

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)

Mary B. Templeton, Esq.
Senior Vice President, General Counsel and Corporate Secretary
Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Ira L. Kotel, Esq.
Dentons US LLP
1221 Avenue of the Americas
New York, New York 10020
(212) 768-6700

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

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 or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered⁽¹⁾	Proposed Maximum Offering Price per Share⁽²⁾	Proposed Maximum Aggregate Offering Price⁽²⁾	Amount of Registration Fee⁽²⁾
Common Stock, \$0.001 par value per share	14,098,000	\$1.11	\$15,648,780	\$1,813.69
Total	14,098,000	\$1.11	\$15,648,780	\$1,813.69

- (1) The Registrant is registering for resale by the selling stockholders identified in the prospectus contained herein up to 14,098,000 shares of common stock, which consists of: (i) 7,049,000 shares of common stock issuable upon conversion of convertible preferred stock held by the selling stockholders and (ii) 7,049,000 shares of common stock issuable upon exercise of common stock purchase warrants held by the selling stockholders. Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
- (2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low price of the Registrant's common stock on April 3, 2017, as quoted on The Nasdaq Capital Market on a day within five business days from the date of filings of this registration statement.

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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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

Subject to Completion, dated April 5, 2017

14,098,000 Shares



COMMON STOCK

This prospectus relates to the resale of up to 14,098,000 shares of our common stock, par value \$0.001 per share (the "Common Stock"), which may be offered for sale from time to time by the selling stockholders identified in this prospectus (the "selling stockholders"). The shares of Common Stock covered by this prospectus consist of: (i) 7,049,000 shares of Common Stock (the "Conversion Shares") issuable to the selling stockholders upon conversion of our Series A Convertible Preferred Stock, par value \$0.001 per share (the "Preferred Stock") and (ii) 7,049,000 shares of Common Stock (the "Warrant Shares") issuable to the selling stockholders upon exercise of our Series A-1 Warrants to purchase Common Stock (the "Warrants"). The Preferred Stock and the Warrants were issued by us to the selling stockholders in a private offering exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), on February 13, 2017 (the "Private Placement"). We are hereby registering the offer and sale of the Conversion Shares and the Warrant Shares to satisfy registration rights that we have granted to the selling stockholders in connection with the Private Placement.

We are not selling any shares of our Common Stock and we will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders. However, upon a cash exercise of the Warrants by the selling stockholders, we will receive a per share exercise price of \$1.37. If the Warrants are exercised in a cashless exercise, we will not receive any proceeds from the exercise of the Warrants. We have agreed to pay certain registration expenses, other than underwriting discounts and commissions.

The selling stockholders may from time to time sell, transfer or otherwise dispose of any or all of their shares of Common Stock in a number of different ways and at varying prices. See "Plan of Distribution" for more information.

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

Our Common Stock is currently listed on The Nasdaq Capital Market ("Nasdaq") under the symbol WINT. On April 4, 2017, the last reported sale price of our Common Stock on Nasdaq was \$1.09 per share.

Investing in our Common Stock involves significant risks. See "Risk Factors" beginning on page 5 of this prospectus.

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

The date of this prospectus is _____, 2017.

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This prospectus is part of a registration statement that we have filed with the SEC pursuant to which the selling stockholders named herein may, from time to time, offer and sell or otherwise dispose of the shares of our Common Stock covered by this prospectus. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares of Common Stock are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference herein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the caption "Where You Can Find More Information" in this prospectus.

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our shares of Common Stock other than the shares of our Common Stock covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

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

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus, is not complete, and does not contain all of the information that you should consider before making your investment decision. You should carefully read the entire prospectus, including the information presented under the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" and the consolidated financial statements and the notes thereto and other documents incorporated by reference in this prospectus before making an investment decision.

Company Overview

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a Delaware corporation, with our principal offices located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania. We were incorporated as a Delaware corporation in 1992. Our telephone number is 215-488-9300 and our corporate website address is www.windtreetx.com. Our common stock is listed on The Nasdaq Capital Market® (Nasdaq), where our symbol is WINT.

We are a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies that are designed to deliver aerosolized KL4 surfactant without invasive procedures. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program utilizing our proprietary technology platform is AEROSURF® (lucinactant for inhalation), which is an investigational combination drug/device product that is being developed for the treatment of respiratory distress syndrome (RDS) in premature infants. AEROSURF has the potential to enable administration of aerosolized KL4 surfactant to premature infants receiving nasal continuous positive airway pressure (nCPAP), without invasive intubation and mechanical ventilation, which are required to administer surfactants currently approved by the United States Food and Drug Administration (FDA). In September 2016, the FDA granted Fast Track designation for AEROSURF. The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs.

As a development company, with limited resources and no operating revenues, we believe that our ability to continue as a going concern in the near term is highly dependent upon our successfully completing the AEROSURF phase 2b clinical trial in mid-2017, as planned, and obtaining results that are sufficiently positive to support a strategic transaction and/or equity financing immediately thereafter. If the results are suboptimal or present an unacceptable benefit/risk profile, we may be unable to secure the additional required capital and ultimately could be forced to curtail our development activities and cease operations.

Initial Focus – Respiratory Distress Syndrome (RDS) in Premature Infants

AEROSURF is focused on improving the management of RDS in premature infants, the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS is a serious condition in premature infants born prior to 37 weeks gestational age who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. RDS can result in long-term respiratory problems, developmental delays and death. Although a higher incidence and severity of RDS is correlated with younger gestational ages, RDS can occur in any premature infant. Our independent third-party market research and other third-party data sources (e.g., IMS Health) indicate that 120,000 to 135,000 premature infants are given respiratory support after birth each year in the United States because they have, or are at risk for, RDS and a significantly greater number globally.

Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system with complications such as increased intracranial pressure and risk for brain injury. Mechanical ventilation can result in ventilator-associated lung injury, chronic lung disease and increased risk of infection.

To avoid the risks of intubation and mechanical ventilation, many premature infants are initially treated with noninvasive respiratory support, such as nCPAP. Unfortunately, nCPAP alone does not address the underlying surfactant deficiency. Many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to premature infants earlier in their course of treatment and without exposing them to the risks associated with intubation and mechanical ventilation.

In April 2016, we completed a multi-year analysis of data collected in a Noninterventional Observational Study (the Observational Study) on the treatment and outcomes of over 2,000 premature infants 26 to 34 week gestational age with RDS. The results of the study have better informed our assessment of the unmet medical need in RDS, the design of a potential Phase 3 trial, and the RDS market opportunity. Based on this study, we have enhanced some of the operational aspects of the AEROSURF phase 2 program.

