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

| FORM 8 |
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CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

August 14, 2017

Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

000-26422

(Commission File Number)

94-3171943

(IRS Employer Identification Number)

2600 Kelly Road, Suite 100 Warrington, Pennsylvania 18976 (Address of principal executive offices)

(215) 488-9300

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

| Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions: |
|---|
| □ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) □ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) □ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) □ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) |
| Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934. |
| Emerging growth company \square |
| If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box |

Item 1.01 Entry into a Material Definitive Agreement.

Effective August 14, 2017 (the "Effective Date"), Windtree Therapeutics, Inc. (the "Company") entered into a Loan Agreement ("Loan Agreement") with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong ("Lee's"). Under the Loan Agreement, Lee's has agreed to lend the Company up to \$3.9 million (the "Loan"). The Loan, which will be funded at Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017, will be used to support the Company's AEROSURF® development activities and sustain its operations through October 31, 2017, while the parties negotiate a potential share purchase agreement ("Share Purchase") and related agreements. The Loan will accrue interest at a rate of 12% per annum. The Company received the initial installment of \$1.3 million from Lee's on August 15, 2017. Under the Share Purchase as currently contemplated, but subject to further negotiation, Lee's would invest \$10 million in the Company and acquire a controlling interest of a majority of the outstanding shares of the Company's common stock at a price per share based on the average 10-day volume-weighted average price per share (VWAP) up to and including the closing date, plus a premium up to, but not exceeding fifteen percent (15%), but in no event greater than \$0.25 per share. As partial consideration for the Share Purchase, the outstanding principal balance of the Loan would be applied in full satisfaction of a like amount of cash consideration payable by Lee's at the closing of such Share Purchase, and the Loan would be discharged in full. In connection with the Loan Agreement, affiliates of Deerfield Management Company, L.P. ("Deerfield"), which hold a security interest in substantially all of the Company's assets to secure a \$25 million loan under a February 2013 Facility Agreement, as amended in July 2015 (the "Deerfield Loan"), entered into a Subordination Agreement, dated as of August 14, 2017, with the Company and Lee's generally granting Lee's a first right through October 31, 2017, to any cash payments (other than regularly scheduled interest payments under the Deerfield Loan) and to the proceeds of sales of assets in a bankruptcy proceeding for up to \$3.9 principal amount plus related interest and expenses, subject to the exceptions set forth in the Subordination Agreement.

As partial consideration for the Loan, the Company and Lee's also agreed to amend the License, Development and Commercialization Agreement dated as of June 12, 2017 between the parties ("License Agreement") and have entered into Amendment No. 1 to the License Agreement (the "Amendment"). Under the terms of the Amendment, reductions have been made to certain of the milestone and royalty payments. As a result, the Company may receive up to \$35.8 million (previously, \$37.5 million) in potential clinical, regulatory and commercial milestone payments. The options to add Japan to the Licensed Territory (as defined in the License Agreement) and to manufacture the Company's aerosol delivery device in and for the Licensed Territory are made effective immediately. In addition, Zhaoke Pharmaceutical (Hefei) Co. Ltd. an affiliate of Lee's, has been made a party to the License Agreement. Except as set forth in the Amendment, all other terms and conditions of the License Agreement remain in full force and effect.

In addition, to facilitate the Share Purchase, the Company is negotiating with Deerfield to restructure the Deerfield Loan ("Loan Restructuring"), effective as of the closing of the Share Purchase. Under the Loan Restructuring as currently contemplated, but subject to further negotiation, the notes issued in connection with the Deerfield Loan would be retired in exchange for (i) \$2.5 million of cash, which would be paid out of the proceeds of the Share Purchase, and (ii) a number of newly-issued shares of the Company's common stock that equals two percent of the Company's outstanding common stock on a fully-diluted basis (to be defined)

as of the closing of the Share Purchase and Loan Restructuring. In addition, Deerfield would be entitled to receive future payments, based on the achievement of regulatory and commercial milestones related to the development and commercialization of AEROSURF potentially totaling \$15 million.

