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

FORM 8-K

CURRENT REPORT

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

June 1, 2017
Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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))

Item 8.01. Other Events.

On June 1, 2017, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing the completion of enrollment in the Company's AEROSURF® phase 2b clinical trial evaluating aerosolized KL4 surfactant for the treatment of respiratory distress syndrome (RDS) in premature infants, 28 to 32 week gestational age, receiving nasal continuous positive airway pressure (nCPAP) for RDS, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K. In addition, the Company reaffirms its plan to announce top-line results for the trial in July 2017.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated June 1, 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, cash flows, future revenues, the timing of planned clinical trials 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. Any forward-looking statement made by the Company in this Current Report on Form 8-K is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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.

By /s/ John Tattory
Name: John Tattory
Title: Senior Vice President and
Chief Financial Officer

Date: June 2, 2017

Windtree Announces Successful Completion of Enrollment in AEROSURF® Phase 2b Clinical Trial for the Treatment of Respiratory Distress Syndrome (RDS) in Premature Infants

-Release of Top-line AEROSURF Phase 2b Data Remains On Track for July 2017-

WARRINGTON, PA – June 1, 2017 – Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today announced completion of enrollment in its AEROSURF® phase 2b clinical trial evaluating aerosolized KL4 surfactant for the treatment of respiratory distress syndrome (RDS) in premature infants, 28 to 32-week gestational age, receiving nasal continuous positive airway pressure (nCPAP) for RDS. A total of 221 patients have been enrolled at 52 sites in North America, Europe and Latin America and the Company reaffirms its plan to announce top-line results for the trial in July 2017.

“Completing enrollment in this phase 2b trial represents a significant milestone in our AEROSURF clinical development program and brings us another step closer to potentially realizing our goal of transforming the management of RDS in premature infants,” commented Steve Simonson, M.D., Senior Vice President and Chief Medical Officer. “We would like to especially thank the families of premature infants who participated in the trial. We are grateful for the broad-based support of the neonatology community and, in particular, thank the clinicians and their caregiver teams that are participating in this important endeavor. We look forward to data analysis and sharing top-line results in July.”

AEROSURF is a novel, investigational drug/device combination product that combines the Company's proprietary KL4 surfactant and aerosolization technologies. AEROSURF is being developed to potentially reduce the need for invasive endotracheal intubation and mechanical ventilation in the treatment of premature infants with respiratory distress syndrome (RDS). In September 2016, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for AEROSURF for the treatment of premature infants with RDS.

AEROSURF Phase 2b Trial Design
The AEROSURF phase 2b clinical trial is a multicenter, randomized, controlled study with masked treatment assignment in up to 240 premature infants receiving nCPAP for RDS, and is designed to evaluate aerosolized KL4 surfactant administered to premature infants 28 to 32 week gestational age in two dose groups (25 and 50 minutes), with up to two potential repeat doses, compared to infants receiving nCPAP alone. The key objectives of this trial are to:

- evaluate efficacy by assessing: (i) incidence of nCPAP failure (defined as the need for intubation and delayed surfactant therapy), (ii) time to nCPAP failure, and (iii) physiological parameters indicating the effectiveness of lung function;
- define the dose regimen(s) for the planned phase 3 clinical program;
- provide an estimation of the expected efficacy margin of AEROSURF treatment; and
- further characterize the AEROSURF safety profile

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 the AEROSURF phase 2b clinical trial and whether the results are sufficient to support a strategic or financing transaction; risks that Windtree will be unable to secure significant additional capital as and when needed, or to access debt or equity financings when needed, if at all; risks related to the transfer of the Company’s common stock to 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:
John Tattory
Senior Vice President and Chief Financial Officer
215.488.9418 or jtattory@windtreetx.com