UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

August 14, 2019
Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

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:
☐ 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))

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	WINT	The OTCQB® Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934: 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 14, 2019, Windtree Therapeutics, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended June 30, 2019 and providing key financial and business updates. The press release is attached as Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 hereto relating to the announcement of the results of operations for the quarter ended June 30, 2019 and all other matters except for those discussed under Item 8.01 below 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, nor shall it be deemed 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 any such filings.

Item 8.01. Other Events.

The press release referred to in Item 2.02 also provides certain program updates relating to the Company's lead programs – istaroxime for acute heart failure and AEROSURF® for respiratory distress syndrome (RDS) in premature infants. In addition, the Company reports that, before any additional financings, the Company anticipates that it will have sufficient cash, cash equivalents and available-for-sale marketable securities to fund its development activities, business operations and debt service through October 2019.

Subject to the note relating to the press release contained in Item 2.02 of this Current Report on Form 8-K, the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release of Windtree Therapeutics, Inc., dated August 14, 2019.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, cash flows, future revenues, the timing of planned clinical trials or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement made by the Company in this Current Report on Form 8-K is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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.

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

Date: August 14, 2019

Exhibit 99.1

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

WARRINGTON, PA – August 14, 2019 – 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 second quarter ended June 30, 2019 and provided key business updates.

Key Business and Financial Updates

During the second quarter of 2019, the Company continued to advance development activities to potentially transition its lead programs – istaroxime for acute heart failure and AEROSURF® for respiratory distress syndrome (RDS) in premature infants – towards phase 3 clinical trials; in addition, the Company continued to progress product development activities for rostafuroxin.

Istaroxime

- In May 2019, the Company presented new safety and efficacy data from a phase 2b study of istaroxime in patients hospitalized with acute heart failure (AHF) at a late-breaker session of the European Society of Cardiology (ESC) 2019 Heart Failure Congress. The study achieved its primary endpoint by demonstrating a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses and the Company observed a well characterized safety profile for istaroxime.

- In June 2019, the Company engaged with the U.S. FDA and gained alignment on the direction of the istaroxime clinical development plan and continues to work with its advisors in preparing for the next clinical trial.

- In August 2019, the Company announced that the U.S. FDA has granted Fast Track Designation for istaroxime for the treatment of acute heart failure.

AEROSURF

- In May 2019, the Company announced the results of a post-hoc, pooled analysis of previously released phase 2 data suggesting that AEROSURF may reduce the overall incidence and severity of bronchopulmonary dysplasia (BPD) in premature infants with RDS, regardless of whether the infant was ultimately intubated. These data were recently presented at the Pediatric Academic Societies (PAS) Meeting, the leading event for academic pediatrics and child health research.

Other Pipeline

- The Company continued to advance its preclinical follow-on oral and intravenous SERCA 2a heart failure compounds.

- In June 2019, the Company and Eleison Pharmaceuticals LLC announced positive results of a feasibility study using the Company’s Aerosol Delivery System (ADS) aerosolization technology to deliver Eleison's inhaled lipid cisplatin (ILC). The results demonstrate the feasibility to aerosolize ILC for potential use in thoracic oncology treatment.

Financial

- As of June 30, 2019, the Company had cash and cash equivalents of $6.1 million and $2.5 million of available-for-sale marketable securities.

- The Company believes that it has sufficient cash, cash equivalents and available-for-sale marketable securities to fund its development activities, business operations and debt service through October 2019.

“Through the second quarter of 2019, we continued to make meaningful advancements in our lead programs – istaroxime and AEROSURF,” commented Craig Fraser, President and Chief Executive Officer. “With the CVie acquisition, we met our goal to create a company with numerous, short- to mid-term value-creating opportunities in important disease areas. I am pleased with the continued strong progress made to advance istaroxime and AEROSURF, as we focus on executing our programs in a thoughtful and rigorous manner. We believe we have favorably positioned the Company with multiple clinical development and business milestones that could potentially be catalysts for value creation. We look forward to keeping our stakeholders updated on our plans, clinical execution and milestone achievements.”

