

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

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**FORM 8-K**

**CURRENT REPORT**

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

**July 18, 2018**

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

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.

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**Item 5.02 (e). Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On July 18, 2018, each of the Named Executive Officers of Windtree Therapeutics, Inc. (the “Company”), Craig Fraser, President and Chief Executive Officer, John Tattory, Senior Vice President and Chief Financial Officer and Steven G. Simonson, M.D., Senior Vice President and Chief Medical Officer, entered into an amendment (the “Amendment”) to his Restricted Stock Unit Award Agreement dated as of November 1, 2017 (“RSU Awards”). The RSU Awards were issued to each executive in lieu of the 2017 and 2018 Annual Bonuses (as defined in such executive’s employment agreement) for shares having a value equal to the combined total value of each such executive’s 2017 and 2018 target Annual Bonus and awarded in connection with the closing of a Securities Purchase Agreement between the Company and LPH Investments Limited (“LPH”), a wholly-owned subsidiary of Lee’s Pharmaceutical Holdings Limited (“Lee’s”). As issued, each award vested in two equal installments on March 15, 2018 and March 15, 2019. An earlier amendment deferred the vesting of the initial installment to August 1, 2018.

The Amendments change the vesting date of the initial installment of each such equity awards from August 1, 2018 to October 1, 2018.

The Amendments for each of Mr. Fraser, Mr. Tattory and Dr. Simonson are attached to this Current Report on Form 8-K as Exhibits 10.1, 10.2, and 10.3, respectively, and incorporated herein by reference.

**Item 8.01. Other Events.**

As previously announced in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”) on July 6, 2018 (“July 6, 2018 Form 8-K”), pursuant to the terms of a Secured Convertible Promissory Note (“Note”), Panacea Venture Management Company Ltd. (“Panacea”) agreed to lend the Company up to \$1.5 million in two tranches. The initial payment of \$1,000,000, was received on July 2, 2018.

On July 23, 2018, the Company received the second payment in the amount of \$500,000. The proceeds are being used to support the Company’s AEROSURF® development activities and sustain its operations.

Also on July 23, 2018, the Company issued a press release announcing that it has successfully completed design verification of its new proprietary aerosol delivery system (ADS) for AEROSURF. The new ADS has been developed under a 2014 collaboration agreement with Battelle Memorial Institute. The Company expects to utilize the new ADS in its planned AEROSURF bridge clinical study, phase 3 clinical program and, if approved, early commercial activities. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The foregoing descriptions of the RSU Awards and the Panacea Note do not purport to be complete and are qualified in their entirety by reference to those agreements. The form of the RSU Awards was filed as Exhibit 10.14 to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the Note was filed as Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on July 6, 2018. The agreements were 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. In connection with these agreements, each of the parties thereto may have made customary representations, warranties and covenants, which 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 such representations, warranties and covenants. Furthermore, 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 thereof. Information concerning the subject matter of such representations, warranties and covenants may change, which subsequent information may or may not be fully reflected in the Company’s reports or other filings with the SEC.

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**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits:

- 10.1 Amendment No. 2 to Restricted Stock Unit Award Agreement of Craig Fraser dated as of July 18, 2018.
- 10.2 Amendment No. 2 to Restricted Stock Unit Award Agreement of John Tattory dated as of July 18, 2018.
- 10.3 Amendment No. 2 to Restricted Stock Unit Award Agreement of Steven G. Simonson, M.D. dated as of July 18, 2018.
- 99.1 Press Release dated July 23, 2018.

**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  
Name: Craig Fraser  
Title: President and Chief Executive Officer

Date: July 24, 2018

AMENDMENT NO. 2 TO  
RESTRICTED STOCK UNIT AWARD AGREEMENT

Effective as of July 18, 2018, Craig Fraser (“Participant”) and Windtree Therapeutics, Inc. (the “Company”) hereby agree to amend the Restricted Stock Unit (“RSU”) Award Agreement between them dated as of November 1, 2017 and the related notice of award (as it may have been previously amended, the “RSU Agreement”) to reflect the revisions set forth herein (“Amendment No. 2”). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the RSU Agreement.