We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing (KL4) surfactant and a less-invasive method of surfactant administration. By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

Beyond RDS

In the future, we believe that we may be able to develop a pipeline of KL4 surfactant products to address serious critical care respiratory conditions in children and adults. While we remain focused on AEROSURF, we have received support, and plan to seek additional support, from the National Institutes of Health (NIH) and other government sources to explore the utility of our KL4 surfactant to address a variety of respiratory conditions with recognized educational and research institutions.

We believe that our aerosolized KL4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, although there can be no assurance, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance, however, that we will secure the additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, we will be successful.

The 2017 Private Placement

Effective February 13, 2017 ("Closing Date"), we entered into a Securities Purchase Agreement (the "SPA") and a Registration Rights Agreement ("Registration Rights Agreement") with select institutional investors ("Investors"), whereby we agreed to issue and sell to the Investors an aggregate of 7,049 Series A Convertible Preferred Stock units (the "Units") at a price per Unit of \$1,495, for an aggregate purchase price of approximately \$10.5 million (the "Offering"). Each Unit consists of: (i) one share of Series A Convertible Preferred Stock ("Preferred Stock") and (ii) 1,000 Series A-1 Warrants ("Warrants") to purchase shares of common stock, par value \$0.001 per share, of the Company ("Common Stock"). Each share of Preferred Stock may be converted at the holder's option at any time into 1,000 shares (the "Conversion Shares") of Common Stock at \$1.37 per share (the "Conversion Price"). Each warrant may be exercised at any time on or after August 15, 2017 through February 15, 2024 at an exercise price equal to \$1.37 per share of Common Stock (the "Exercise Price"). The Preferred Stock and the Warrants may not be converted or exercised to the extent that the holder thereof would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of the outstanding shares of our Common Stock. The Preferred Stock and Warrants also contain customary provisions that adjust the number of shares of Common Stock which the Preferred Stock and Warrants is convertible and exercisable into, respectively, as well as the Conversion Price or Exercise Price, in the event of a stock split or other similar recapitalization.

We received approximately \$10.5 million in net proceeds from this Offering, including approximately \$1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017, after deducting the estimated offering expenses of approximately \$70,000.

In addition to the Offering, the SPA also provides that, until February 13, 2018, the Investors shall be entitled to participate in our subsequent bona fide capital raising transactions.

Except as may be required under Delaware corporate law, the Preferred Stock does not have voting rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up or a Deemed Liquidation Event (as defined in the Designation of Preferences, Rights and Limitations of the Preferred Stock (“Designations”)), the holders of Preferred Stock then outstanding shall be entitled to be paid out of the assets available for distribution to stockholders (i) before any payment is made to the holders of Common Stock, an amount per share of Preferred Stock equal to \$1,495 (the “Liquidation Value”), and after payment of any other preferential amounts payable to holders of other outstanding classes of preferred stock, (ii) out of the remaining assets of the Company available for distribution to its stockholders, the holders of the Preferred Stock and Common Stock and any other capital stock of the Corporation entitled to share in such distribution, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock in accordance with their terms; provided that if the aggregate amount which the holders of Preferred Stock are entitled to receive exceeds an amount per share equal to three times (3x) the Liquidation Value (as defined in the Designations), then the holders of Preferred Stock shall be entitled to receive, if greater, the amount such holder would have received if all Preferred Stock had been converted into Common Stock immediately prior to such distribution.

We may cause the Preferred Stock to be mandatorily converted if after the first anniversary of the original issue date, the market value per share of the Common Stock equals or exceeds \$4.11 for at least 20 consecutive trading days. Such mandatory conversion shall be subject to the beneficial ownership limitation described above.

Pursuant to the Registration Rights Agreement, we agreed to file within 50 days of the Closing Date this registration statement with the Securities and Exchange Commission to register for subsequent resale the Conversion Shares and the Warrant Shares.

Corporate Information

Our principal executive offices are located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania, 18976, our telephone number is 215-488-9300 and our corporate website address is www.windtreetx.com. Neither our website nor any information contained on our website is part of this prospectus. Our Common Stock is listed on Nasdaq under the ticker symbol WINT.

THE OFFERING

Common stock offered by the selling stockholders	14,098,000 shares of Common Stock, which consists of: (i) 7,049,000 Conversion Shares and (ii) 7,049,000 Warrant Shares.
Common stock outstanding	9,439,365 shares (as of March 23, 2017)
Use of proceeds	We will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders in this offering. See "Use of Proceeds."
Risk factors	Investing in our Common Stock involves significant risks. See "Risk Factors" beginning on page 5 of this prospectus, which incorporates by reference the risk factors set forth in our most recent Annual Report on Form 10-K.
Nasdaq ticker symbol	WINT

RISK FACTORS

An investment in our securities involves significant risks. You should carefully consider each of the risk factors set forth in our most recent Annual Report on Form 10-K, which was filed with the SEC on March 31, 2017, and as may be updated from time to time by our Quarterly Reports on Form 10-Q and other SEC filings filed after such annual report, and future filings with the SEC, which are incorporated by reference into this prospectus. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus and any prospectus supplement. Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, cash flows and results of operations. If that occurs, the trading price of our Common Stock could decline materially and you could lose all or part of your investment.

The risks we have incorporated by reference into this prospectus are not the only risks we face. We may experience additional risks and uncertainties not currently known to us, or as a result of developments occurring in the future. Conditions that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, cash flows, results of operations and prospects.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations and continue as a going concern. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to our development and potential regulatory plans to secure marketing authorization for AEROSURF®, if approved, and other potential future products that we may develop; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant product candidates, our aerosol delivery system (ADS) based on our proprietary aerosol technology for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs), materials and medical devices; plans regarding potential strategic alliances and collaborative arrangements to develop, manufacture and market our products, and other potential strategic transactions.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

Risks Related to Capital Resource Requirements

- the risk that, as a development company, with limited resources and no operating revenues, our ability to continue as a going concern in the near term is highly dependent upon our successfully completing the AEROSURF phase 2b clinical trial in mid-2017, as planned, and obtaining results that are sufficiently positive to support a strategic transaction and/or equity financing immediately thereafter. If the results are suboptimal or present an unacceptable benefit/risk profile, we may be unable to secure the additional required capital, which would severely limit our ability to continue as a going concern;
- the risk that we currently have sufficient capital resources to fund our research and development programs, support our business operations and pay our debt service obligations on a timely basis to mid-year 2017, and, if for any reason we are unable to raise additional capital before our resources are exhausted, we would likely experience a liquidity shortfall that would severely limit our ability to continue as a going concern;

