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): August 13, 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**
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 2.02 Results of Operations and Financial Condition

On August 13, 2020, Windtree Therapeutics, Inc. (the "***Company***") issued a press release announcing its financial results for the quarter ended June 30, 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

Exhibit No.	Document
99.1	Press Release of Windtree Therapeutics, Inc., dated August 13, 2020, announcing financial results for the quarter ended June 30, 2020, furnished herewith.

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: August 14, 2020

Exhibit 99.1

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

WARRINGTON, PA – August 13, 2020 – Windtree Therapeutics, Inc. (NASDAQ: 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 second quarter ended June 30, 2020 and provided key business updates.

Key Business and Financial Updates

- Completed an underwritten public offering of 3,172,413 units, offered at a price of $7.25 per unit, which included the full exercise of the underwriters' over-allotment option. Each unit issued in the offering consisted of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $7.975 per share. The gross proceeds to Windtree from this offering, including the over-allotment, were approximately $23 million, before deducting underwriting discounts and commissions and other estimated offering expenses. In connection with the offering, Windtree's common stock began trading on The Nasdaq Capital Market and began trading under the symbol "WINT" on May 20, 2020.

- Presented a new subset analysis from a phase 2b study of istaroxime in patients hospitalized with acute heart failure at the American College of Cardiology 2020 virtual meeting. The new post-hoc analysis characterized the responses between Caucasian and Asian patients and showed the istaroxime dose of 0.5 µg/kg/min produced a similar response on E/e', the primary study endpoint, and stroke volume index, an important measure of cardiac performance. The Company previously presented overall results of the study, where the primary endpoint demonstrated a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses.

- Announced first patient enrolled in its AEROSURF Phase 2b Bridging Study in premature infants with respiratory distress syndrome (RDS). The Company also announced that all initial European trial sites are active and enrolling or able to enroll patients into its AEROSURF® Phase 2b bridging study in premature infants with respiratory distress syndrome (RDS). In addition, the Company announced that select patients in this study may be co-enrolled in an investigator-sponsored study, being run in parallel to the bridging study. The concomitant study will evaluate changes in cerebral electroencephalography (EEG) and cerebral oxygenation during surfactant administration. The bridging study is a multicenter, randomized, controlled study with masked treatment assignment in up to 90 premature infants 26 to 32 weeks gestational age receiving nasal continuous positive airway pressure for RDS. If successful, the bridging study is intended to complete the Phase 2 clinical program for AEROSURF and prepare the transition of clinical development to a Phase 3 program.

- Announced the hiring of John Hamill as chief financial officer. Also, enhanced the team responsible for clinical execution with other new hires, including Dr. Pratap Paruchuru as executive director of clinical development, Catherine Kacprzycki as director of clinical operations and Tracy Rarick as head of operations and program management.

- Hosted a business update call in June, highlighting the Company's clinical programs in acute cardiovascular and pulmonary diseases.

"Windtree made considerable progress this quarter on both the business and clinical development fronts," said Craig Fraser, president, and chief executive officer of Windtree. "We successfully completed a public offering and concurrently up-listed to The Nasdaq Capital Market, which provides us with the funding to support advancement of our lead clinical programs, and, we believe increases our market visibility as we move toward planned milestones with our multiple clinical and business development activities. We are focused on execution and look forward to an exciting second half of 2020 that we anticipate will include initiating the Phase 2b study in early cardiogenic shock in the third quarter, progressing toward a planned initial trial of our proprietary KL4 surfactant to impact key respiratory parameters in ventilated COVID-19 patients, and other development activity in line with our strategy."

Select Financial Results for the Second Quarter ended June 30, 2020

For the second quarter ended June 30, 2020, the Company reported an operating loss of $7.9 million, compared to an operating loss of $6.5 million in the second quarter of 2019.

Research and development expenses were $4.5 million for the second quarter of 2020, compared to $3.4 million for the second quarter of 2019. The increase in research and development expenses is primarily due to increases in direct program and active pharmaceutical ingredient costs.

General and administrative expenses for the second quarter of 2020 were $3.4 million, compared to $3.2 million for the second quarter of 2019.

The Company reported a net loss of $9.6 million ($0.63 per basic share) on 15.1 million weighted-average common shares outstanding for the quarter ended June 30, 2020, compared to a net loss of $6.4 million ($0.60 per basic share) on 10.7 million weighted average common shares outstanding for the comparable period in 2019.

As of June 30, 2020, the Company reported cash and cash equivalents of $31.5 million which is expected to be sufficient to fund operations through at least the next twelve months. Subsequent to the end of the quarter, the Company received additional payment from its partner Lee’s Pharmaceutical Holdings (HK) Ltd. of approximately $1.4 million and paid down debt on its credit facility of approximately $2.3 million.

Readers are referred to, and encouraged to read in its entirety, the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which will be filed with the Securities and Exchange Commission on August 14, 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 advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to save patients in their moments of crisis. Using new clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate istaroxime as a first-in-class treatment for acute heart failure and early cardiogenic shock in heart failure. Windtree is also developing AEROSURF® as a paradigm shifting non-invasive surfactant treatment for premature infants with respiratory distress syndrome, as well as evaluating other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions such as preventing lung injury. Also in its portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

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.

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Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	June 30, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 31,515	$ 22,578
Prepaid expenses and other current assets	2,121	1,283
Total current assets	33,636	23,861
Property and equipment, net	727	798
Restricted cash	154	154
Operating lease right-of-use assets	1,034	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 128,323	$ 118,975
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,223	$ 1,708
Collaboration and device development payable, net	968	1,972
Accrued expenses	3,676	3,226
Operating lease liabilities - current portion	651	750
Loans payable - current portion	5,714	161
Total current liabilities	12,232	7,817
Operating lease liabilities - non-current portion	506	794
Loans payable - non-current portion	-	4,608
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	1,000	-
Deferred tax liabilities	16,129	15,821
Total liabilities	44,867	44,040
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2020 and December 31, 2019; 16,868,756 and 13,697,419 shares issued at June 30, 2020 and December 31, 2019, respectively; 16,868,732 and 13,697,395 shares outstanding at June 30, 2020 and December 31, 2019, respectively	17	14
Additional paid-in capital	787,707	763,097
Accumulated deficit	(701,214)	(685,122)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	83,456	74,935
Total liabilities & stockholders' equity	$ 128,323	$ 118,975

Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
License revenue with affiliate	$ -	$ 158	$ -	$ 198
Total revenues	-	158	-	198
Expenses:				
Research and development	4,495	3,413	7,956	6,755
General and administrative	3,453	3,240	6,695	6,595
Total operating expenses	7,948	6,653	14,651	13,350
Operating loss	(7,948)	(6,495)	(14,651)	(13,152)
Other income (expense):				
Interest income	5	39	94	99
Interest expense	(31)	(117)	(75)	(253)
Other income (expense), net	(1,584)	136	(1,460)	332
Total other income (expense), net	(1,610)	58	(1,441)	178
Net loss	$ (9,558)	$ (6,437)	$ (16,092)	$ (12,974)
Net loss per common share				
Basic and diluted	$ (0.63)	$ (0.60)	$ (1.12)	$ (1.21)
Weighted average number of common shares outstanding				
Basic and diluted	15,091	10,730	14,394	10,722