Notwithstanding anything to the contrary set forth in the RSU Agreement, or in Participant’s Employment Agreement, as amended, the vesting date for the RSU awarded to Participant effective November 1, 2017 is hereby changed from August 1, 2018 to October 1, 2018. The second vesting date for the balance of the RSU award shall remain unchanged.

Except as amended herein, the remaining terms and conditions of the RSU Agreement shall remain in full force and effect. This Amendment No. 2 confirms an agreement between Participant and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the RSU Agreement and mutual promises made in connection therewith. The parties have executed this Amendment No. 2 as of the day and date first set forth above.

Windtree Therapeutics, Inc.

By: /s/ Kathy Cole  
Name: Kathy Cole  
Title: SVP, Human Resources

/s/ Craig Fraser  
Name: Craig Fraser

AMENDMENT NO. 2 TO  
RESTRICTED STOCK UNIT AWARD AGREEMENT

Effective as of July 18, 2018, John Tattory (“Participant”) and Windtree Therapeutics, Inc. (the “Company”) hereby agree to amend the Restricted Stock Unit (“RSU”) Award Agreement between them dated as of November 1, 2017 and the related notice of award (as it may have been previously amended, the “RSU Agreement”) to reflect the revisions set forth herein (“Amendment No. 2”). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the RSU Agreement.

Notwithstanding anything to the contrary set forth in the RSU Agreement, or in Participant’s Employment Agreement, as amended, the vesting date for the RSU awarded to Participant effective November 1, 2017 is hereby changed from August 1, 2018 to October 1, 2018. The second vesting date for the balance of the RSU award shall remain unchanged.

Except as amended herein, the remaining terms and conditions of the RSU Agreement shall remain in full force and effect. This Amendment No. 2 confirms an agreement between Participant and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the RSU Agreement and mutual promises made in connection therewith. The parties have executed this Amendment No. 2 as of the day and date first set forth above.

Windtree Therapeutics, Inc.

By: /s/ Kathy Cole  
Name: Kathy Cole  
Title: SVP, Human Resources

/s/ John Tattory  
Name: John Tattory

AMENDMENT NO. 2 TO  
RESTRICTED STOCK UNIT AWARD AGREEMENT

Effective as of July 18, 2018, Steven G. Simonson, M.D. (“Participant”) and Windtree Therapeutics, Inc. (the “Company”) hereby agree to amend the Restricted Stock Unit (“RSU”) Award Agreement between them dated as of November 1, 2017 and the related notice of award (as it may have been previously amended, the “RSU Agreement”) to reflect the revisions set forth herein (“Amendment No. 2”). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the RSU Agreement.

Notwithstanding anything to the contrary set forth in the RSU Agreement, or in Participant’s Employment Agreement, as amended, the vesting date for the RSU awarded to Participant effective November 1, 2017 is hereby changed from August 1, 2018 to October 1, 2018. The second vesting date for the balance of the RSU award shall remain unchanged.

Except as amended herein, the remaining terms and conditions of the RSU Agreement shall remain in full force and effect. This Amendment No. 2 confirms an agreement between Participant and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the RSU Agreement and mutual promises made in connection therewith. The parties have executed this Amendment No. 2 as of the day and date first set forth above.

Windtree Therapeutics, Inc.

By: /s/ Kathy Cole  
Name: Kathy Cole  
Title: SVP, Human Resources

/s/ Steven G. Simonson, M.D.  
Name: Steven G. Simonson, M.D.



