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): April 2, 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 April 2, 2020, Windtree Therapeutics, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended December 31, 2019 and providing key financial and business updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information disclosed under 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 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 April 2, 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 Fraser
Name: Craig Fraser
Title: President and Chief Executive Officer

Date: April 3, 2020

Exhibit 99.1

Windtree Therapeutics Reports Fourth Quarter 2019 Financial Results and Provides Key Business Updates

WARRINGTON, PA – April 2, 2020 – Windtree Therapeutics, Inc. (OTCQB: WINT), 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 fourth quarter ended December 31, 2019 and provided key business updates.

Key Business and Financial Updates

- In December 2019, the Company completed a $26.4 million private placement of common stock and warrants. After offering expenses and the cancellation of $2.95 million of existing indebtedness in exchange for the securities offered, the Company received net proceeds of approximately $23.0 million.

- The Company recently 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.

- In March 2020, the AEROSURF bridge study clinical sites in Poland were initiated. Notwithstanding certain delays to ensure appropriate staffing and evolving COVID-19 hospital procedures are put into place, these study sites are still active, and the Company anticipates first patient dosed early in the second quarter.

- As of December 31, 2019, the Company had cash and cash equivalents of $22.6 million and current liabilities of $7.8 million.

- In March 2020, the Company amended its bank credit facility agreement ($4.6 million outstanding as of December 31, 2019) to extend the maturity date from March 2020 to March 2022.

"We made tremendous progress in 2019, capped by a $26 million private placement closed during the fourth quarter. Our strengthened balance sheet allows us to focus on our multiple clinical development programs as we move forward with istaroxime for early cardiogenic shock and acute heart failure study start-up activities, and with AEROSURF for respiratory distress syndrome in premature infants. Additionally, we have applied for a listing on the Nasdaq Capital Market and are working to secure this objective," commented Craig Fraser, President and Chief Executive Officer of Windtree. "While we are certain of our ability to execute upon our strategic plan, we are faced with uncertainty as our nation and global communities combat the global pandemic and impacts of COVID-19. We are committed to help mitigate the devastating impact of this virus and announced recently our intent to pursue a clinical study treating patients with COVID-19 lung injury with our KL4 surfactant therapy upon securing the non-dilutive capital resources to fully fund the study. Along with clinical development, we are highly engaged in business development activities. The December 2018 acquisition of additional late stage products focused on areas with high unmet need along with successful financings to execute against these opportunities, have positioned Windtree for sustained growth and success. We are optimistic about the prospects for the Company and look forward to keeping our stakeholders updated in the coming months."

Select Financial Results for the Fourth Quarter ended December 31, 2019

For the quarter ended December 31, 2019, the Company reported an operating loss of $4.6 million, compared to $4.9 million for the fourth quarter of 2018.

Research and development expenses were $2.1 million for the fourth quarter of 2019, compared to $2.4 million for the fourth quarter of 2018. The decrease in research and development expenses is primarily due to a decrease in employee incentive compensation expense.

General and administrative expenses for the fourth quarter of 2019 were $2.4 million, compared to $2.8 million for the fourth quarter of 2018. The decrease in general and administrative expenses is primarily due to decreases in employee incentive compensation expense and professional fees, partially offset by an increase in non-cash stock compensation expense.

In the fourth quarter of 2019, the Company recorded a $1.8 million net loss on debt extinguishment as a result of the conversion of $2.95 million of existing loans payable obligations as part of the December 2019 private placement financing. In the fourth quarter of 2018, the Company recorded a $3.3 million net loss on debt extinguishment as a result of the conversion of $6.0 million of existing loans payable obligations as part of a December 2018 private placement financing.

The Company reported a net loss of $7.4 million ($0.21 per basic share) on 34.6 million weighted-average common shares outstanding for the quarter ended December 31, 2019, compared to a net loss of $23.6 million ($3.24 per basic share) on 7.2 million weighted average common shares outstanding for the comparable period in 2018. The 2018 net loss includes a $12.5 million charge related to issuance of the AEROSURF warrant dividend and a $1.7 million charge for a non-cash deemed dividend on preferred stock.

As of December 31, 2019, the Company reported cash and cash equivalents of $22.6 million, current liabilities of $7.8 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 Annual Report on Form 10-K for the year ended December 31, 2019 which will be filed with the Securities and Exchange Commission on April 3, 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:

John Tattory
Senior Vice President and Chief Financial Officer
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Windtree Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Grant revenue	$ –	$ –	$ –	$ 765
License revenue with affiliate	–	304	198	1,023
	–	304	198	1,788
Operating expenses: [1]				
Research and development	2,140	2,368	12,687	10,562
General and administrative	2,414	2,787	12,404	7,421
Total operating expenses	4,554	5,155	25,091	17,983
Operating loss	(4,554)	(4,851)	(24,893)	(16,195)
Net loss on debt extinguishment	(1,794)	(3,345)	(1,794)	(3,345)
Interest and other income / (expense), net	(1,027)	(846)	(788)	(993)
Net loss	$ (7,375)	$ (9,042)	$ (27,475)	$ (20,533)
AEROSURF warrant dividend	–	(12,505)	–	(12,505)
Deemed dividend on Series A preferred stock	–	(1,718)	–	(1,718)
Net loss attributable to common shareholders	$ (7,375)	(23,625)	$ (27,475)	$ (34,756)
Net loss per common share – basic and diluted	$ (0.21)	$ (3.24)	$ (0.84)	$ (7.74)
Weighted avg. common shares outstanding – basic and diluted	34,597	7,191	32,784	4,493

[1] For the three months ended December 31, 2019 and 2018, the charges for depreciation and stock-based compensation were $1.5 million ($0.3 million in R&D and $1.2 million in G & A) and $0.3 million ($0.1 million in R&D and $0.2 million in G & A), respectively. For the twelve months ended December 31, 2019 and 2018, the charges for depreciation and stock-based compensation were $6.9 million ($2.1 million in R&D and $4.8 million in G & A) and $1.1 million ($0.4 million in R&D and $0.7 million in G & A), respectively.

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

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,578	$ 11,187
Available-for-sale marketable securities	–	13,959
Prepaid expenses and other current assets	1,283	507
Total current assets	23,861	25,653
Property and equipment, net	798	802
Restricted cash	154	171
Operating lease right-of-use assets	1,390	–
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total Assets	$ 118,975	$ 119,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, collaboration and device development payable and accrued expenses	$ 6,906	$ 12,461
Operating lease liabilities – current portion	750	–
Deferred revenue – current portion	–	198
Loans payable – current portion	161	7,974
Total current liabilities	7,817	20,633
Operating lease liabilities – non-current portion	794	–
Loans payable – non-current portion	4,608	–
Restructured debt liability – contingent milestone payments	15,000	15,000
Deferred tax liabilities	15,821	15,476
Other liabilities	–	175
Stockholders' Equity	74,935	68,114
Total Liabilities and Stockholders' Equity	$ 118,975	$ 119,398