- the risk that, given our limited cash resources, should we experience any further delay in completing the AEROSURF phase 2b clinical trial or should any other complications arise, including, for example, with respect to the pace of patient enrollment, regulatory requirements, drug and device availability, clinical supplies, and device performance, we likely would be compelled to end the phase 2b clinical trial earlier than planned, which may potentially have a negative impact on the results of the trial. Under such circumstances, we may find it difficult to raise additional capital needed to continue our development programs and support our operations, which could have a material adverse effect on our business and operations;
- the risk that, even if we successfully complete the AEROSURF phase 2b clinical trial in accordance with our plan, we will continue to require significant additional infusions of capital to support our research and development activities, including additional AEROSURF clinical development programs, and our business operations, debt service obligations, and our activities to potentially identify and secure potential strategic transactions; and the risk that our ability to raise such capital may be adversely impacted by future developments;
- the risk that we may be unable to regain compliance with The NASDAQ Stock Market (Nasdaq) listing requirements within the time provided, in particular, (i) the minimum stockholders' equity requirement (\$2.5 million) with respect to which, after receiving an initial deficiency notification on May 19, 2016, we recently received a second extension from a Nasdaq Hearings Panel until May 15, 2017, subject to certain requirements, or (ii) the alternative minimum market value of outstanding shares requirement (\$35 million); if we fail to regain compliance on or before May 15, 2017, our common stock will be delisted and the value of our common stock may decrease;
- the risk that our ability to raise additional capital is subject to certain other risks, including (i) limitations on the amount that we can raise under our 2014 universal shelf registration statement on Form S-3 (2014 Universal Shelf), including under our "at-the-market" equity sales program (ATM Program); (ii) the risk that our stockholders may not approve a financing transaction priced at a discount and involving issuance of more than 20% of our outstanding common stock, and for which stockholder approval is required under Nasdaq listing rules; (iii) that our 2014 Universal Shelf will expire on June 12, 2017 and we may be unable to file a replacement universal shelf if our common stock is no longer listed on Nasdaq, and, in such event, we would lose access to our ATM Program; (iv) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and \$25 million of debt, may make it difficult to conduct equity-based financings, and (v) that unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution of stockholders' interests;
- risks relating to our pledge of substantially all of our assets to secure our obligations under our \$25 million secured loan with affiliates of Deerfield Management Company, L.P. (Deerfield), which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;
- risks relating to our ability to manage our limited resources effectively and timely modify our business strategy as needed to respond to developments in our research and development activities, as well as in our business, our industry and other factors;

Risks related to Development Activities

- risks related to our AEROSURF development program, including with respect to our ADS, lyophilized KL4 surfactant and clinical development activities, that might arise and could affect the AEROSURF development program and potential future research and development activities, and potentially have a material adverse effect on our business and operations;
- risks related to our efforts to gain regulatory approval in a timely and successful manner, in the U.S. and in international markets, for our drug products and combination drug/device product candidates, including AEROSURF, including that changes in the national or international political and regulatory environment may make it more difficult to gain United States Food and Drug Administration (FDA) or international regulatory approvals for our product candidates;
- risks relating to the rigorous regulatory approval processes required for approval of any drug, medical device or combination drug/device product that we may develop, whether independently, with strategic partners or pursuant to collaboration arrangements, including that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we may submit; or the FDA or other regulatory authorities may not agree on matters raised during the review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates; or that the FDA or other regulatory authorities may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

Risks Related to Strategic and Other Transactions

- the risk that we may be unable to identify and enter into strategic alliances, collaboration agreements or other strategic transactions that would provide capital to support our AEROSURF development activities and resources and expertise to support the registration and commercialization of AEROSURF in various markets and potentially support the development and, if approved, commercialization, of our other potential KL4 surfactant pipeline products;

Risks related to Manufacturing

- the risk that we, our contract manufacturing organizations (CMOs) or any of our third-party suppliers, most of which are single-source providers, may encounter problems in manufacturing our KL4 surfactant, the APIs used in the manufacture of our KL4 surfactant, the ADS and related components, and other materials on a timely basis or in an amount sufficient to support our needs;
- risks relating to the transfer of our KL4 surfactant manufacturing technology to our CMOs, and our CMOs' ability to manufacture our lyophilized KL4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for our research and development activities and, if approved, commercial applications;
- risks related to ongoing manufacturing process development by our suppliers of APIs and our ability to comply with ultimate drug approval specifications;
- risks relating to our and our device manufacturer and assembler's ability to develop and manufacture our ADS and related components for preclinical and clinical studies of our combination drug/device product candidates and, if approved, commercial activities;

Other Risks Affecting our Business

- the risk that, even if we are able to secure regulatory approval for our products in one or more of the U.S. and international markets, reimbursement and health care reform may adversely affect our ability to secure appropriate reimbursement; or that market conditions and other factors may make it difficult to gain access to certain markets and patient populations, which could have a material adverse effect on our business;
- the risk that we, our strategic partners or collaborators will be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel, which could have a material adverse effect on our commercial and development activities and our operations;
- the risk that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;
- the risk that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense; and
- other risks and uncertainties detailed in "Risk Factors" on page 5 of this prospectus, which incorporates by reference the risk factors set forth in our most recent Annual Report on Form 10-K, and in the documents incorporated by reference in this prospectus.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this report or the documents incorporated by reference herein speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Trademark Notice

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

USE OF PROCEEDS

The shares of our Common Stock being offered by this prospectus are solely for the account of the selling stockholders. We will not receive any proceeds from the sale of these shares by the selling stockholders. However, upon a cash exercise of the Warrants by the selling stockholders, we will receive a per share exercise price of \$1.37. If the Warrants are exercised in a cashless exercise, we will not receive any proceeds from the exercise of the Warrants.

SELLING STOCKHOLDERS

This prospectus relates to the resale by the selling stockholders of (i) the Conversion Shares issuable upon conversion of the Preferred Stock and (ii) the Warrant Shares issuable upon conversion of the Warrants. The Preferred Stock and the Warrants were issued by us to the selling stockholders on February 13, 2017 in the Private Placement. For additional information regarding the issuance of these securities, see “Prospectus Summary — The 2017 Private Placement” above. We are filing the registration statement of which this prospectus is a part pursuant to the provisions of the registration rights agreement we entered into with the selling stockholders in connection with the Private Placement. Except as otherwise disclosed below in the footnotes to the selling stockholders table below, the selling security holders have not had any material relationship with us within the past three years.