The Share Purchase and Loan Restructuring agreements are expected to include such customary representations, warranties, covenants, conditions and indemnities for certain losses and other terms as are acceptable to the parties. While the Company believes that it will be able to reach agreement with Lee's and Deerfield and close the Share Purchase and Loan Restructuring agreements in a timely manner, there can be no assurance that it will be successful. At this time, the Company does not have an alternative source of funding available, such that, if it is unable to complete these transactions for any reason on or before October 31, 2017, it may be forced to curtail some or all of its activities, including the AEROSURF development program and, ultimately, may be compelled to cease operations.

The foregoing descriptions of the Loan Agreement, the Subordination Agreement, and the Amendment do not purport to be complete and are qualified in their entirety by reference to the agreements themselves. The Company expects to file the License Agreement with the Securities and Exchange Commission ("SEC") as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, on August 21, 2017. A copy of the Loan Agreement is attached as Exhibit 10.1 to this Current Report on Form 8-K. The License Agreement and Loan Agreement are being filed to provide investors and the Company's stockholders with information regarding the terms thereof and in accordance with applicable rules and regulations of the SEC. Pursuant to the License Agreement and Loan Agreement, each of the parties thereto made customary representations, warranties and covenants and agreed to indemnify each other for certain losses arising out of breaches of such representations, warranties, covenants and other specified matters. The representations, warranties and covenants were made by the parties to and solely for the benefit of each other and any expressly intended third party beneficiaries in the context of all of the terms and conditions of the agreements and in the context of the specific relationship between the parties. Accordingly, investors and stockholders should not rely on the representations, warranties and covenants as characterizations of the actual state of facts or continuing intentions of the parties, since they were only made as of the date of the agreements. Information concerning the subject matter of such representations, warranties and covenants may change after the date of the agreements, which subsequent information may or may not be fully reflected in the Company's reports or other filings with the Commission.

Item 8.01. Other Events.

Reference is made to Item 1.01. On August 18, 2017, the Company issued a press release and announced the execution and delivery of the Loan Agreement and the Amendment as well as plans related to the potential Share Purchase and Loan Restructuring described above. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

As of June 30, 2017 the Company had cash and cash equivalents of \$2.5 million. As of August 15, 2017, after receipt of the initial advance under the Loan Agreement, the Company had cash and cash equivalents of approximately \$2.9 million and currently anticipates that, assuming receipt of the two additional installments under the Loan Agreement, and before any additional financings, it will have sufficient cash resources to fund its operations through November 2017.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits
- 10.1 Loan Agreement between the Company and Lee's Pharmaceutical (HK) Ltd.
- 99.1 Press release dated August 18, 2017

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Windtree Therapeutics, Inc.

By: /s/ Craig Fraser

Craig Fraser

President and Chief Executive Officer

Date: August 18, 2017

Loan Agreement

This Loan Agreement (this "Loan Agreement"), dated as of August 14, 2017, is entered into between Windtree Therapeutics, Inc., a Delaware corporation with its principal offices at 2600 Kelly Rd., Suite 100, Warrington, PA 18976 (the "Borrower"), and Lee's Pharmaceutical (HK) Ltd., a Hong Kong company organized and existing under the laws of Hong Kong with its principal offices at Unit 110-111, Bio-Informatics Centre, No. 2 Science Park West Avenue, Hong Kong Science Park, Shatin, Hong Kong (the "Lender").

RECITALS

WHEREAS, the Borrower and the Lender have previously entered into that certain License, Development and Commercialization Agreement (the "License Agreement") dated as of June 12, 2017, pursuant to which Borrower, as Licensor thereunder, has licensed to the Lender, as Licensee thereunder, certain rights with respect to Borrower's technology with the aim of advancing the Development, registration and Commercialization of the Surfaxin Product, Surfaxin LS[®], Aerosurf[®], and any other pharmaceutical composition containing synthetic KL4 Surfactant in the Licensed Territory (as such terms are defined in the License Agreement);

