

**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): March 19, 2021

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-26422
(Commission
File Number)

94-3171943
(I.R.S. Employer
Identification No.)

2600 Kelly Road, Suite 100, Warrington, Pennsylvania
(Address of principal executive offices)

18976
(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 March 19, 2021, Windtree Therapeutics, Inc. (the “**Company**”), through its wholly-owned subsidiary, CVie Therapeutics Ltd. (“**CVie**”), entered into an Agreement for Scientific Collaboration (the “**New SERCA2a Agreement**”) with Universita degli Studi di Milano-Bicocca (“**Bicocca**”), which extends its collaboration with Bicocca for the discovery and development of new SERCA2a compounds for the potential treatment of chronic and acute human heart failure. The New SERCA2a Agreement amends and restates the recently expired terms of the Collaboration Agreement, by and between Bicocca and CVie, dated April 14, 2015 and extended on August 14, 2018, and the Research Agreement by and between Bicocca and CVie, dated April 19, 2018.

Under the New SERCA2a Agreement, the Company will provide Bicocca with approximately € 177,000 for research activities and to cover laboratory space and operation costs. Results obtained from the collaboration will be jointly owned by the parties. However, Bicocca will assign to the Company its interest in patent applications and patents covering any new SERCA2a compounds and diagnostic products suitable for further clinical development. The Company has agreed to pay Bicocca (corresponding to stage of development): (i) € 25,000 (approximately \$30,000) for execution of an assignment to the Company of Bicocca’s interest in the patent at issue, (ii) € 75,000 (approximately \$90,000) for new SERCA2a compounds developed up to phase 1 studies in humans upon the completion and availability of the proof of concept of biological efficacy of new compounds on modulating the SERCA2a activity in cell-free systems, or its functional counterpart in isolated cells and (iii) € 1.5 million (approximately \$1.8 million) upon obtaining marketing authorization in the U.S., EU, or China of new compounds with the corresponding companion diagnostic assay. The Company has also agreed to pay royalties on products generated from the collaboration in the range of a fraction of a single digit to a low single digit percent of net sales for any products sold in any country for a period of ten years from the date of the first commercial sale or until the expiry of patent(s) covering the products.

The New SERCA2a Agreement also contains representations, warranties, and indemnity obligations customary for agreements of this type.

The foregoing description of the terms of the New SERCA2a Agreement do not purport to be complete and is qualified in its entirety by reference to the full text of the agreement, which will be filed with the Company’s Quarterly Report on Form 10-Q for the quarter ending on March 31, 2021.

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, thereunto duly authorized.

WINDTREE THERAPEUTICS, INC.

Date: March 22, 2021

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