The selling stockholders may from time to time offer and sell pursuant to this prospectus any or all of the Conversion Shares and Warrant Shares that they acquire upon conversion of the Preferred Stock and exercise of the Warrants, respectively.

The following table presents information regarding the selling stockholders and the shares that any of the selling stockholders may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholders, and reflects holdings as of March 20, 2017. As used in this prospectus, the term “selling stockholders” includes the selling stockholders and any donees, pledges, transferees or other successors in interest of the selling stockholders. The number of shares in the column “Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus” represents all of the shares that the selling stockholders may offer under this prospectus. The selling stockholders may sell some, all or none of its shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares.

The Preferred Stock and the Warrants contain limitations that prevent the holder of any Preferred Stock or Warrants from acquiring shares upon conversion of the Preferred Stock, or exercise of a Warrant, that would result in the number of shares beneficially owned by it and its affiliates exceeding 9.99% (or such lesser percent as designated by each selling stockholder) of the total number of shares of our common stock then issued and outstanding. The beneficial ownership percentage in the third and sixth columns for certain selling stockholders reflect these limitations, which are further described in footnotes relating to each selling stockholder. The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, as amended, and includes shares of Common Stock with respect to which the selling stockholders have voting and investment power. The offering is based on 9,404,496 shares of our Common Stock actually outstanding on March 20, 2017.

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering ⁽¹⁾	% of Shares of Common Stock Beneficially Owned Prior to Offering ⁽¹⁾	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Beneficially Owned After Offering ^{(1) (2)}	Percentage of Common Stock Beneficially Owned After Offering ^{(1) (2)}
Baker Brothers Life Sciences, L.P. ⁽³⁾	7,515,780	4.99%	3,646,000	3,869,780	4.99%
667, L.P. ⁽⁴⁾	681,765	4.99%	368,000	313,765	3.12%
Broadfin Healthcare Master Fund, Ltd. ⁽⁵⁾	4,688,559	9.99%	2,006,000	2,682,559	9.99%
DAFNA Lifescience L.P. ⁽⁶⁾	320,357	3.29%	200,000	120,357	1.24%
DAFNA Lifescience Select L.P. ⁽⁷⁾	216,619	2.25%	134,000	82,619	*
Kingsbridge Capital ⁽⁸⁾	416,285	4.24%	402,000	14,285	*
Hudson Bay Master Fund Ltd. ⁽⁹⁾	1,338,000	9.99%	1,338,000	-	*
Alyeska Master Fund LP ⁽¹⁰⁾	950,289	9.42%	590,000	360,289	3.57%
Alyeska Master Fund 2 LP ⁽¹¹⁾	691,645	6.98%	414,000	277,645	2.80%
Lee's Pharmaceutical Holdings Limited ⁽¹²⁾	2,676,000	9.99%	2,676,000	-	*
Battelle Memorial Institute ⁽¹³⁾	2,297,143	4.99%	2,190,000	107,143	*
John R. Leone ⁽¹⁴⁾	46,177	*	26,000	20,177	*
Joseph M. Mahady ⁽¹⁵⁾	45,567	*	34,000	11,567	*
Bruce A. Peacock ⁽¹⁶⁾	47,901	*	34,000	13,901	*
Craig Fraser ⁽¹⁷⁾	93,481	*	14,000	79,481	*
Steven G. Simonson, M.D. ⁽¹⁸⁾	54,071	*	6,000	48,071	*
Lawrence Weinstein ⁽¹⁹⁾	46,048	*	20,000	26,048	*

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- (1) We have determined beneficial ownership in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, as amended. Certain shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions and/or exercise restrictions, as further described in the footnotes below.
 - (2) Assumes that all of the shares of Common Stock represented by this prospectus have been sold.
 - (3) The number of shares beneficially owned prior to the offering includes 1,823,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 5,460,810 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 4.99% and furthermore, 1,823,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, Baker Brothers Life Sciences, LP would beneficially own approximately 482,000 shares, which is approximately 4.99% of our outstanding shares as of March 20, 2017 adjusted for any additional shares of Common Stock issued in connection with the conversion of Preferred Stock or exercise of warrants. Baker Brothers Life Sciences, LP and 667, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 4.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The names of the natural persons who have voting or investment control over the shares are Julian C. Baker and Felix J. Baker. The address for this selling stockholder is 667 Madison Avenue, 21st Floor, New York, NY 10065.
 - (4) The number of shares beneficially owned prior to the offering includes 184,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 474,762 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 4.99% and furthermore, 184,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, 667, L.P. would beneficially own approximately 493,000 shares, which is approximately 4.99% of our outstanding shares as of March 20, 2017 adjusted for any additional shares of Common Stock issued in connection with the conversion of Preferred Stock or exercise of warrants. Baker Brothers Life Sciences, LP and 667, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 4.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The names of the natural persons who have voting or investment control over the shares are Julian C. Baker and Felix J. Baker. The address for this selling stockholder is 667 Madison Avenue, 21st Floor, New York, NY 10065.
 - (5) The number of shares beneficially owned prior to the offering includes 1,003,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 2,907,762 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 9.99% and furthermore, 1,003,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, Broadfin Healthcare Master Fund, Ltd. would beneficially own approximately 958,000 shares, which is approximately 9.99% of our outstanding shares as of March 20, 2017 adjusted for any additional shares of Common Stock issued in connection with the conversion of Preferred Stock or exercise of warrants. The name of the natural person who has voting or investment control over the shares is Kevin Kotler. The address for this selling stockholder is 300 Park Avenue, 25th Floor, New York, NY 10022.
 - (6) The number of shares beneficially owned prior to the offering includes 100,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 220,357 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 4.99% and furthermore, 100,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such exercise restriction, DAFNA Lifescience, L.P. would beneficially own 220,357 shares, which is approximately 2.29% of our outstanding shares as of March 20, 2017. DAFNA Lifescience, L.P. and DAFNA Lifescience Select, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 4.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The names of the natural persons who have voting or investment control over the shares are Nathan Fischel and Fariba Ghodsian. The address for this selling stockholder is 10990 Wilshire Boulevard, Suite 1400, Los Angeles, CA 90024.