Select Financial Results for the Second Quarter ended June 30, 2019

For the quarter ended June 30, 2019, the Company reported an operating loss of $6.5 million compared to $3.0 million for the second quarter of 2018. The increase was primarily due to increases of $2.0 million in general and administrative expenses and $0.5 million in research and development expenses.

Research and development expenses were $3.4 million for the second quarter of 2019 compared to $2.9 million for the second quarter of 2018.

General and administrative expenses for the second quarter of 2019 were $3.2 million compared to $1.2 million for the second quarter of 2018. The increase was primarily due to a $1.1 million increase in non-cash stock compensation expense as a result of employee stock option grants in the fourth quarter of 2018 and during 2019. There were no employee stock option grants in the first half of 2018. Also, there were increases of $0.5 million related to professional fees and $0.3 million related to employee incentive bonuses.

For the quarter ended June 30, 2019, the Company reported a net loss of $6.4 million ($0.20 per share) compared to a net loss of $3.1 million ($0.81 per share) for the second quarter of 2018.

As of June 30, 2019, the Company had cash and cash equivalents of $6.1 million and available-for-sale marketable securities of $2.5 million. In addition, as of June 30, 2019, the Company had current liabilities of $15.5 million (including $8.0 million in debt). The Company anticipates that its cash, cash equivalents and marketable securities are sufficient to fund its planned development activities, business operations and debt service through October 2019. The Company plans, and is currently actively engaged in discussions with various parties, to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time.

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, 2019 which is expected to be filed with the Securities and Exchange Commission on or before August 14, 2019 and includes a discussion of 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 and multiple pre-clinical 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 with a potentially favorable safety profile; AEROSURF®, an innovative combination drug/device product candidate that is designed to deliver the Company’s proprietary synthetic, peptide-containing surfactant non-invasively 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 products 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

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties include: the risk that, as a development company with limited resources and no operating revenues, the Company's ability to continue as a going concern in the near term is highly dependent upon successful and timely advancement of its clinical development programs for istaroxime and AEROSURF®; risks that Windtree will be unable to secure significant additional capital as and when needed, or to access debt or equity financings, which could result in substantial equity dilution; risks related to Windtree's development programs, which may involve time-consuming and expensive pre-clinical studies and clinical trials and which may be subject to potentially significant delays or regulatory holds, or fail; risks related to technology transfers to contract manufacturers and manufacturing development, and problems or delays encountered by Windtree, 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 Windtree 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 Windtree's products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; risks related to Windtree's efforts to maintain and protect the patents and licenses related to its products; and other risks and uncertainties described in Windtree's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:

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

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30, (unaudited)	
	2019	2018	2019	2018
Revenues:				
Grant revenue	$ –	$ 695	$ –	$ 695
License revenue with affiliate	158	356	198	560
Total revenue	158	1,051	198	1,255
Operating expenses:				
Research and development	3,413	2,879	6,755	5,997
General and administrative	3,240	1,208	6,595	3,134
Total operating expenses	6,653	4,087	13,350	9,131
Operating loss	(6,495)	(3,036)	(13,152)	(7,876)
Interest expense, net	(78)	(88)	(154)	(174)
Other income, net	136	72	332	486
Net loss	$ (6,437)	$ (3,052)	$ (12,974)	$ (7,564)
Net loss per common share – basic and diluted	$ (0.20)	$ (0.81)	$ (0.40)	$ (2.17)
Weighted avg. common shares outstanding – basic and diluted	32,189	3,751	32,166	3,491

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

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,124	$ 11,187
Available-for-sale marketable securities	2,540	13,959
Prepaid expenses and other current assets	1,219	507
Total current assets	9,883	25,653
Property and equipment, net	893	802
Restricted cash	153	171
Operating lease right-of-use assets	1,544	–
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 105,245	$ 119,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, collaboration and device development payable and accrued expenses	$ 6,832	$ 12,461
Operating lease liabilities – current portion	656	–
Deferred revenue	–	198
Loan payable	8,047	7,974
Total current liabilities	15,535	20,633
Operating lease liabilities – non-current portion	1,070	–
Restructured debt liability – contingent milestone payments	15,000	15,000
Deferred tax liabilities	15,276	15,476
Other liabilities	94	175
Stockholders' Equity	58,270	68,114
Total liabilities and stockholders' equity	$ 105,245	$ 119,398