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): **August 17, 2022**

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 1.01 Entry Into a Material Definitive Agreement.

On August 17, 2022, Windtree Therapeutics, Inc. (the "Company") entered into an Amended and Restated License, Development and Commercialization Agreement (the "A&R License Agreement") with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong ("Lee's"), and Zhaoke Pharmaceutical (Hefei) Co. Ltd., a company organized under the laws of the People's Republic of China ("Zhaoke," and together with Lee's, "Licensee"), effective as of August 9, 2022. The A&R License Agreement amends, restates and supersedes that certain License, Development and Commercialization Agreement, dated as of June 12, 2017, and amended as of August 14, 2017 (the "Original Agreement").

The Original Agreement previously granted Licensee an exclusive license to develop, market and sell non-aerosolized KL4 surfactant for the treatment of human diseases and aerosolized KL4 surfactant (including AEROSURF®, the Company's investigative combination drug/device product) for the treatment of human respiratory diseases, in each case in Greater China, Japan, South Korea and certain other Southeast Asia countries. Under the A&R License Agreement, the Company granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute and otherwise commercialize the Company's KL4 surfactant products, including SURFAXIN®, which was approved by the U.S. Food and Drug Administration ("FDA") in 2012 for the prevention of respiratory distress syndrome in premature infants, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation and/or treatment of any respiratory disease, disorder or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal and Spain (the "Licensed Territory"), which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A. ("Esteve") under the Amended and Restated Sublicense and Collaboration Agreement dated December 3, 2004. If and when the exclusive license granted to Esteve terminates as to any country, such country automatically becomes part of the Licensed Territory of Licensee.

Under the Original Agreement, Licensee previously made an upfront payment to the Company of $1 million. The Company also may receive up to $78.9 million in potential clinical, regulatory and commercial milestone payments. The Company is also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income.

The Company is also eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the A&R License Agreement) that ranges from low single digit to low teen percentages, depending on the product. Royalties are payable on a product-by-product and country-by-country basis until the latest of (A) the expiration of the last valid patent claim covering the product in the country of sale, (B) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (C) ten (10) years after the first commercial sale of the product in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each product but at substantially reduced rates. In addition, the royalty rates are subject to reduction by as much as 50% in a given country based on generic competition in such country.

Under the A&R License Agreement, Licensee will be solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of licensed products in the Licensed Territory including all royalties payable in respect of third-party intellectual property rights sublicensed by the Company to Licensee and all intellectual property prosecution, maintenance and defense activities and costs. Licensee may sublicense certain activities under the A&R License Agreement to an affiliate of Licensee but may not grant sublicenses to unaffiliated third parties without the prior consent of the Company. A sublicensee and a subcontractor may not be a competitor identified by the Company. Sublicenses under the A&R License Agreement do not include the right to further sublicense.

The term of the A&R License Agreement will continue on a country-by-country basis for the commercial life of the products. Either party may terminate the A&R License Agreement in the event of bankruptcy or a material breach of the A&R License Agreement by the other party that remains uncured for a period of sixty (60) days (or within 30 days after delivery of a Default Notice (as defined in the A&R License Agreement) if such material breach is solely based on the breaching party's failure to pay amount due under the A&R License Agreement). At any time after the second anniversary of the A&R License Agreement, Licensee may terminate the A&R License Agreement in its entirety or on a product-by-product basis. In addition, either party may terminate the A&R License Agreement with respect to any individual product in a country if a regulatory authority in such country terminates, suspends or discontinues development of such product and such termination, suspension or discontinuance persists for a period in excess of eighteen (18) months. Upon termination of the A&R License Agreement in its entirety or with respect to a particular product or country, generally all related rights and licenses granted to Licensee will terminate, all rights under the Company's technology will revert to the Company, and Licensee will cease all use of the Company's technology, in each case in relation to the terminated product(s) and country(ies), as applicable.

The foregoing description of the A&R License Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of the A&R License Agreement, which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022.