- (7) The number of shares beneficially owned prior to the offering includes 67,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 149,619 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 4.99% and furthermore, 67,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such exercise restriction, DAFNA Lifescience Select, L.P. would beneficially own 149,619 shares, which is approximately 1.57% of our outstanding shares as of March 20, 2017. DAFNA Lifescience, L.P. and DAFNA Lifescience Select, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 4.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The names of the natural persons who have voting or investment control over the shares are Nathan Fischel and Fariba Ghodsian. The address for this selling stockholder is 10990 Wilshire Boulevard, Suite 1400, Los Angeles, CA 90024.
- (8) The number of shares beneficially owned prior to the offering includes 201,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 201,000 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 9.99% and furthermore, all 201,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such exercise restriction, Kingsbridge Capital would beneficially own 215,285 shares, which is approximately 2.24% of our outstanding shares as of March 20, 2017. The name of the natural person who has voting or investment control over the shares is William Adam James Gurney. The address for this selling stockholder is 2nd Floor, Palm Grove House, Wickhams Cay, PO Box 3340, Road Town, Tortola, British Virgin Islands.
- (9) The number of shares beneficially owned prior to the offering includes 669,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 669,000 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 9.99% and furthermore, all 669,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, Hudson Bay Master Fund Ltd. would beneficially own 669,000 shares, which is approximately 6.64% of our outstanding shares as of March 20, 2017. The name of the natural person who has voting or investment control over the shares is Sander Gerber. The address for this selling stockholder is 777 Third Avenue, 30th Floor, New York, NY 10017.
- (10) The number of shares beneficially owned prior to the offering includes 295,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 385,074 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 9.99% and furthermore, 295,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such exercise restriction, Alyeska Master Fund, L.P. would beneficially own 655,289 shares, which is approximately 6.69% of our outstanding shares as of March 20, 2017. Alyeska Master Fund, L.P. and Alyeska Master Fund 2, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 9.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The name of the natural person who has voting or investment control over the shares is Anand Parekh. The address for this selling stockholder is c/o Alyeska Investment Group, L.P., 77 West Wacker Drive, 7th Floor, Chicago, IL 60601.
- (11) The number of shares beneficially owned prior to the offering includes 207,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 295,496 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon 207,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such exercise restriction, Alyeska Master Fund 2, L.P. would beneficially own 484,645 shares, which is approximately 5.00% of our outstanding shares as of March 20, 2017. Alyeska Master Fund, L.P. and Alyeska Master Fund 2, L.P. are entities under common control, and therefore, their affiliates may be deemed to be the beneficial owners of shares held by each of them, subject to the 9.99% beneficial ownership limitation provisions on their Preferred Stock and warrants. The name of the natural person who has voting or investment control over the shares is Anand Parekh. The address for this selling stockholder is c/o Alyeska Investment Group, L.P., 77 West Wacker Drive, 7th Floor, Chicago, IL 60601.
- (12) The number of shares beneficially owned prior to the offering includes 1,338,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 1,338,000 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 9.99% and furthermore, all 1,338,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, Lee's Pharmaceutical Holdings Limited would beneficially own approximately 1,044,000 shares, which is approximately 9.99% of our outstanding shares as of March 20, 2017 adjusted for any additional shares of Common Stock issued in connection with the conversion of Preferred Stock or exercise of warrants. The names of the natural persons who have voting or investment control over the shares are Leelalertsuphakun Wane, Lee Siu Fong and Li Xiaoyi. The address for this selling stockholder is Unit 110-111, Bio-Informatics Centre, No. 2 Science Park West Avenue, Hong Kong Science Park, Shatin, Hong Kong.
- (13) The number of shares beneficially owned prior to the offering includes 1,095,000 shares of Common Stock issuable upon conversion of the Preferred Stock and 1,202,143 shares of Common Stock issuable upon exercise of warrants. The shares of Common Stock issuable upon conversion of Preferred Stock and exercise of warrants are subject to beneficial ownership limitation provisions of 4.99% and furthermore, 1,095,000 of such warrants may not be exercised until August 15, 2017. If we had calculated beneficial ownership taking into effect such beneficial ownership limitation and exercise restriction, Battelle Memorial Institute would beneficially own approximately 495,000 shares, which is approximately 4.99% of our outstanding shares as of March 20, 2017 adjusted for any additional shares of Common Stock issued in connection with the conversion of Preferred Stock or exercise of warrants. The name of the natural persons who have voting or investment control over the shares are the members of its board of directors and its corporate officers, who are John K. Welch, Vicky A. Bailey, Kirkland H. Donald, Frank L. Douglas, Michael L. Gasser, Lester L. Lyles, Michael G. Morris, Sean C. O'Keefe, Subra Suresh, Suzanne Vautrinot, Jeffrey Wadsworth, David C. Evans, Ronald C. Townsend, Stephen E. Kelly, Russell P. Austin, Malesa A. Litteral, Patrick F. Jarvis, Steven F. Ashby, Mark T. Peters, Thomas E. Mason, Thomas E. Sharpe, Brian R. Smith, and Robert J. Dillon. The address for this selling stockholder is 505 King Avenue, Columbus, OH 43201. We entered into a Collaboration Agreement with Battelle Memorial Institute in October 2014, which was amended on August 2015 and March 2016, for the development of a new version of our aerosol delivery system. Under the Collaboration Agreement, we and Battelle have agreed to share development costs for a three-stage development plan.

- (14) The number of shares beneficially owned prior to the offering includes 13,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 16,571 shares of Common Stock issuable upon exercise of warrants (13,000 of which may not be exercised until August 15, 2017), and 5,356 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Mr. Leone is on the Board of Directors of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.
- (15) The number of shares beneficially owned prior to the offering includes 17,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 17,000 shares of Common Stock issuable upon exercise of warrants, all of which may not be exercised until August 15, 2017, and 5,356 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Mr. Mahady is on the Board of Directors of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.
- (16) The number of shares beneficially owned prior to the offering includes 17,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 17,000 shares of Common Stock issuable upon exercise of warrants, all of which may not be exercised until August 15, 2017, and 7,690 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Mr. Peacock is on the Board of Directors of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.
- (17) The number of shares beneficially owned prior to the offering includes 7,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 7,000 shares of Common Stock issuable upon exercise of warrants, all of which may not be exercised until August 15, 2017, and 68,288 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Mr. Fraser is the Company's President and Chief Executive Officer and is on the Board of Directors of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.
- (18) The number of shares beneficially owned prior to the offering includes 3,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 4,191 shares of Common Stock issuable upon exercise of warrants, (3,000 of which may not be exercised until August 15, 2017) and 33,572 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Dr. Simonson is Senior Vice President and Chief Development Officer of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.
- (19) The number of shares beneficially owned prior to the offering includes 10,000 shares of Common Stock issuable upon conversion of the Preferred Stock, 10,000 shares of Common Stock issuable upon exercise of warrants, all of which may not be exercised until August 15, 2017, and 17,977 shares issuable upon exercise of stock options currently exercisable or exercisable within 60 days after March 20, 2017. Mr. Weinstein is Vice President, Medical Device Development of the Company. The address for this selling stockholder is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.

