

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 12, 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))

**Item 1.01** **Entry into a Material Definitive Agreement.**

Effective June 12, 2017 (the “**Effective Date**”), Windtree Therapeutics, Inc. (the “**Company**”) entered into a License, Development and Commercialization Agreement (“**License Agreement**”) with Lee’s Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong (“**Lee’s**”). Under the License Agreement, the Company has granted to Lee’s an exclusive license with a right to sublicense, (i) to develop and 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 (“**RDS**”) in premature infants, SURFAXIN LS™, the lyophilized dosage form of SURFAXIN; and AEROSURF®, the Company’s investigative combination drug/device product that is designed to deliver aerosolized KL4 surfactant noninvasively, and (ii) to register and manufacture SURFAXIN and SURFAXIN LS for use in the Licensed Territory, which includes the People’s Republic of China (“**PRC**”), Hong Kong, Thailand, Taiwan and 12 other countries (the “**Licensed Territory**”). In addition, the Company has granted Lee’s options to potentially add Japan to the Licensed Territory and to manufacture the Company’s aerosol delivery device in the Licensed Territory, in each case subject to conditions set forth in the License Agreement.

Under the License Agreement, Lee’s will make an upfront payment to the Company of \$1 million on or before July 5, 2017. (Lee’s also invested \$2 million in the Company’s recent private placement of Convertible Preferred Stock units that was effective February 13, 2017.) The Company also may receive up to \$37.5 million in potential clinical, regulatory and commercial milestone payments. The Company also will share in any sublicense income Lee’s may receive at a rate equal to low double digits. In addition, Lee’s will be responsible for all costs and expenses in and for the Licensed Territory related to development activities, including a planned AEROSURF phase 3 clinical trial, regulatory activities, and commercialization activities.

The Company also will be eligible to receive tiered royalties based on a percent of Net Sales, depending on the product, in the range of high single to low-to-mid double digit percentages. Royalties are payable on a 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 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 and, for the initial three years, shall be in the range of low-to-mid single digits. In addition, in the event that one or more generic products are introduced, the royalty rates will be reduced, subject to certain minimums if the Company has continuing obligations at the time to pay royalties under its in-license agreements.

Under the License Agreement, Lee’s will be responsible for all activities related to development, regulatory approval and commercialization of the Company’s KL4 surfactant and combination drug / device products in the Licensed Territory. Lee’s will hold the product licenses for all non-aerosolized products in the Licensed Territory and will seek regulatory approval initially for SURFAXIN and SURFAXIN LS for RDS. The Company will hold the

product license in the Licensed Territory (except where prohibited by law) for all aerosolized products and will designate Lee's its exclusive agent and representative to develop and register AEROSURF and other aerosolized products in the name of and on behalf of the Company. Lee's also has agreed that, except as provided in the License Agreement, for a period of ten (10) years beginning with the later of the first commercial sale of the first aerosolized product and the first commercial sale of the first non-aerosolized product in the PRC, it will not develop, register, manufacture, or commercialize any product for the prevention and/or treatment of RDS in premature infants or other diseases and conditions in humans, in either case that administers, utilizes or contains pulmonary surfactant without the Company's prior written consent.

Under the License Agreement, the Company and Lee's will establish a Joint Steering Committee ("JSC") to oversee the development, registration and commercialization of the products in the Licensed Territory. In addition, the Company and Lee's will establish a Joint Development Committee to prepare and oversee the development plan for the Licensed Territory, and at the appropriate time, a Joint Commercialization Committee to implement a commercialization plan and oversee the commercialization of approved products in the Licensed Territory.

Lee's may sublicense certain activities under the License Agreement to an affiliate of Lee's, 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 License Agreement do not include the right to further sublicense. In addition, the Company and Lee's plan to negotiate (i) a technology transfer agreement under which the Company will transfer to Lee's the manufacturing processes for SURFAXIN and SURFAXIN LS; (ii) a manufacturing agreement providing for the manufacture of SURFAXIN and SURFAXIN LS by Lee's and giving the Company access to such products outside the Licensed Territory; (iii) a manufacturing and supply agreement providing for the manufacture and supply of AEROSURF drug and medical device components by the Company to Lee's; and (iv) such other agreements and amendments as may be necessary for the parties to perform their obligations under the License Agreement.

The term of the License Agreement commenced on the Effective Date and will continue on a country-by-country basis for the commercial life of the products. Either party may terminate the License Agreement in the event of bankruptcy or a material breach of the License Agreement by the other party that remains uncured for a period of sixty (60) days. In addition, either party may terminate the License Agreement in its entirety or with respect to any individual product or country if a regulatory authority terminates, suspends or discontinues development of a product and such termination, suspension or discontinuance persists for a period in excess of eighteen (18) months. Upon termination of the License Agreement in its entirety or with respect to a particular product or country, generally all related rights and licenses granted to Lee's will terminate, all rights under the Company's technology will revert to the Company, and Lee's will cease all use of the Company's technology.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement which is expected to be filed 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. The License Agreement will be 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, each of the Company and Lee's 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. 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 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 June 12, 2017, the Company issued a press release and announced the execution and delivery of the License Agreement described above. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In addition, the Company will host a conference call and webcast (including a slide presentation) at 8:00 a.m. EDT on Tuesday, June 13, 2017 to discuss the License Agreement and answer questions. The live webcast, including a slide presentation, can be accessed at <http://windtreex.investorroom.com/events> . To participate in the live call and take part in the question and answer session, dial (844) 802-2436 (domestic) or (412) 317-5129 (international).