WHEREAS, Borrower is in immediate need of capital to support its continuing operations, maintenance of its technology and continued performance of its obligations under the License Agreement and Lender and Borrower have expressed an interest in exploring a potential strategic transaction to assure the continued performance of the License Agreement and potential expansion of the relationship between them; and

WHEREAS, to satisfy Borrower's immediate need for cash and to allow for time for the parties to negotiate and enter into a potential share purchase agreement (the "Share Purchase Agreement") pursuant to which Lender shall acquire a controlling interest in Borrower at a price per share not greater than \$0.25 (as described in Section 4.7), Lender has agreed to advance funds to Borrower on the terms provided in this Loan Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I

DEFINITIONS

"Loan" means the loan made by the Lender to the Borrower in the amount of Three Million Nine-Hundred Thousand Dollars (\$3,900,000), which amount is payable in three equal installment on August 15, 2017, September 10, 2017 and October 10, 2017.

"Encumbrance" has the meaning set forth in Section 2.5.

"Maturity Date" means the earlier of (i) the closing date (the "Closing Date") of the Share Purchase Agreement between the parties that would result in Lender obtaining a controlling interest in the Borrower on such terms and conditions as are described in Section 4.7 and set forth in such agreement, and (ii) October 31, 2017.

"Share Purchase Agreement" has the meaning set forth in Section 4.7.

ARTICLE II

TERM LOAN

- 2.1 <u>Agreement to Make Loan</u>. On the terms and subject to the conditions of this Loan Agreement, Lender agrees to fund the Loan to Borrower in three equal installments of One Million Three Hundred Thousand Dollars (\$1,300,000) on each of August 15, 2017, September 10, 2017 and October 10, 2017. The proceeds of the Loan shall be paid by wire transfer to an account designated in writing by the Borrower.
- 2.2 <u>Payment Terms</u>. The entire unpaid principal balance of the Loan, together with accrued interest thereon, shall be due and payable on the Maturity Date. The parties intend that, under the terms of the Share Purchase Agreement, in lieu of cash, the outstanding principal balance of the Loan shall be applied in full satisfaction of a like amount of cash consideration payable by Lender to Borrower at the closing of such Share Purchase Agreement, and the Loan shall thereby be discharged in full.
- 2.3 <u>Interest Rate</u>. The Loan shall bear interest on the outstanding principal amount of the Loan at a rate per annum equal to twelve percent (12%) ("the Contracted Interest Rate"). If Borrower fails to repay the principal amount of the Loan on the due date, Lender shall charge Borrower interest at a rate equal to the lower of 30% above the Contracted Interest Rate (referred to as the "Defaulted Interest Rate") or the maximum interest rate permitted by law on overdue sums from and including the due date to the actual payment date. If Borrower fails to repay the accrued interest and default interest on the due date, the Default Interest Rate shall be calculated monthly on the interest payment date.
- 2.4 <u>Prepayment</u>. The Borrower may, at its option, prepay the Loan, in whole or in part, prior to the Maturity Date. Each prepayment shall include interest on the amount prepaid to the date of prepayment.
- 2.5 <u>Negative Pledge. The Borrower shall not</u>, without the prior written consent of the Lender, which consent shall not be unreasonably withheld or delayed, create, suffer to exist, or permit to subsist, any mortgage, pledge, lien, charge, privilege, priority, encumbrance or other security interest of any kind or nature whatsoever and howsoever arising (referred to as the "Encumbrance") upon all or any part of its present or future undertakings, assets, or revenues, except for the following ("Permitted Encumbrances"):
- (a) any such Encumbrance created in the ordinary course of the Borrower's development activities and business transactions, including without limitation,
 - (i) with respect to accounts maintained in the ordinary course and held at financial institutions to secure standard fees for services charged by such institutions, including liens of a collection bank arising in the ordinary course;