(*) Less than 1%

PLAN OF DISTRIBUTION

We are registering 14,098,000 shares of Common Stock under this prospectus on behalf of the selling stockholders. The selling stockholders will pay any brokerage commissions and similar selling expenses attributable to the sale of the shares. We will not receive any of the proceeds from the sale of the shares by the selling stockholders. However, upon a cash exercise of the Warrants by the selling stockholders, we will receive a per share exercise price of \$1.37. If the Warrants are exercised in a cashless exercise, we will not receive any proceeds from the exercise of the Warrants.

These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein: ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers; block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction; purchases by a broker-dealer as principal and resale by the broker-dealer for its account; an exchange distribution in accordance with the rules of the applicable exchange; privately negotiated transactions; short sales; through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share; a combination of any such methods of sale; and any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

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

The aggregate proceeds to the selling stockholders from the sale of the Common Stock offered by them will be the purchase price of the Common Stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of Common Stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the Warrants by payment of cash, however, we will receive the exercise price of the Warrants.

To the extent required, the shares of our Common Stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the Common Stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Common Stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying any applicable prospectus delivery requirements of the Securities Act.

We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

The selling stockholders and any broker-dealers that act in connection with the sale of the shares may be deemed to be "underwriters" as the term is defined in Section 2(11) of the Securities Act. Consequently, any commissions received by these broker-dealers and any profit on the resale of the shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

LEGAL MATTERS

The validity of our Common Stock offered by this prospectus will be passed upon for us by Dentons US LLP, New York, New York.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 3 to the consolidated financial statements) which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (including the exhibits, schedules and amendments thereto) under the Securities Act with respect to our Common Stock offered hereby by the selling stockholders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to us and the Common Stock offered hereby by the selling stockholders, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus as to the contents of any contract, agreement or any other document are summaries of the material terms of this contract, agreement or other document and are not necessarily complete. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to the exhibits for a more complete description of the matter involved. A copy of the registration statement, and the exhibits and schedules thereto, may be inspected without charge at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549. Copies of these materials may be obtained, upon payment of a duplicating fee, from the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is www.sec.gov.

We also make available free of charge on our website at www.windtreetworks.com our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on our website is not incorporated by reference into this prospectus and you should not consider information contained on our website as part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we have filed with the SEC. This means we can disclose important information to you without actually including the specific information in this prospectus by referring to those documents. The information incorporated by reference is an important part of this prospectus.

If information in incorporated documents conflicts with information in this prospectus, you should rely on the most recent information. If information in an incorporated document conflicts with information in another incorporated document, you should rely on the most recent incorporated document. We incorporate by reference the documents listed below:

- our Annual Report on Form 10-K for the year ended December 31, 2016;
- our Current Reports on Forms 8-K filed with the SEC on January 24, 2017, February 15, 2017, February 16, 2017, March 3, 2017, and March 31, 2017 (excluding the information in Item 2.02 therein); and
- the description of our Common Stock contained in our registration statement on Form 8-A filed with the SEC on July 13, 1995 and February 6, 2004.

All documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, other than the information furnished pursuant to Item 2.02 or Item 7.01 of Form 8-K, prior to the filing of a post-effective amendment to this Registration Statement which indicates that all securities covered by this Registration Statement have been sold or which deregisters all of the securities then remaining unsold, shall be deemed to be incorporated by reference in this Registration Statement and to be part of this document from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference in this document, will be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in this document or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this document modifies or supersedes such statement. Any such statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement. We will provide a copy of these filings (including certain exhibits that are specifically incorporated by reference therein) to each person, including any beneficial owner, to whom a prospectus is delivered. You may request a copy of any or all of these filings at no cost, by writing or calling us at:

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300
Attention: Mary B. Templeton, Esq.

Copies of certain information filed by us with the SEC, including our annual report and quarterly reports, are also available on our website at www.windtretrx.com. Information contained on our website or that can be accessed through our website is not incorporated by reference herein.

You should read the information relating to us in this prospectus together with the information in the documents incorporated by reference. Nothing contained herein shall be deemed to incorporate information furnished to, but not filed with, the SEC.

14,098,000 Shares



Common Stock

Prospectus

, 2017

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses payable by the Registrant expected to be incurred in connection with the issuance and distribution of Common Stock being registered hereby (other than underwriting discounts and commissions). All of such expenses are estimates, except for the Securities and Exchange Commission ("SEC") registration fee.

SEC registration fee	\$	1,814
Legal fees and expenses		50,000
Accounting fees and expenses		10,000
Total	\$	<u>61,814</u>

Item 14. Indemnification of Directors and Officers.

Article Eight of our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law 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 (i) any breach of their duty of loyalty to the corporation or its stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware or (iv) any transaction from which the director derives an improper personal benefit.

Our Amended and Restated By-Laws (By-Laws) provide that we shall indemnify our directors and officers, the directors and officers of any of our subsidiaries and any other individuals acting as directors or officers of any other corporation at our request, to the fullest extent permitted by law.

We have entered into indemnification agreements with certain of our executive officers and directors containing provisions that may require us, among other things, to indemnify them against liabilities that may arise by reason of their status or service as officers or directors, as applicable, other than liabilities arising from willful misconduct of a culpable nature and to advance certain expenses incurred as a result of any proceeding against them as to which they could be indemnified. We have obtained limited directors' and officers' liability insurance.

These provisions in our Certificate of Incorporation and our By-Laws do not eliminate the officers' and directors' fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer's or director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

Item 15. Recent Sales of Unregistered Securities.

We have sold the securities described below within the past three years which were not registered under the Securities Act. All of the sales listed below were made pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Regulation D thereunder, as the securities were issued to accredited investors, without a view to distribution, and were not issued through any general solicitation or advertisement.

