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 7, 2023

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39290**	**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 7, 2023, Windtree Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. 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 August 7, 2023, announcing financial results for the quarter ended June 30, 2023, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: August 7, 2023

Exhibit 99.1

Windtree Therapeutics Reports Second Quarter 2023 Financial Results and Provides Key Business Updates

Company plans to initiate a Phase 2 SEISMiC extension study of istaroxime in early cardiogenic shock in Q3; Study start-up for a Phase 2 SCAI Stage C cardiogenic shock study underway

Completed $12.4 million public offering including full exercise of overallotment option

WARRINGTON, PA – August 7, 2023 – Windtree Therapeutics, Inc. ("Windtree" or "the Company") (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for cardiovascular disorders, today reported financial results for the second quarter ended June 30, 2023 and provided key business updates.

"During the second quarter, we completed a successful $12.4 million financing to strengthen the company's balance sheet and support our istaroxime development efforts. We next plan to move the istaroxime program in cardiogenic shock to Phase 3 readiness by advancing two clinical trials. First, we are building upon the positive data from the SEISMiC study by initiating the SEISMiC extension dose optimization study in the third quarter. Additionally, we are progressing start-up activities for a study of istaroxime in more severe SCAI Stage C cardiogenic shock patients that, with adequate resourcing, we anticipate will begin enrollment in the fourth quarter," said Craig Fraser, Chief Executive Officer of Windtree. "The SEISMiC extension study will focus on extended dosing to illuminate the effects and potential benefits of SERCA2a activation. The study is expected to enroll up to 30 subjects and we anticipate reporting data in the second quarter of 2024. Additionally, this quarter noted progress with our next generation, dual mechanism SERCA2a activators, along with istaroxime potential in both cardiogenic shock and acute heart failure, creating a multi-asset platform that we seek to leverage in our business development activities."

Key Business Updates

- Raised $12.4 million in gross proceeds, before deducting underwriting discounts, commissions and other estimated offering expenses, in an April 2023 underwritten public offering of 4,238,906 shares of its common stock and warrants to purchase up to 4,238,906 shares of common stock, which includes the full exercise of the underwriter's overallotment option. Net proceeds from the offering were approximately $10.8 million. Cash and cash equivalents as of June 30, 2023 were $11.5 million.

- Hosted a virtual R&D and Investor Day on June 14, 2023, focusing on the cardiogenic shock market, including company strategy and upcoming milestones for lead compound istaroxime.

- The European Patent Office granted Patent No. 3599243, providing patent coverage for the dual mechanism SERCA2a activator class of drug candidates. The new patent, titled "17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE," is expected to provide patent protection until July 2038 for the family of compounds with a dual mechanism of action.

- Announced Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for its patent application covering the Company's dual mechanism SERCA2a Activators. A notice of allowance is issued by the USPTO to indicate that the application has passed examination.

- Appointed Mark Strobeck, Ph.D. to the Board of Directors. Dr. Strobeck brings over 20 years of operating, business development, capital raising and investing experience in the life sciences industry for both private and public biotechnology companies. Dr. Strobeck currently serves as President and Chief Executive Officer of Rockwell Medical, Inc., a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management.

Select Second Quarter 2023 Financial Results

- For the second quarter ended June 30, 2023, the Company reported an operating loss of $6.8 million, compared to an operating loss of $17.5 million in the second quarter of 2022. Included in the operating loss for the second quarter of 2023 is non-cash expense of $2.6 million related to the impairment of goodwill. Included in operating loss for the second quarter of 2022 is non-cash expense of $11.6 million related to the impairment of goodwill.

- Research and development expenses were $1.8 million for the second quarter of 2023, compared to $3.0 million for the second quarter of 2022. The decrease in research and development expenses is primarily due to (i) a decrease of $0.8 million related to the KL4 surfactant platform as the Company continues to focus its resources on the development of its istaroxime pipeline; (ii) a decrease of $0.3 million following the completion of enrollment in the SEISMiC study in March 2022; and (iii) a decrease of $0.1 million for expenditures related to the development of istaroxime for AHF primarily due to toxicology studies that were completed in 2022.