- (ii) obligations in respect of purchase money financing, capital lease obligations and equipment financing facilities covering existing and newly- acquired equipment, including for the acquisition, installation, qualification and validation of such equipment;
- (iii) liens in favor of landlords under real property leases granted by Borrower, and letter of credit deposits related thereto;
- (iv) liens related to workers' compensation, unemployment insurance and other social security legislation;
- (v) liens arising under leases, licenses or subleases granted to others not interfering in any material respect with the business of Borrower; and
- (vi) and liens on advances in favor of a vendor providing goods or services;
- (b) any Encumbrance in favor of Lender;
- (c) statutory liens created by operation of law;
- (d) liens for taxes, assessments or governmental charges or levies; and
- (e) any Encumbrance in existence as of the date hereof and disclosed by the Borrower in writing prior to the date hereof, and any renewals or extensions thereof.
- 2.7 <u>Cancellation/Suspension</u>. Lender may cancel or suspend further drawing of any undrawn amounts under this Loan Agreement at its sole and absolute discretion; <u>provided</u>, that,
- (a) Lender shall deliver to Borrower and Borrower shall have received written notice of Lender's decision to cancel or suspend further drawing of any undrawn amounts under this Loan Agreement, and
- (b) if such notice is received by Borrower after the end of the previous calendar month and before a payment due date, Lender shall make a final payment to Borrower in the amount of two-hundred and fifty thousand dollars (\$250,000).

ARTICLE III

DEFAULTS AND REMEDIES

- 3.1 Events of Default. Any one or more of the following events shall constitute an event of default hereunder (an "Event of Default"):
- a) the Borrower fails to make any required payment required on the Loan within five (5) days after the Borrower's receipt of written notice of default from the Lender;
- b) if, pursuant to the United States Bankruptcy Code or any other federal or state law relating to insolvency or relief of debtors (a "Bankruptcy Law"), the Borrower shall (i) commence a voluntary case or proceeding; (ii) consent to the entry of an order for relief against it in an involuntary case; (iii) consent to the appointment of a trustee, receiver, assignee, liquidator or similar official; (iv) make an assignment for the benefit of its creditors; or (v) admit in writing its inability to pay its debts as they become due; or

- c) if a court enters an order or decree under any Bankruptcy Law that (i) is for relief against the Borrower in an involuntary case, (ii) appoints a trustee, receiver, assignee, liquidator or similar official for the Borrower or substantially all of Borrower's properties, or (iii) orders the liquidation of the Borrower.
 - 3.2 <u>Remedies</u>. Upon the occurrence of an Event of Default, the Lender, at its option, may take one or more of the following remedial steps:
- a) Upon notice to the Borrower, the entire principal amount of the Loan shall become immediately due and payable, without presentment, demand for payment, protest, notice of nonpayment or protest, notice of dishonor or any other notice or demand, all of which are hereby expressly waived; and
- b) Take any action at law or in equity to collect from the Borrower the payments then due and thereafter to become due under the Loan or to enforce performance and observance of any obligation or agreement of the Borrower under the Loan.
- 3.3 <u>No Remedy Exclusive</u>. No remedy of the Lender is intended to be exclusive of any other available remedy, but each such remedy shall be cumulative and shall be in addition to every other remedy given under this Loan Agreement or by applicable law. No delay or omission to exercise any right or power accruing upon any Event of Default shall impair any such right or power or shall be construed to be a waiver thereof.

ARTICLE IV

MISCELLANEOUS

- 4.1 <u>Notice</u>. Any notice to a party to this Agreement shall be in writing and sent to the respective addresses set forth in the introductory paragraph of this Agreement (or such other address as a party shall designate in writing) by certified mail, return receipt requested, or by nationally recognized overnight courier. All notices shall be effective upon the earlier of (a) three days after being sent or (b) receipt.
- 4.2 <u>Successors and Assigns</u>. This Loan Agreement contains the entire agreement of the parties with respect to its subject matter and may not be amended except by a written instrument signed by the party to be charged with such amendment. This Loan Agreement shall be binding on and inure to the benefit of the successors and assigns of the parties, except that the Borrower shall not have the right to assign its rights or obligations hereunder.
- 4.3 <u>Judicial Proceedings</u>. This Loan Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to conflict of laws principles. All claims or actions arising from this Loan Agreement shall be litigated in the federal courts for the Southern District of New York or the state courts located in the county of New York. The Borrower and the Lender hereby irrevocably submit to the jurisdiction of such courts and waive any claim that any action brought in such a court has been brought in an inconvenient forum

- 4.4 <u>Captions</u>. The section headings of this Loan Agreement are for reference purposes only and shall not affect the interpretation of this Agreement.
- 4.5 <u>Severability</u>. If any provision of this Loan Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision.