Item 8.01 Other Events

On August 23, 2022, the Company issued a press release announcing its entrance into the A&R License Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

The following exhibit is being filed herewith:

(d) Exhibits

Exhibit No.	**Document**
99.1	Press Release, dated August 23, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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, thereunto duly authorized.

Date: August 23, 2022

Windtree Therapeutics, Inc.

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

Exhibit 99.1

Windtree Therapeutics Announces
KL4 Surfactant and AEROSURF® Global License Agreement

Windtree may receive up to $78.9 million in development, regulatory and commercial milestones
plus low double digit royalties
Development and all other costs to be assumed by Lee's Pharmaceutical and Zhaoke Pharmaceutical

WARRINGTON, PA – August 23, 2022 – Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular disorders, today announced it has entered into a global licensing agreement with Lee's Pharmaceutical (HK) Limited, (Lee's) and its affiliate Zhaoke Pharmaceutical (Hefei) Co. Ltd., (Zhaoke) for the development and commercialization of Windtree's acute pulmonary pipeline treatments KL4 surfactant and drug/device combination, AEROSURF®, for the treatment of preterm infants with respiratory distress syndrome (RDS) and other potential applications. RDS often occurs in preterm infants when the lung is not fully developed with natural lung surfactant and may require surfactant therapy to sustain life.

"We are excited to announce this global licensing transaction for our KL4 surfactant platform given the value it can provide to the Company, its shareholders and critically ill patients," said Craig Fraser, President and Chief Executive Officer of Windtree. "The out-licensing of the KL4 platform supports our portfolio prioritization and increases non-dilutive resources to progressing istaroxime on the significant opportunity in the major markets of cardiogenic shock and heart failure where recent positive data has created what we believe could be a relatively fast and less expensive developmental pathway in cardiogenic shock. Given the clinical potential of KL4 surfactant and AEROSURF to help preterm infants with RDS, we desired a partner who was capable of fully assuming execution of the platform and could build value. Over the past few years, we have worked with the Lee's and Zhaoke's teams as they invested significantly in building manufacturing, analytical and clinical capabilities to move the KL4 platform into late-stage development. This transaction strengthens Windtree's resources for its core programs and delivers significant potential value to its shareholders on assets we were no longer progressing ourselves."

Under terms of the global license agreement, Lee's and Zhaoke will receive a global license to develop and commercialize Surfaxin®, lyophilized lucinactant and AEROSURF for any potential indications and applications. Lee's and Zhaoke will be responsible for funding all development, intellectual property, manufacturing, and commercialization activities and provide developmental, regulatory and eventual commercial sales milestones for Windtree of up to $78.9 million plus potential double-digit royalties. Windtree had previously granted a regional license to Lee's and Zhaoke for KL4 and AEROSURF for the territory of Greater China for which Windtree received an upfront payment, and this new agreement expands that territory globally. With the execution of this agreement, Windtree will no longer have ongoing maintenance and operating costs for the KL4 platform.

About Lyophilized Lucinactant and AEROSURF®
Lyophilized lucinactant is an investigational synthetic peptide (KL4 surfactant) containing drug product that is being developed to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. AEROSURF® (lucinactant for inhalation) is a drug/device combination designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary ADS technology and potentially may meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, may meaningfully reduce the number of premature infants who are subjected to invasive surfactant administration, and potentially provide transformative clinical and pharmacoeconomic benefits. The FDA has granted Fast Track designation for AEROSURF to treat RDS and the program has Orphan Drug designation.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular disorders to treat patients in moments of crisis. Using new scientific and 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 for early cardiogenic shock. Windtree's heart failure platform includes follow-on oral pre-clinical SERCA2a activator assets as well. Included in Windtree's portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

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, clinical trial timelines or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime and the Company's other product candidates; the impacts of political unrest, including as a result geopolitical tension, including escalation in the conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan), and any additional resulting sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries which could have an adverse impact on the Company's operations, including through disruption in supply chain or access to potential international clinical trial sites, and through disruption, instability and volatility in the global markets, which could have an adverse impact on the Company's ability to access the capital markets; 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, 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 that the Company may never realize the value of its intangible assets and have to incur future impairment charges; 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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