- General and administrative expenses for the second quarter of 2023 were $2.4 million, compared to $2.9 million for the second quarter of 2022. The decrease in general and administrative expenses is primarily due to (i) a decrease of $0.3 million in non-cash stock-based compensation expense as we have not granted equity to employees as of June 2023; (ii) a decrease of $0.2 million in incentive bonus expense; (iii) a decrease of $0.1 million in personnel costs; and (iv) a decrease of $0.1 million in insurance costs; partially offset by (v) an increase of $0.2 million in professional fees.

- The Company reported a net loss of $6.6 million ($1.64 per basic share) on 4.0 million weighted-average common shares outstanding for the quarter ended June 30, 2023, compared to a net loss of $17.3 million ($29.68 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2022.

- As of June 30, 2023, the Company reported cash and cash equivalents of $11.5 million, which is expected to be sufficient to support our development activities and fund our business operations through the first quarter of 2024.

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, 2023, which will be filed with the Securities and Exchange Commission on August 7, 2023, and includes detailed discussions about the Company's business plans and operations, financial condition, and results of operations.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is advancing late-stage interventions for cardiovascular disorders to treat patients in moments of crisis. Using new scientific and clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate, istaroxime, being developed as a first-in-class treatment for acute heart failure and for early cardiogenic shock. Windtree's heart failure platform includes follow-on pre-clinical SERCA2a activator assets as well. In pulmonary care, Windtree has focused on facilitating the transfer of the KL4 surfactant platform, to its licensees, Lee's Pharmaceutical (HK) Ltd. and Zhaoke Pharmaceutical (Hefei) Co. Ltd. Included in Windtree's portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

Forward Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company 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 economic and social consequences of the COVID-19 pandemic, including any adverse impact on the Company's clinical trials, clinical trial timelines or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime 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, and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the U.S. Food and Drug Administration 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 that the Company may never realize the value of its intangible assets and have to incur future impairment charges; 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; the rate and degree of market acceptance of the Company's product candidates, if approved; and the impacts of political unrest, including as a result of geopolitical tension, including the conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan), and any sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries which could have an adverse impact on the Company's operations, including through disruption in supply chain or access to potential international clinical trial sites, and through disruption, instability and volatility in the global markets, which could have an adverse impact on the Company's ability to access the capital markets. These and other risks are described in the Company's periodic reports, including its 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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+++++ Tables to Follow +++++

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,467	$ 6,172
Prepaid expenses and other current assets	1,852	1,205
Total current assets	13,319	7,377
Property and equipment, net	216	262
Restricted cash	150	154
Operating lease right-of-use assets	1,640	1,853
Intangible assets	25,250	25,250
Goodwill	-	3,058
Total assets	$ 40,575	$ 37,954
LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 964	$ 249
Accrued expenses	1,731	1,552
Operating lease liabilities - current portion	399	404
Loans payable	700	252
Total current liabilities	3,794	2,457
Operating lease liabilities - non-current portion	1,397	1,624
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	4,980	5,061
Total liabilities	28,971	27,942
Mezzanine Equity:		
Series A redeemable preferred stock, $0.001 par value; 0 and 40,000 shares authorized; 0 and 38,610.119 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	-	-
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 and 4,960,000 shares authorized; 0 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2023 and December 31, 2022; 5,148,220 and 772,203 shares issued at June 30, 2023 and December 31, 2022, respectively; 5,148,219 and 772,202 shares outstanding at June 30, 2023 and December 31, 2022, respectively	5	-
Additional paid-in capital	849,897	837,598
Accumulated deficit	(835,244)	(824,532)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	11,604	10,012
Total liabilities, mezzanine equity & stockholders' equity	$ 40,575	$ 37,954

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Expenses:				
Research and development	$ 1,763	$ 2,995	$ 3,178	$ 8,340
General and administrative	2,420	2,907	4,712	5,895
Loss on impairment of goodwill	2,574	11,636	3,058	11,636
Total operating expenses	6,757	17,538	10,948	25,871
Operating loss	(6,757)	(17,538)	(10,948)	(25,871)
Other income (expense):				
Interest income	108	17	152	18
Interest expense	(13)	(13)	(25)	(26)
Other income, net	61	201	109	419
Total other income, net	156	205	236	411
Net loss	$ (6,601)	$ (17,333)	$ (10,712)	$ (25,460)
Net loss per common share				
Basic and diluted	$ (1.64)	$ (29.68)	$ (4.36)	$ (44.28)
Weighted average number of common shares outstanding				
Basic and diluted	4,030	584	2,455	575