Securities Purchase Agreement

Effective February 13, 2017 ("Closing Date"), we entered into a Securities Purchase Agreement (the "SPA") and a Registration Rights Agreement ("Registration Rights Agreement") with select institutional investors ("Investors"), whereby we agreed to issue and sell to the Investors an aggregate of 7,049 Series A Convertible Preferred Stock units (the "Units") at a price per Unit of \$1,495, for an aggregate purchase price of approximately \$10.5 million (the "Offering"). Each Unit consists of: (i) one share of Series A Convertible Preferred Stock ("Preferred Stock") and (ii) 1,000 Series A-1 Warrants to purchase Common Stock ("Warrants"). Each share of Preferred Stock may be converted at the holder's option at any time into 1,000 shares (the "Conversion Shares") of common stock, par value \$0.001 per share, of the Company ("Common Stock") at \$1.37 per share (the "Conversion Price"). Each warrant may be exercised at any time on or after August 15, 2017 through February 15, 2024 at an exercise price equal to \$1.37 per share of Common Stock (the "Exercise Price"). The Preferred Stock and the Warrants may not be converted or exercised to the extent that the holder thereof would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of the outstanding shares of our Common Stock. The Preferred Stock and Warrants also contain customary provisions that adjust the number of shares of Common Stock which the Preferred Stock and Warrants is convertible and exercisable into, respectively, as well as the Conversion Price or Exercise Price, in the event of a stock split or other similar recapitalization. We conducted the Offering pursuant to Rule 506(b) and Section 4(a)(2) of the Securities Act of 1933. The closing for the purchase of the Units occurred on Wednesday, February 15, 2017. The Offering was made to select investors directly without an underwriter or broker. The Company received approximately \$10.5 million in net proceeds from this Offering, including approximately \$1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017, after deducting the estimated offering expenses of approximately \$70,000.

Grant of Options to Craig Fraser

Effective February 1, 2016, our Board of Directors appointed Craig E. Fraser to serve as our President and Chief Executive Officer. On the same date, and in accordance with Nasdaq Listing Rule 5635(c)(4), our Compensation Committee granted to Mr. Fraser an option to purchase 204,863 shares of Common Stock, representing 2.5% of our outstanding shares of Common Stock, at an exercise price of \$2.33 per share, which was the closing price on February 2, 2016 and the price next determined after approval of the grant. Subject to Mr. Fraser's continued employment with the Company, one-third of the options will vest and become exercisable on each of the next three anniversary dates of the grant, such that the options will be exercisable in full on the third anniversary of the date of grant. The option has a term of 10 years. The award was issued outside our 2011 Long-Term Incentive Plan, but will be subject to terms and conditions generally consistent with those in the 2011 Plan and the form of option agreement in effect under the 2011 Plan. We conducted the Offering pursuant to Section 4(a)(2) of the Securities Act of 1933.

Collaboration Agreement with Battelle

We entered into a Collaboration Agreement with Battelle Memorial Institute ("Battelle") in October 2014, which was amended on August 2015 and March 2016, for the development of a new version (NextGen) of our aerosol delivery system. Under the Collaboration Agreement, we and Battelle have agreed to share development costs for a three-stage development plan.

In connection with the Collaboration Agreement, as amended, we issued to Battelle two warrants to purchase shares of our Common Stock, each having an exercise price of \$70 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 71,429 shares of our common stock, exercisable upon successful completion by Battelle of the Stage 3 activities ("Initial Warrant"), and (ii) a warrant to purchase up to 35,714 shares of our Common Stock ("Additional Warrant," and together with the Initial Warrant, the "Battelle Warrants"), exercisable if and only if Battelle successfully completes the Stage 3 activities no later than the November 15, 2016, which date may be adjusted as provided in the Collaboration Agreement. The Battelle Warrants were issued in reliance on the exemption from registration in Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D.

Management Consulting Services

During the three months ended June 30, 2014, we issued 625 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during the three-month period ended May 31, 2014. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(a)(2) of the Securities Act.

During the three months ended March 31, 2014, we issued 625 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during 2014. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(a)(2) of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

See the Exhibit Index immediately following the signature page hereto, which is incorporated by reference as if fully set forth herein.

(b) Financial Statement Schedules.

None.

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 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 SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(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 SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement.

(2) that, for the purpose 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 that time shall be deemed to be the initial bona fide offering thereof.

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

(4) that, for the purpose of determining liability under the Securities Act to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(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 Section 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.

(c) 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 foregoing provisions, 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 this 5th day of April, 2017.

Windtree Therapeutics, Inc.

By: /s/ Craig E. Fraser
Name: Craig E. Fraser
Title: President and Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of Windtree Therapeutics, Inc., and each of us, do hereby constitute and appoint each of Craig E. Fraser, Mary B. Templeton, Esq., and John A. Tattory, or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, to do any and all acts and things in our name, place and stead, in any and all capacities, in connection with this registration statement on Form S-1 under the Securities Act, or any registration statement for the same offering that is to be effective upon filing under the Securities Act, including, without limitation, to sign for us or any of us in our names in the capacities indicated below any and all amendments or supplements to this registration statement, including any and all post-effective amendments to the registration statement, and to sign any and all additional registration statements relating to the same offering of securities as this registration statement that are filed pursuant to Rule 462(b) under the Securities Act, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, 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 might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, 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 held on the dates indicated.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Craig E. Fraser</u> Craig E. Fraser	President, Chief Executive Officer and Director (Principal Executive Officer)	<u>April 5, 2017</u>
<u>/s/ John A. Tattory</u> John A. Tattory	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	<u>April 5, 2017</u>
<u>/s/ John R. Leone</u> John R. Leone	Chairman of the Board of Directors	<u>April 5, 2017</u>
<u>/s/ Joseph M. Mahady</u> Joseph M. Mahady	Director	<u>April 5, 2017</u>
<u>/s/ Bruce A. Peacock</u> Bruce A. Peacock	Director	<u>April 5, 2017</u>
<u>/s/ Marvin E. Rosenthale</u> Marvin E. Rosenthale	Director	<u>April 5, 2017</u>

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Amended and Restated Certificate of Incorporation of Windtree Therapeutics, Inc. (Windtree) filed on April 18, 2016	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 18, 2016.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended, filed on June 23, 2016	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 23, 2016.
3.3	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of Windtree, dated February 15, 2017	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
3.4	Amended and Restated By-Laws of Windtree, as amended effective April 19, 2016	Incorporated by reference to Exhibit 3.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 18, 2016.
4.1	Form of Warrant dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Windtree and Deerfield	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.2	Form of Warrant dated December 3, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) on December 3, 2013 under a Facility Agreement dated as of February 13, 2012 between Windtree and Deerfield	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 6, 2013.
4.3	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Windtree and Battelle Memorial Institute	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.
4.4	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Windtree and Battelle Memorial Institute	Incorporated by reference to Exhibit 4.12 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
4.5	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.
4.6	Form of Pre-Funded Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.7	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.
4.8	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.

