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): May 14, 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**

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

Common Stock, par value $0.001 per share

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 2.02 Results of Operations and Financial Condition

On May 14, 2020, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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 May 14, 2020 announcing financial results for the quarter ended March 31, 2020.

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.

Windtree Therapeutics, Inc.

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

Date: May 14, 2020

Exhibit 99.1

Windtree Therapeutics Reports First Quarter 2020 Financial Results and Provides Key Business Updates

WARRINGTON, PA – May 14, 2020 – Windtree Therapeutics, Inc. (OTCQB: WINTD), a biotechnology and medical device company focused on developing drug product candidates and medical device technologies to address acute cardiovascular and pulmonary diseases, today reported financial results for the first quarter ended March 31, 2020 and provided key business updates.

Key Business and Financial Updates

- In March 2020, the Company announced that it is developing plans to study its KL4 surfactant for treatment of lung injury resulting from severe COVID-19 infection, if it is able to secure the required additional capital resources necessary to initiate and complete the study. The Company is actively pursuing multiple non-dilutive funding opportunities, including from government agencies and private foundations.

- In March 2020, the Company entered into a binding term sheet with Lee's Pharmaceutical Holdings (HK) Ltd ("Lee's") pursuant to which Lee's will provide up to $3.9 million of non-dilutive project funding for the six month period beginning April 1, 2020 for the continued development of the Company's lead acute pulmonary product candidate, AEROSURF® for the treatment of preterm infants with respiratory distress syndrome ("RDS"). The financing will fund the AEROSURF phase 2b bridge study, which if successful, is intended to transition the product into a phase 3 ready clinical program. The Company and Lee's will negotiate, in good faith, the terms of a definitive agreement that will set forth additional semi-annual non-refundable payments to fund the continued development of AEROSURF subsequent to September 30, 2020. The arrangement is intended to fund the AEROSURF bridge study, as well as support the Company's focus of cash resources on opportunities in our istaroxime cardiovascular clinical programs.

- As of March 31, 2020, the Company had cash and cash equivalents of $16.8 million.

- In March 2020, the Company amended its bank credit facility agreement ($4.6 million outstanding as of March 31, 2020) to extend the maturity date from March 2020 to March 2022.

- In April 2020, the Company announced it has enrolled the first patient into the AEROSURF bridging study in premature infants with RDS. This bridging study is intended to complete the phase 2 clinical program for AEROSURF and transition clinical development to phase 3 by validating the performance of the new aerosol delivery system (ADS) and a more intensive dosing regimen.

"We continued to make excellent progress this quarter, including securing additional non-dilutive project financing for the AEROSURF development program with the binding term sheet with Lee's; enrolling the first patient in our AEROSURF bridging study; and very importantly, announcing plans to study our KL4 surfactant in COVID-19 as a potential treatment to mitigate the pulmonary effects in patients with this severe infection upon securing the capital resources to fully fund the study," commented Craig Fraser, President and Chief Executive Officer of Windtree. "From a business perspective, we have applied to list our common stock on the Nasdaq Capital Market, or Nasdaq, and our common stock has been approved for listing contingent upon satisfaction of certain listing requirements. We are optimistic about the prospects for the Company as we continue successfully executing upon our strategy, and we look forward to keeping our stakeholders updated in the coming months."

Select Financial Results for the First Quarter ended March 31, 2020

For the quarters ended March 31, 2020 and 2019, the Company reported an operating loss of $6.7 million.

Research and development expenses were $3.5 million for the first quarter of 2020, compared to $3.3 million for the first quarter of 2019.

General and administrative expenses for the first quarter of 2020 were $3.2 million, compared to $3.4 million for the first quarter of 2019. The decrease in general and administrative expenses is primarily due to decreases in personnel and employee incentive bonus costs, partially offset by an increase in professional fees.

The Company reported a net loss of $6.5 million ($0.48 per basic share) on 13.7 million weighted-average common shares outstanding for the quarter ended March 31, 2020, compared to a net loss of $6.5 million ($0.61 per basic share) on 10.7 million weighted average common shares outstanding for the comparable period in 2019.

As of March 31, 2020, the Company reported cash and cash equivalents of $16.8 million, current liabilities of $6.9 million and loans payable – non-current of $4.6 million. The loans payable – non-current is payable in March 2022.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 which was filed with the Securities and Exchange Commission on May 13, 2020, which includes detailed discussions about the Company's business plans and operations, financial condition and results of operations.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is a clinical-stage, biopharmaceutical and medical device company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Windtree has three lead clinical development programs spanning respiratory and cardiovascular disease states, including istaroxime, a novel, dual-acting agent being developed to improve cardiac function in patients with acute heart failure and cardiogenic shock; AEROSURF®, an innovative combination drug/device product candidate that is designed to deliver the Company's proprietary synthetic, peptide-containing surfactant noninvasively to premature infants with respiratory distress syndrome (RDS); and rostafuroxin, a novel precision drug product being developed to target hypertensive patients with certain genetic profiles in the important group of patients with resistant hypertension. Windtree also has multiple pre-clinical programs, including potential heart failure therapies delivered orally that are based on SERCA2a mechanism of action.

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. We 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® 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.

Contact Information:
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Windtree Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended March 31,	
	2020	2019
Revenues:		
License revenue with affiliate	$ -	$ 40
Total revenue	-	40
Expenses:		
Research and development	3,461	3,342
General and administrative	3,242	3,355
Total operating expenses	6,703	6,697
Operating loss	(6,703)	(6,657)
Interest income / (expense), net	45	(76)
Other income, net	124	196
Net loss	$ (6,534)	$ (6,537)
Net loss per common share – basic and diluted	$ (0.48)	$ (0.61)
Weighted avg. common shares outstanding – basic and diluted	13,697	10,714

Windtree Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 16,799	$ 22,578
Prepaid expenses and other current assets	1,299	1,283
Total current assets	18,098	23,861
Property and equipment, net	756	798
Restricted cash	154	154
Operating lease right-of-use assets	1,213	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 112,993	$ 118,975
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, collaboration and device development payable and accrued expenses	$ 6,239	$ 6,906
Operating lease liabilities – current portion	700	750
Loan payable	-	161
Total current liabilities	6,939	7,817
Operating lease liabilities – non-current portion	654	794
Loans payable – non-current portion	4,551	4,608
Restructured debt liability – contingent milestone payments	15,000	15,000
Deferred tax liabilities	15,759	15,821
Stockholders' Equity	70,090	74,935
Total liabilities and stockholders' equity	$ 112,993	$ 118,975