A replay of the conference call will be accessible one hour after completion through June 20, 2017 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference number 10108999. An archive of the webcast can be accessed on the Company's website at <http://windtreex.investorroom.com/events>.

**Item 9.01. Financial Statements and Exhibits.**

- (d) Exhibits
- 99.1 Press release dated June 12, 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: June 12, 2017

## **Windtree Therapeutics and Lee's Pharmaceutical (HK) Limited Enter Into Exclusive License and Collaboration Agreement for Development and Commercialization of KL4 Surfactant Technology Platform in Asia**

*-Windtree and Lee's collaborate to advance the development of AEROSURF®, SURFAXIN® and SURFAXIN LS™ in Asia-*

*-Windtree receives initial payments from Lee's totaling \$3 million, including a prior equity investment and an upfront license fee, with potential future milestone payments and development support totaling over \$40 million plus royalties-*

*-Windtree to host investor conference call tomorrow June 13, 2017 at 8:00 AM ET-*

**WARRINGTON, PA and SHATIN, HONG KONG – June 12, 2017** – Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, and Lee's Pharmaceutical (HK) Limited, a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited ("Lee's Pharm", SEHK Stock Code: 0950), today announced that they have entered into an exclusive license and collaboration agreement for the development and commercialization of KL4 surfactant products in select Asian markets using Windtree's proprietary KL4 surfactant and aerosolization technologies. The agreement includes AEROSURF® as well as the non-aerosol products SURFAXIN® (approved in the U.S.) and SURFAXIN LS (an improved lyophilized formulation of SURFAXIN). Also, Windtree has granted Lee's an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory.

"China and the surrounding Asian markets represent a significant market opportunity for Windtree and our KL4 surfactant technology. Through our collaboration with Lee's, we will be able to access and grow the KL4 surfactant opportunity outside of the U.S. and pursue development of AEROSURF and our other KL4 surfactant products with a proven partner," commented Craig Fraser, President and Chief Executive Officer of Windtree Therapeutics. "I am excited about the potential of AEROSURF to both transform and expand the management of respiratory distress syndrome (RDS) worldwide and this collaboration with Lee's will significantly enhance our development and realization of this goal."

"We are delighted to announce this collaboration with Windtree. Given the size of the RDS population and as a high growth, current top surfactant market, we are enthusiastic about our prospects to develop and market AEROSURF and the other KL4 surfactant products for our premature infants with RDS," commented Dr. Benjamin Li, Chief Executive Officer of Lee's Pharm. "We also see real potential to address other acute pulmonary diseases and conditions and plan to explore these opportunities with Windtree. Together with the Group's other assets, this partnership will strengthen the Group's position in neonatal critical care."

In anticipation of finalizing the agreement, Lee's Pharm invested \$2 million in Windtree's February 2017 private placement offering. Under terms of the license agreement, Windtree will receive an upfront license fee of \$1.0 million and will also be eligible for up to \$37.5 million in contingent clinical, regulatory and commercialization milestone payments and escalating high single digit to mid-teens percentage royalties across all products. In addition, Lee's will be responsible for all development costs in the licensed territory.

### **Conference Call and Webcast Details**

The Company will host a conference call and webcast (including a slide presentation) at 8:00 a.m. EDT on Tuesday, June 13, 2017 to discuss this important collaboration with Lee's Pharm.

The live webcast, including a slide presentation, can be accessed at <http://windtreetxt.investorroom.com/events>. To participate in the live call and take part in the question and answer session, dial (844) 802-2436 (domestic) or (412) 317-5129 (international).

A replay of the conference call will be accessible one hour after completion through June 20, 2017 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference number 10108999. An archive of the webcast can be accessed on the Company's website at <http://windtreetxt.investorroom.com/events>.

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

### **About Lee's Pharmaceutical Holdings Limited ("Lee's Pharm")**

Lee's Pharm is a research-based Hong Kong biopharmaceutical company listed in Hong Kong with more than 20 years of operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with more than 20 international companies and currently has 15 products in the market place. Lee's Pharm focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. The company's development program is lauded with over 40 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies, including promising compounds to treat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's Pharm is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life.

Additional information about Lee's Pharm is available at [www.leespharm.com](http://www.leespharm.com).

**Forward-Looking Statement for Windtree Therapeutics**

*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 are 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.*

**Forward-Looking Statement for Lees Pharm**

*The performance and the results of operation of Lee's Pharm during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's Pharm. This news release may contain forward-looking statements and opinions that involve risks and uncertainties. Actual results may differ materially from expectations discussed in such forward-looking statements and opinions. Neither Lee's Pharm nor the Directors, employees or agents of Lee's Pharm assume (a) any obligation to correct or update the forward-looking statements or opinions contained in this news release; and (b) any liability in the event that any of the forward-looking statements or opinions does not materialize or turns out to be incorrect.*

**Contact Information:**Windtree Therapeutics

John Tattory  
Senior Vice President and Chief Financial Officer  
215.488.9418 or jtattory@windtreetx.com

Lee's Pharm

Vivian Fung  
Licensing & Regulatory Manager  
852.23141282 or info@leespharm.com