5.1	Opinion of Dentons US LLP	Filed herewith.
10.1+	Sublicense Agreement, dated as of 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 by and between Windtree and Philip Morris USA Inc., d/b/a/ Chrysalis Technologies, dated March 28, 2008	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+	License Agreement by and between Windtree and Philip Morris Products S.A., dated March 28, 2008	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.
10.4+	Amended and Restated Sublicense and Collaboration Agreement made as of December 3, 2004, between Windtree and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.28 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.5+	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Windtree and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.29 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.6*	Windtree's 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.
10.7*	Form of 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.
10.8*	Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Appendix II to Windtree's Definitive Proxy Statement on Form DEF 14A, as filed with the SEC on August 15, 2011 (Commission File Number 000-26422).
10.9*	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.
10.10*	Form of Non-Employee Director Option Agreement under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 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.
10.11*	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.
10.12*	Windtree's Amended and Restated 2011 Long-Term Incentive Plan effective as of January 22, 2016	Incorporated by reference to Exhibit 10.12 in the Original Filing.

10.13*	Employment Agreement by and between the Company and Craig Fraser dated as of February 1, 2016.	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.
10.14*	Inducement Stock Option Award Agreement dated February 1, 2016 between Craig Fraser and Windtree under Windtree's 2011 Long-Term Incentive Plan	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.
10.15*	Employment Agreement dated as of December 19, 2014, by and 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.
10.16*	Amendment dated December 29, 2014 to Employment Agreement dated as of December 19, 2014, effective as of April 1, 2015, by and 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.
10.17*	Employment Agreement dated as of March 21, 2014, by and between Windtree and John A. Tattory	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 12, 2014.
10.18*	Amendment dated December 29, 2014 to Employment Agreement dated as of March 21, 2014, by and between Windtree and John A. Tattory	Incorporated by reference to Exhibit 10.19 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.
10.19	Form of Indemnification Agreement between the Company and its 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
10.20	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and 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.
10.21	Second Amendment to Lease Agreement, dated January 3, 2013 by and between TR Stone Manor Corp. and Windtree	Incorporated by reference to Exhibits 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 8, 2013.
10.22	Fourth Amendment to Lease Agreement, dated April 29, 2016, by and between PH Stone Manor LP and Windtree	Incorporated by reference to Exhibits 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 31, 2016.
10.23+	Master Services Agreement dated October 24, 2013 between Windtree and DSM Pharmaceuticals, Inc. (now known as Patheon Manufacturing Services LLC)	Incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 12, 2013.
10.24+	Supply Agreement dated as of December 22, 2010 between by and 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.
10.25+	Collaboration Agreement made as of October 10, 2014, by and between Windtree and Battelle Memorial Institute	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
10.26	Amendment dated as of August 4, 2015 to Collaboration Agreement dated as of October 14, 2014 between Windtree and Battelle Memorial Institute.	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on August 10, 2015.

10.27	Second Amendment to Collaboration Agreement between Windtree and Battelle Memorial Institute dated March 31, 2016.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 5, 2016.
10.28+	Facility Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.29	Amendment dated July 9, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 9, 2015.
10.30	Second Amendment dated July 22, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 24, 2015.
10.31	Registration Rights Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.32	Security Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.33	At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Windtree and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 13, 2013.
10.34	Amendment No. 1 dated February 11, 2016, to the At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Windtree and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 16, 2016.
10.35	Security Purchase Agreement dated as of February 13, 2017 between Windtree and selected investors	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
10.36	Registration Rights Agreement dated as of February 13, 2017 between Windtree and selected investors	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
21.1	Subsidiaries of Windtree	Incorporated by reference to Exhibit 21.1 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC on March 31, 2017.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm	Filed herewith.
23.2	Consent of Dentons US LLP	Filed herewith (included in the opinion filed as Exhibit 5.1).
24.1	Power of Attorney	Filed herewith (included on signature page to this registration statement).

+Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

*A management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report pursuant to Item 15(b) of Form 10-K.

EXHIBIT 5.1

April 5, 2017

Board of Directors
Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976-3622

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the filing by Windtree Therapeutics, Inc., a Delaware corporation (the "**Company**"), of a Registration Statement on Form S-1 (the "**Registration Statement**") with the Securities and Exchange Commission on April 5, 2017, including a related prospectus filed with the Registration Statement (the "**Prospectus**"), covering the sale of an aggregate of 14,098,000 shares of the Company's common stock, \$0.001 par value per share, (the "**Shares**") issuable upon (i) the conversion of the Company's Series A Preferred Stock (the "**Preferred Stock**") and (ii) upon the exercise of the Company's Series A-1 Warrants (the "**Warrants**").

We are delivering this opinion to you at your request in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Act.

In connection with rendering this opinion, we have examined and are familiar with (i) the Company's Amended and Restated Certificate of Incorporation, including the Designation of Preferences, Rights and Limitations of the Preferred Stock (the "**Designation**") (ii) the Company's By-Laws, (iii) the Registration Statement, including the Prospectus, (iv) corporate proceedings of the Company relating to the issuance of the Preferred Stock and the Warrants (v) the certificates evidencing the Warrants and (vi) such other instruments and documents as we have deemed relevant under the circumstances.

In making the aforesaid examinations, we have assumed the genuineness of all signatures and the conformity to original documents of all copies furnished to us as original or photostatic copies. We have also assumed that the corporate records furnished to us by the Company include all corporate proceedings taken by the Company to date. As to certain factual matters, we have relied upon a certificate of officers of the Company and have not sought to independently verify such matters.

Based upon the foregoing, and in reliance thereon, and subject to the qualifications, limitations and exceptions stated herein, we are of the opinion, having due regard for such legal considerations as we deem relevant, that the Shares have been duly authorized by the Company and, when issued in accordance with the terms set forth in the Registration Statement and the Prospectus, and when issued in accordance with the terms of the Designation or the Warrants, as applicable, will be validly issued, fully paid and nonassessable.

The foregoing opinion is limited to laws of the State of New York and Delaware corporate law (which includes the Delaware General Corporation Law and applicable provisions of the Delaware constitution, as well as reported judicial opinions interpreting same), and we do not purport to express any opinion on the laws of any other jurisdiction.

We hereby consent to the use of our opinion as an exhibit to the Registration Statement and to the reference to this firm and this opinion under the heading "Legal Matters" in the Registration Statement. In giving such consent, we do not hereby admit that we come within the category of persons whose consent is required under Section 7 of the Act, or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Dentons US LLP

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 31, 2017, in the Registration Statement (Form S-1 No. 333-00000) and related Prospectus of Windtree Therapeutics, Inc. for the registration of 14,098,000 shares of its common stock.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 31, 2017