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): January 12, 2024

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-39290	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.

License Agreement with Lee's Pharmaceutical (HK) Ltd.

On January 12, 2024 Windtree Therapeutics, Inc. (the "Company") entered into a License, Development and Commercialization Agreement with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong ("Lee's"), effective as of January 7, 2023 (the "Lee's License Agreement").

Under the Lee's License Agreement, the Company granted to Lee's an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute and otherwise commercialize products that incorporate istaroxime for intravenous administration, rostafuroxin for oral administration, and the Company's proprietary dual-mechanism SERCA2a activators for intravenous or oral administration (collectively, the "Products" and each, a "Product"), in each case for the prevention, mitigation and/or treatment of any disease, disorder or condition in humans including acute decompensated heart failure, cardiogenic shock, and chronic use following discharge of an individual hospitalized for acute decompensated heart failure ("Field") in the People's Republic of China, Hong Kong, Macau, Taiwan, Singapore, South Korea, Thailand, Vietnam, Brunei, Myanmar, Cambodia, East Timor, Indonesia, Laos, Malaysia, and the Philippines (the "Licensed Territory").

Under the Lee's License Agreement, the Company may receive up to $3.1 million in potential upfront pre-development, development, clinical, and regulatory milestone payments and up to $135.25 million in sales milestone payments. The Company is also entitled to receive a low double-digit percentage of Lee's non-royalty sublicense income.

The Company is eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the Lee's License Agreement) that ranges from low single-digit to low double-digit 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 Lee's License Agreement, Lee's will be solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of Products in the Licensed Territory, with the exception of certain costs in connection with filing fees payable to regulatory authorities in the Licensed Territory relative to a Product for which the Company holds the applicable marketing authorization. Lee's may sublicense its rights to its affiliates and may grant sublicenses to third-party subcontractors to perform certain activities under the Lee's License Agreement on behalf of Lee's or its affiliates but may not otherwise 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 granted under the Lee's License Agreement may not include the right to further sublicense. The Lee's License Agreement establishes a joint steering committee and a joint development committee to oversee the regional development (with the Company retaining final decision rights over clinical protocols) and a joint commercialization committee.

During the term of the Lee's License Agreement the Company receives an exclusive (even as to Lee's), sublicensable license under any Lee's and its affiliate's intellectual property that covers a Product (including its manufacture and use) and any improvements to the licensed technology developed solely by or on behalf of Lee's or jointly with the Company, to (i) develop Product in the Field to obtain or maintain regulatory approval outside of the Licensed Territory, and (ii) use, sell, offer for sale, import, export, make, have made, distribute, warehouse, market, promote, apply for and submit applications for drug approval and reimbursement approval and otherwise commercialize Product in the Field outside of the Licensed Territory. After the term of the Lee's License Agreement, or in the event that the Company wishes to obtain an exclusive license under certain patent rights during or after the term, the Company has the option to negotiate an exclusive royalty-bearing license under any such intellectual property, provided that such royalties shall not exceed specified low single-digit caps.

Under the Lee's License Agreement, each party is responsible for prosecution and maintenance of its respective solely-owned patents, and the parties shall decide on a case-by-case basis the appropriate allocation of costs and control concerning matters regarding the prosecution, maintenance, defense and infringement of any jointly-owned patents. The Lee's License Agreement provides for cooperation between the parties with respect to enforcement of patent rights. As between the parties, the Company has the first right to enforce patent rights against third parties at its own expense. If the Company declines to enforce such rights, Lee's has the right to enforce such rights at its own expense. In the event that a third party claims that a Product used or sold by Lee's (or its affiliate or sublicensee) is infringing on a patent in the Licensed Territory, Lee's is responsible for defending against such third party claim at its cost and expense, with the exception of certain counterclaims that the Company may bring.

The term of the Lee's License Agreement will continue on a country-by-country basis for the commercial life of the Products. Either party may terminate the Lee's License Agreement in the event of bankruptcy or a material breach of the Lee's 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 Lee's License Agreement) if such material breach is solely based on the breaching party's failure to pay amount due under the Lee's License Agreement). In addition, either party may terminate the Lee's 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 Lee's 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, in each case in relation to the terminated Product(s) and country(ies), as applicable.

Amendment No. 1 to the Amended and Restated License Agreement with Philip Morris USA for Aerosolization Technology

On January 16, 2024, the Company entered into Amendment No. 1 to the Amended and Restated License Agreement with Philip Morris USA Inc. ("PM USA"), effective as of January 17, 2024 (the "PM USA License Amendment"), which amended the Amended and Restated License Agreement, dated March 28, 2008, between the Company and PM USA (the "PM USA License Agreement"). The PM USA License Agreement licenses U.S. intellectual property rights to the Company in respect of the Company's former acute pulmonary care platform that was globally outlicensed to Lee's Pharmaceutical (HK) Ltd. and its affiliate, Zhaoke Pharmaceutical (Hefei) Co. Ltd. (collectively, "Lee's"), in August 2022. Pursuant to the PM USA License Amendment, the Company agreed to pay PM USA (1) $100,000 by January 18, 2024, (2) $400,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 and (3) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from Lee's. Additionally, under the PM USA License Amendment, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 7.3 of the PM USA License Agreement as in effect immediately prior to January 17, 2024. The PM USA License Amendment also grants PM USA the right to terminate the PM USA License Agreement upon 30 days prior written notice to the Company if the Company has not paid a milestone payment to PM USA by January 1, 2028.

Amendment No. 1 to the License Agreement with Philip Morris Products for Aerosolization Technology

On January 16, 2024, the Company also entered into Amendment No. 1 to the License Agreement with Philip Morris Products S.A. ("PMPSA"), effective as of January 17, 2024 (the "PMPSA License Amendment"), which amended the License Agreement, dated March 28, 2008, between the Company and PMPSA (the "PMPSA License Agreement"). The PMPSA License Agreement licenses ex-U.S. intellectual property to the Company in respect of its former acute pulmonary care platform that was globally outlicensed to Lee's in August 2022. Pursuant to the PMPSA License Amendment, the Company agreed to pay PMPSA (1) $75,000 by January 19, 2024 (the "Upfront Payment"), (2) $325,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 (together with the Upfront Payment, the "Fixed Payments") and (3) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from Lee's. Additionally, but contingent upon the Company's timely payment of the Fixed Payments, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 6.2 of the PMPSA License Agreement as in effect immediately prior to January 17, 2024.

The foregoing descriptions of the Lee's License Agreement, PM USA License Amendment and the PMPSA License Amendment are general descriptions only, do not purport to be complete descriptions of the rights and obligations of the parties thereunder, and are qualified in their entirety by reference to the terms of such agreements, which will be attached as exhibits to the Company's next periodic filing.

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: January 17, 2024

Windtree Therapeutics, Inc.

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