4.6 <u>Waiver of Jury Trial</u>. THE BORROWER AND THE LENDER HEREBY WAIVE ALL RIGHTS TO DEMAND A JURY TRIAL FOR ANY ACTIONS ARISING FROM THIS LOAN AGREEMENT.

4.7 <u>Share Purchase Agreement</u>. Upon funding of the initial Loan installment under this Agreement, the parties shall enter into negotiations to potentially enter into the Share Purchase Agreement no later than October 31, 2017, pursuant to which Lender shall purchase \$10 million common stock of Borrower, at a price based on the average of the daily per share volume-weighted average price as displayed under the heading "Bloomberg VWAP" on Bloomberg page "WINT <equity> AQR" over the 10-trading day period ending on and including the Closing Date, plus a premium not to exceed fifteen percent (15%), provided that such price shall not exceed \$0.25 per share. On the Closing Date, the outstanding principal balance of the Loan shall be applied in full satisfaction of a like amount of the purchase price for the shares and the Loan Agreement shall thereby be terminated and discharged in full.

In Witness Whereof, the parties hereto have caused this Loan Agreement to be executed by their duly authorized officers as of the date first written above.

WINDTREE THERAPEUTICS, INC.

LEE'S PHARMACEUTICAL (HK) LTD.

By: /s/ Craig Fraser
By: /s/ Benjamin Li, Ph.D.
Name: Craig Fraser
Name: Benjamin Li, Ph.D.

Citle: President and Chief Executive Officer Title: Chief Executive Officer



Windtree Announces Initiation of Financial Restructuring Program

- Enters into \$3.9 Million Loan Agreement with Lee's Pharmaceutical (HK) Limited
- Windtree and Lee's will negotiate \$10 million share purchase agreement for Lee's to acquire a controlling interest in Windtree
- Deerfield will then simultaneously agree to restructure and retire \$25 million long-term debt
- Transactions expected to strengthen Windtree's capital structure

WARRINGTON, PA – August 18, 2017 – Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today announced that it has initiated a financial restructuring program intended to result in an improved capital structure, which will better enable the Company to raise the necessary additional capital to fund its AEROSURF® respiratory distress syndrome (RDS) program and further develop its pipeline of surfactant products utilizing its proprietary KL4 and aerosol device technologies. As the initial step in this program, the Company has entered into a loan agreement with Lee's Pharmaceutical (HK) Limited ("Lee's"), pursuant to which Lee's has agreed to advance up to \$3.9 million that will be funded at Lee's discretion in three equal installments in August, September and October, 2017, to support AEROSURF® development activities and sustain the Windtree's operations through October 31, 2017, while the parties negotiate a share purchase agreement for Lee's to acquire a controlling interest in Windtree. The initial installment of the loan was received by the Company on August 15, 2017.

Under the share purchase agreement currently being negotiated, it is contemplated that Lee's would purchase from Windtree \$10 million of common stock and acquire a controlling interest of the outstanding shares of Windtree at a price per share based on the average 10-day volume-weighted average price per share (VWAP) through the closing date, plus a premium not to exceed fifteen percent (15%), but in no event greater than \$0.25 per share. As partial consideration for the share purchase, any principal amount outstanding under the \$3.9 million loan would be retired.

"After the release of AEROSURF phase 2b data in late June, we worked to secure the required funding to enable the continued advancement of the AEROSURF development program as we prepare for phase 3, and to bridge us to a potential strategic transaction. If successfully completed, an agreement with Lee's achieves these objectives in a manner that we believe supports a broader restructuring and materially strengthens the Company for long term financial sustainment and a better ability to realize the full potential of AEROSURF and our KL4 surfactant and aerosol delivery platforms," commented Craig Fraser, President and Chief Executive Officer. "We look forward to sharing our vision and plans for Windtree upon completion of these potential transactions."

