone Manor Corp. and Windtree \(incorporated by reference to Exhibit 10.29 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 31, 2023\).](#)
- 10.33 [Fourth Amendment to Lease Agreement dated April 29, 2016, between PH Stone Manor LP and Windtree \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 31, 2016\).](#)
- 10.34 [Fifth Amendment to Lease Agreement dated February 23, 2018, between PH Stone Manor LP and Windtree \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 1, 2018\).](#)
- 10.35† [Supply Agreement dated December 22, 2010 between Corden Pharma \(formerly Genzyme Pharmaceuticals LLC, now known as Corden Pharma\) and Windtree \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 29, 2010\).](#)
- 10.36 [Exchange and Termination Agreement dated October 27, 2017, between Windtree and Deerfield \(incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017\).](#)
- 10.37 [Registration Rights Agreement dated October 27, 2017, between Windtree and LPH Investments Limited \(incorporated by reference to Exhibit 99.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017\).](#)
- 10.38 [Registration Rights Agreement dated March 30, 2018, between Windtree and LPH II Investments Limited \(incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018\).](#)
- 10.39†† [Collaboration Agreement dated as of October 14, 2014, by and between Battelle Memorial Institute and Discovery Laboratories, Inc. \(predecessor-in-interest to Windtree\) \(incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020\).](#)
- 10.40 [Payment Restructuring Agreement effective December 7, 2018, between Windtree and Battelle Memorial Institute \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 7, 2018\).](#)
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- 10.41 [Amendment No. 1 dated March 30, 2020 to Payment Restructuring Agreement, effective December 7, 2018, between Windtree and Lee's Pharmaceutical \(HK\) LTD \(incorporated by reference to Exhibit 10.48 to Windtree's Registration Statement on Form S-1/A \(File No. 333-236085\), as filed with the SEC on May 6, 2020\).](#)
- 10.42 [Loan Agreement dated October 25, 2018, between CVie Therapeutics, Lee's Pharmaceutical Holdings Limited, and O-Bank Co., Ltd. \(incorporated by reference to Exhibit 10.34 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.43 [Shareholder Loan Agreement dated April 24, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics \(incorporated by reference to Exhibit 10.35 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.44 [Shareholder Loan Agreement dated September 20, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics \(incorporated by reference to Exhibit 10.36 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.45 [Shareholder Loan Agreement dated October 26, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics \(incorporated by reference to Exhibit 10.37 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.46 [Shareholder Loan Agreement dated November 16, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics \(incorporated by reference to Exhibit 10.38 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019\).](#)
- 10.47 [Merger Agreement dated December 21, 2018, between Windtree, WT Acquisition Corp., and CVie Investments Limited \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018\).](#)
- 10.48 [Indemnification Letter Agreement dated December 21, 2018, between Windtree and Lee's Pharmaceutical Holdings Limited \(incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018\).](#)
- 10.49 [Securities Purchase Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto \(incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018\).](#)
- 10.50 [Registration Rights Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto \(incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018\).](#)
- 10.51 [Loan Agreement dated October 24, 2019 between Windtree and LPH II Investments Ltd. \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on October 28, 2019\).](#)
- 10.52 [Form of Securities Purchase Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019\).](#)
- 10.53 [Form of Registration Rights Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019\).](#)
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- 10.54 [Common Stock Purchase Agreement dated June 26, 2024 by and between Windtree and Seven Knots, LLC \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024\).](#)
- 10.55 [Registration Rights Agreement dated June 26, 2024 by and between Windtree and Seven Knots, LLC \(incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024\).](#)
- 10.56 [Form of Securities Purchase Agreement dated July 18, 2024 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.1 to Windtree's Form 8-K, as filed with the SEC on July 22, 2024\).](#)
- 10.57 [Form of Registration Rights Agreement dated July 18, 2024 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.2 to Windtree's Form 8-K, as filed with the SEC on July 22, 2024\).](#)
- 10.58 [Form of Securities Purchase Agreement dated July 26, 2024 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.1 to Windtree's Form 8-K, as filed with the SEC on July 29, 2024\).](#)
- 10.59 [Form of Registration Rights Agreement dated July 26, 2024 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.2 to Windtree's Form 8-K, as filed with the SEC on July 29, 2024\).](#)
- 10.60# [Employment Agreement dated March 1, 2020, between Windtree and Eric Curtis \(incorporated by reference to Exhibit 10.46 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020\).](#)
- 10.61 [Amendment to No. 1 dated February 20, 2020 to the Securities Purchase Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto \(incorporated by reference to Exhibit 10.47 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020\).](#)
- 10.62 [Project Financing Agreement, dated August 12, 2020, by and between Windtree and Lee's Pharmaceutical \(HK\) Ltd. \(incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 16, 2020\).](#)
- 10.63# [Employment Agreement by and between Windtree and John Hamill, dated as of July 20, 2020 \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 23, 2020\).](#)
- 10.64# [Employment Agreement by and between Windtree and Diane Carman, dated as of July 1, 2021 \(incorporated by reference to Exhibit 10.54 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 31, 2022\).](#)
- 10.65 [Form of Inducement Letter dated January 20, 2023 \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 26, 2023\).](#)
- 10.66 [Form of Inducement Letter dated February 21, 2023 \(incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 22, 2023\).](#)
- 10.67†† [License, Development and Commercialization Agreement, by and between the Company and Lee's Pharmaceutical \(HK\) Ltd., dated January 12, 2024 \(incorporated by reference to Exhibit 10.61 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2024\).](#)
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10.68††	<u>Exchange and Termination Agreement, by and between the Company and affiliates of Deerfield Management Company, L.P., effective upon January 24, 2024 (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 25, 2024).</u>
10.69	<u>Registration Rights Agreement, by and between the Company and affiliates of Deerfield Management Company, L.P., effective upon January 24, 2024 (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 25, 2024).</u>
10.70+	<u>Form of Securities Purchase Agreement by and between Windtree Therapeutics, Inc. and the Buyers named therein, dated April 2, 2024 (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024).</u>
10.71+	<u>Form of Registration Rights Agreement, by and between Windtree Therapeutics, Inc. and the Buyers named therein, dated April 2, 2024 (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024).</u>
10.72††	<u>Master Services Agreement and Work Orders Nos. 11 and 12, by and between the Company and Momentum Research, Inc., dated February 13, 2020 (incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed on May 15, 2024).</u>
10.73††	<u>Amendment No. 1 to Master Services Agreement and Work Orders Nos. 11 and 12, by and between the Company and Momentum Research, Inc., effective upon May 9, 2024 (incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q, as filed on May 15, 2024).</u>
21.1	<u>Subsidiaries of Windtree (incorporated by reference to Exhibit 21.1 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).</u>
23.1*	<u>Consent of EisnerAmper LLP, independent registered public accounting firm.</u>
23.2*	<u>Consent of Goodwin Procter LLP (included in Exhibit 5.1).</u>
24.1	<u>Power of Attorney (included on the signature page to this registration statement).</u>
107*	<u>Filing Fee Table.</u>