### Windtree Announces Completion of New Design Development for its Aerosol Delivery System (ADS) including Successful Performance Testing

*New ADS meets phase 3 and commercial design needs for performance and reliability*

*Company expects to initiate the AEROSURF® bridge study with the ADS in Q4 of 2018.*

**Warrington, PA – July 23, 2018** - Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today announced that it has successfully completed design verification of its new proprietary aerosol delivery system (ADS) for AEROSURF®. This important milestone indicates that the ADS has met rigorous performance and reliability testing criteria and may be used in future clinical trials and, if approved, commercially. The ADS enables noninvasive delivery of aerosolized KL4 surfactant to premature infants with respiratory distress syndrome (RDS). AEROSURF is a drug-device combination product in late stage development that utilizes Windtree's proprietary ADS technology and a lyophilized dosage form of the Company's KL4 surfactant that was previously approved by the FDA in a different dosage form for use in RDS. In previously completed phase 2 clinical trials using a prototype ADS, AEROSURF demonstrated the potential to decrease the need for invasive intubation and mechanical ventilation in premature infants and possibly impact longer term sequelae of RDS such as bronchopulmonary dysplasia (BPD).

"Completing design verification of the ADS represents a significant milestone for Windtree and the AEROSURF program. We have an extensive history evaluating our KL4 surfactant in RDS and multiple phase 2 clinical trials suggest that AEROSURF, when dosed as intended, produces a level of efficacy and safety that gives us confidence in the drug component of AEROSURF. Now, with our move from our prototype device to the new improved ADS, which has passed comprehensive performance and reliability testing, we believe that we have significantly advanced this aspect of our program. We are excited to utilize this new device in late-stage AEROSURF clinical development" commented Craig Fraser, President and Chief Executive Officer. "As we noted in announcing a recent research collaboration, we also look forward to potentially leveraging our innovative drug and device technology beyond RDS."

In advancing the ADS from the phase 2 prototype to the phase 3 design, Windtree incorporated several important advancements in ease of use, set-up, and reliability, and multiple design enhancements intended to mitigate filter clogging that occurred in the phase 2 prototype. These improvements were made while maintaining the same aerosol delivery characteristics. The results obtained demonstrate that the new phase 3 ADS provides both significant improvement in reliability and in performance compared to the phase 2 prototype.

#### Phase 2 Prototype ADS



#### Phase 3 / Commercial Design ADS



- Same aerosol drug delivery technology and drug characteristics as the phase 2 prototype device for bridging of device and data
- Redesigned drug path, filters, and specifications
- Enhanced ergonomics and user interface
- Simplified, faster set up
- Enhanced controls and dose monitoring
- Modular design

The Company has initiated a transfer of medical device design and manufacturing to Mack Medical, the medical product arm of FDA-registered Mack Molding Co. As a contract manufacturer of class 2 and 3 medical devices, Mack boasts an outstanding reputation built on a nearly 100-year track record of exceptional service, quality and compliance. “We believe that Mack will help us realize our vision to have robust, high quality manufacturing capabilities for our new medical device platform. We look forward to shifting focus to manufacturing readiness and preparation for our next AEROSURF clinical study,” commented Larry Weinstein, Vice President, Medical Device Development.

“Following ADS demonstrations with several of our clinician partners, we share their enthusiasm to be taking this ADS into the Neonatal Intensive Care Unit (NICU). This ADS was designed to be easier for NICU staff to use and potentially may allow for more rapid initiation of treatments, which could potentially have therapeutic benefit,” said Steve Simonson, MD, Senior Vice President and Chief Medical Officer. “We are looking forward to initiating our next clinical trial, which will be focused on gaining clinical experience with the new ADS, studying more intensive dosing and potentially confirming and extending the clinical effect seen when AEROSURF was delivered as intended in our phase 2b trial last year as a transition to planned phase 3 clinical development.”

#### **About AEROSURF®**

Windtree’s lead product candidate is AEROSURF (lucinactant for inhalation), a novel, investigational combination drug/device product that combines the Company’s proprietary KL4 surfactant and aerosolization technologies. AEROSURF is being developed to potentially reduce or eliminate the need for endotracheal intubation and mechanical ventilation in the treatment of premature infants with respiratory distress syndrome (RDS).

#### **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](http://www.windtreetx.com).

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**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 those risks related to Windtree's aerosolized KL4 surfactant development programs, including for AEROSURF, which may involve time-consuming and expensive clinical trials that 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 the manufacture by contract manufacturers or suppliers of drug products, drug substances, ADS and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including those of the U.S. Food and Drug Administration 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 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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