In partial consideration for the loan, Lee's and Windtree also have entered into an amendment to the previously announced exclusive license and collaboration agreement for the development and commercialization of KL4 surfactant products in select Asian markets to reduce certain milestone and royalty payments and, in lieu of a future option, added Japan to the licensed territory.

In connection with the loan agreement, affiliates of Deerfield Management Company, L.P. ("Deerfield"), which hold a security interest in substantially all of the Company's assets to secure a \$25 million loan, entered into a subordination agreement with Lee's and the Company generally granting Lee's a first payment priority through October 31, 2017, other than with respect to regularly scheduled interest payments under the Deerfield loan, for up to \$3.9 million principal amount plus related interest and expenses. In addition, to facilitate the share purchase, Deerfield has agreed to negotiate to restructure its loan, effective as of the closing of the share purchase. Under the loan restructuring as currently contemplated, in exchange for return and retirement of the Deerfield notes, Windtree will (i) pay to Deerfield \$2.5 million in cash, and (ii) issue to Deerfield a number of dhares of common stock equal to two percent of Windtree's common stock post-closing on a fully-diluted basis (to be defined in the loan restructuring agreement). In addition, Deerfield will be eligible to receive up to \$15 million in future AEROSURF regulatory and commercial milestones beginning with the filing for marketing approval in the United States.

"While there is much work to do to finalize the share purchase by Lee's and resulting retirement of the Deerfield debt, we are excited about the prospect of improving our capital structure and eliminating the financial overhang of long-term debt. We believe this will better position us to raise the additional capital necessary to fund continued development of AEROSURF and our future growth," commented John Tattory, Senior Vice President and Chief Financial Officer.

Disclosure Notice

The Share Purchase and Loan Restructuring agreements are expected to include such customary representations, warranties, covenants and indemnities for certain losses and other terms as are acceptable to the parties. While the Company believes that it will be able to reach agreement with Lee's and Deerfield and close the Share Purchase and Loan Restructuring agreements in a timely manner, there can be no assurance that it will be successful.

Readers are referred to, and encouraged to read in its entirety, the Company's Current Report on Form 8-K to be filed with the SEC today which includes a detailed discussion regarding the transactions summarized above.

About Windtree Therapeutics

Windtree Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel surfactant therapies for respiratory diseases and other potential applications. Windtree's proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant and novel drug-delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. Windtree is focused initially on improving the management of respiratory distress syndrome (RDS) in premature infants and believes that its proprietary technology may make it possible, over time, to develop a pipeline of KL4 surfactant product candidates to address a variety of respiratory diseases for which there are few or no approved therapies.

For more information, please visit the Company's website at www.windtreetx.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties include: the risk that, as a development company, with limited resources and no operating revenues, the Company's ability to continue as a going concern in the near term is highly dependent upon the success of AEROSURF clinical trials and whether they are sufficient to support a strategic or financing transaction and enable initiation of phase 3 development; risks that Windtree will be unable to secure significant additional capital as and when needed, if at all, whether through debt or equity financings or other strategic transaction; risks related to having the Company's common stock trade on the OTCQB® market; risks related to Windtree's AEROSURF development program and other aerosolized KL4 surfactant development programs in the future, which may involve time-consuming and expensive preclinical and clinical trials and which may be subject to potentially significant delays or regulatory holds, or fail; risks related to the development of aerosol delivery systems (ADS) and related components; risks related to technology transfers to contract manufacturers and problems or delays encountered by Windtree, contract manufacturers or suppliers in manufacturing drug products, drug substances, ADS on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including those of (i) the FDA or other regulatory authorities that may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of Windtree's products and (ii) changes in the national or international political and regulatory environment, which may make it more difficult to gain regulatory approvals; and other risks and uncertainties described in Windtree's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:

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