* Filed herewith.

** To be filed by amendment.

Compensation Related Contract.

† Confidential treatment received for certain portions of this exhibit.

†† Certain confidential portions have been omitted from this exhibit pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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

(b)

Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(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 purposes of determining any liability under the Securities Act, 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 the 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 of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, 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;

(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.

(5) That, for purposes of determining any liability under the Securities Act:

(i) the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective; and

(ii) each post-effective amendment that contains a form of prospectus 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.

(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 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 August 23, 2024.

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig E. Fraser

Name: *Craig E. Fraser*

Title: *President and Chief Executive Officer (Principal Executive Officer)*

POWER OF ATTORNEY

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

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

Signature	Title	Date
<u>/s/ Craig E. Fraser</u> Craig E. Fraser	Director, President, and Chief Executive Officer <i>(Principal Executive Officer and Principal Financial Officer)</i>	August 23, 2024
<u>/s/ Jamie McAndrew</u> Jamie McAndrew	Vice President, Controller & Chief Accounting Officer	August 23, 2024
<u>/s/ Jed Latkin</u> Jed Latkin	Director	August 23, 2024
<u>/s/ Sandra Pelletier</u> Sandra Pelletier	Director	August 23, 2024
<u>/s/ Robert A. Scott, M.D.</u> Robert A. Scott, M.D.	Director	August 23, 2024
<u>/s/ Mark Strobeck, Ph.D</u> Mark Strobeck, Ph.D	Director	August 23, 2024



