UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): September 29, 2020

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
2600 Kelly Road, Suite 100, Warrington, Pennsylvania		**18976**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (215) 488-9300

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	WINT	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events.

On September 29, 2020, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing that the United States Food and Drug Administration has accepted the Company's Investigational New Drug application for a Phase 2 clinical trial studying lyo lucinactant, its KL4 surfactant drug, in COVID-19 associated lung injury and acute respiratory distress syndrome patients. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Press Release of Windtree Therapeutics, Inc., dated September 29, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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 E. Fraser
Name: Craig E. Fraser
Title: President and Chief Executive Officer

Date: September 29, 2020

Exhibit 99.1

Windtree Announces FDA Acceptance of IND Application for a Phase 2 Clinical Trial Studying KL4 Surfactant in Acute Lung Injury in Adults with COVID-19

Company Provides Update on COVID-19 Program

WARRINGTON, PA – September 29, 2020 – Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced that United States Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for a Phase 2 clinical trial studying lyo lucinactant, its KL4 surfactant drug, in COVID-19 associated lung injury and acute respiratory distress syndrome (ARDS) patients. Lucinactant is also used in the Company's drug and device combination development program called AEROSURF®, being developed for treating preterm infants with Respiratory Distressed Syndromes.

The SARS-CoV-2 virus causing COVID-19 uses the angiosten-converting enzyme 2 (ACE2) receptor for entry into host cells. ACE2 is a surface molecule on alveolar Type 2 cells in the lungs. The Type 2 cells are the source of surfactant production in the lung. Damage or loss of Type 2 cells and the viral pneumonia often associated with COVID-19 may result in impaired surfactant production leading to a loss of lung compliance and impaired gas exchange. This increases the likelihood of ARDS that may manifest by respiratory failure and the need for mechanical ventilation. There are no approved drug therapies for ARDS, yet surfactant abnormalities are a known characteristic of the condition. The Company believes its synthetic KL4 surfactant may have the potential to mitigate surfactant deficiency and resist the widespread surfactant destruction that can occur as a result of COVID-19 associated lung injury.

"KL4 surfactant has been studied in several preclinical models of acute lung injury, including in highly pathogenic H5N1 viral pneumonia, and has demonstrated structural and functional beneficial effects. Additionally, previous clinical experience in ARDS patients provides a foundation upon which we can evaluate KL4 surfactant in acute lung injury that can occur in COVID-19. KL4 surfactant has been safely administered to neonates and adults with various surfactant deficient conditions, " said Steve Simonson, M.D., chief medical officer at Windtree Therapeutics. "We look forward to studying KL4 surfactant in COVID-19 patients with acute lung injury with the objective of improving lung function to facilitate recovery and decrease the need for mechanical ventilation."

Initial COVID-19 Phase 2 Study:

The initial study will evaluate changes in physiological parameters in COVID-19 patients who are intubated and mechanically ventilated for associated lung injury and ARDS. The study will establish the dosing regimen, tolerability, and functional changes in gas exchange and lung compliance after KL4 surfactant administration. The study is being guided by co-principle investigators from the Brigham and Womens Hospital in Boston and Duke University Medical Center in North Carolina.

- Up to 20 patients with COVID-19 and ARDS and on mechanical ventilation from 4-5 U.S. sites
- Dosing through the endotracheal tube, repeat dosing based on changes in oxygenation
- Planned outcome measures:
    - Physiologic response - oxygenation Index (OI)
    - Lung compliance on the ventilator
    - Clinical parameters including time on mechanical ventilator, days in intensive care unit and mortality (although this first study will not be powered for these measures)
- The Company plans to start the study within the next several weeks and expects recruitment to take 3-6 months (depending on COVID-19 rates at study sites)

Potential Expanded COVID-19 Program as the Next Step:

If the initial Phase 2 study results demonstrate adequate safety/tolerability and efficacy on physiological variables, Windtree would plan to initiate two additional clinical trials. One study would more fully assess the impact of KL4 surfactant on clinical endpoints such as time on mechanical ventilation, time in the ICU, mortality. The second study would be to utilize the Company's novel and proprietary Aerosolized Delivery System (ADS) to aerosolize and deliver the KL4 surfactant noninvasively in COVID-19 patients that are at high risk of respiratory failure with an intent to avoid mechanical ventilation, similar to the Company's respiratory distress syndrome studies in preterm infants. Further details will be available at a future date.

"Given the pronounced impact of respiratory failure in COVID-19 infected patients, the scientific understanding of the role of surfactant in these patients and Windtree's history of several preclinical and clinical studies across acute lung conditions, we had a call to action that we wanted to address with a program designed and executed in collaboration with top institutions and experts," said Craig Fraser, CEO and president of Windtree Therapeutics. "Additionally, we have engaged with the U.S. Biomedical Advanced Research and Development Authority (BARDA) and plan to continue those discussions as the program transitions to clinical execution of this study and in planning for follow-on work."

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to treat patients in moments of crisis. Using new clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate istaroxime being developed as a first-in-class treatment for acute heart failure and early cardiogenic shock in heart failure. Windtree is also developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, as well as evaluating other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions including lung injury due to viral, chemical and radiation induced insults. Also in its portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

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

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are based on information available to the Company as of the date of this press release and are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. Examples of such risks and uncertainties include: risks and uncertainties associated with the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the Company's clinical trials or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime, AEROSURF®, KL4 surfactant and the Company's other product candidates; the Company's ability to secure significant additional capital as and when needed; the Company's ability to access the debt or equity markets; the Company's ability to manage costs and execute on its operational and budget plans; the results, cost and timing of the Company's clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; risks related to technology transfers to contract manufacturers and manufacturing development activities; delays encountered by the Company, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol delivery systems (ADS) and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with the Company on matters raised during regulatory reviews, 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 the Company's product candidates, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals and risks related to the Company's efforts to maintain and protect the patents and licenses related to its product candidates; risks related to the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; and the rate and degree of market acceptance of the Company's product candidates, if approved. These and other risks are described in the Company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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