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August 23, 2024

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

Re: Securities Registered under Registration Statement on Form S-1

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (as amended or supplemented, the "Registration Statement") filed by Windtree Therapeutics, Inc., a Delaware corporation (the "Company") on the date hereof with the Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by the Company of up to 10,679,758 shares of the Company's common stock, par value \$0.001 per share ("Common Stock"), for resale by Seven Knots, LLC ("Seven Knots"), as a selling stockholder listed in the Registration Statement under "Selling Stockholder," consisting of (i) up to 10,574,018 shares of Common Stock (the "Purchase Shares") that the Company may elect, in its sole discretion, to issue and sell to Seven Knots pursuant to a Common Stock Purchase Agreement, dated as of June 26, 2024, by and between the Company and Seven Knots (the "Purchase Agreement"), and (ii) up to 105,740 shares of Common Stock issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the convertible promissory note issued to Seven Knots as consideration for it entering into the Purchase Agreement (the "Note Shares").

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 our opinions set forth below, we have assumed (i) the approval by the Company's board of directors (the "Board of Directors") (or duly authorized designees of the Board of Directors) of each issuance of the Purchase Shares, (ii) the issuance of the Purchase Shares in accordance with such approval, for a price per share equal to or greater than the minimum price, if any, authorized by the Board of Directors (or duly authorized designees of the Board of Directors) prior to the date of issuance (the "Minimum Price"), (iii) the receipt by the Company of stockholder approval of the issuance of any Purchase Shares in excess of the maximum amount permitted under applicable stock exchange rules, with such stockholder approval obtained in accordance with applicable stock exchange rules, (iv) the receipt by the Company of the consideration (which shall not be less than the par value of such Purchase Shares) to be paid in accordance with such approval and (v) that no event occurs that causes the total number of Purchase Shares that may be issued for the Minimum Price, when added to the number of shares of Common Stock issued, subscribed for, or otherwise committed to be issued, to exceed the number of authorized shares of Common Stock available for issuance by the Company.

The opinions set forth below are limited to the Delaware General Corporation Law.

Based on the foregoing, and subject to the additional qualifications set forth below, we are of the opinion that:

1. The Purchase Shares have been duly authorized and, subject to issuance by the Company at a price not less than the Minimum Price, when delivered and paid for in accordance with the Purchase Agreement and in accordance with any reservation of shares or other restrictions or limitations imposed by the Board of Directors (or duly authorized designees of the Board of Directors) on sales of Purchase Shares by the Company under the Purchase Agreement, will be validly issued, fully paid and nonassessable.

2. The Note Shares have been duly authorized and, when issued in accordance with the terms of the Purchase Agreement, will be validly issued, fully paid and nonassessable.

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

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

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of Windtree Therapeutics, Inc. on Form S-1 to be filed on or about August 21, 2024 of our report dated April 16, 2024, on our audit of the financial statements as of December 31, 2023 and 2022 and for each of the years then ended, which report was included in the Annual Report on Form 10-K filed April 16, 2024. 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
August 21, 2024

Calculation of Filing Fee Tables

Form S-1
(Form Type)Windtree Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities 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	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial Effective Date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to Be Paid	Equity	Common Stock, par value \$0.001 per share	457(c)	10,679,758(3)	\$10.64	\$113,632,625.12	0.00014760	\$16,772.18				
Fees Previously Paid	—	—	—	—	—	—	—	—				
Carry Forward Securities												
Carry Forward Securities	—	—	—	—	—	—	—	—	—	—	—	—
	Total Offering Amounts					\$113,632,625.12		\$16,772.18				
	Total Fees Previously Paid							—				
	Total Fee Offsets							—				
	Net Fee Due							\$16,772.18				

- Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”), this Registration Statement shall also cover an indeterminate number of shares of common stock, par value \$0.001 per share (“Common Stock”), of Windtree Therapeutics, Inc. (the “Registrant”) that may be issued and resold resulting from stock splits, stock dividends or similar transactions.
- Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the shares of Common Stock on the Nasdaq Capital Market on August 22, 2024. This calculation is in accordance with Rule 457(c) of the Securities Act.
- Includes (i) 10,574,018 shares of Common Stock that the Registrant may elect, in its sole discretion, to issue and sell to Seven Knots, LLC (“Seven Knots”) pursuant to a Common Stock Purchase Agreement, dated as of June 26, 2024, by and between the Registrant and Seven Knots (the “Purchase Agreement”) and (ii) 105,740 shares of Common Stock issuable upon the conversion of the outstanding unpaid principal balance, together with all accrued and unpaid interest, if any, of the convertible promissory note issued to Seven Knots as consideration for it entering into the Purchase Agreement.