



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

November 9, 2023

WARRINGTON, Pa., Nov. 09, 2023 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2023 and provided key business updates.

"During the third quarter, we initiated our plan to move the istaroxime program in cardiogenic shock to Phase 3 readiness by advancing two clinical trials. First, we began building upon the positive data from the SEISMiC study by progressing the SEISMiC Extension Study for dose optimization in U.S., Europe and Latin American countries and sites. Additionally, we continued to progress 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. "Additionally, this quarter noted progress with our next generation, dual mechanism SERCA2a activators, including additional research and the awarding by the U.S. Patent and Trademark Office of a new composition of matter patent. Beyond multiple development activities, we are engaged in business development discussions. This is a busy time for Windtree, and over this and the next few quarters, we expect to deliver several milestones and events."

### Key Business Updates

- Progressed study and research site startup activities and regulatory filings in the U.S., Europe, and Latin America for both the SEISMiC Extension Study and the SCAI Stage C Study for istaroxime in cardiogenic shock.
- In August 2023, the Company announced that the United States Patent and Trademark Office issued US Patent No. 11,730,746 providing patent coverage for the dual mechanism SERCA2a Activators. The new composition of matter patent, titled: "17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE," provides patent protection through late 2039.
- Company management recently attended several investor conferences including the Dawson James Small Cap Growth Conference; and the ThinkEquity Conference; and participated in a panel discussion titled, "Cardiac Kids: Late-Stage Advancement for Cardiovascular Disorders," at the Lytham Partners Fall 2023 Investor Conference.
- Cash and cash equivalents as of September 30, 2023 were \$7.4 million.

### Select Third Quarter 2023 Financial Results

For each of the quarters ended September 30, 2023 and 2022, the Company reported an operating loss of \$4.7 million. Included in operating loss for the third quarter of 2022 is non-cash expense of \$0.5 million related to the impairment of goodwill.

Research and development expenses were \$2.1 million for the third quarter of 2023, compared to \$1.5 million for the third quarter of 2022. The increase in research and development expenses is primarily due to (i) an increase of \$0.6 million due to the initiation of the SEISMiC Extension study during the third quarter of 2023 and planning and start-up costs for the potential study of istaroxime in more severe SCAI Stage C cardiogenic shock; and (ii) a \$0.6 million reversal of royalty expense in the third quarter of 2022 related to the KL4 surfactant platform; partially offset by (iii) a decrease of \$0.4 million in personnel costs related to reductions in headcount; (iv) a decrease of \$0.1 million related to the KL4 surfactant platform as the Company continues to focus its resources on the development of its istaroxime pipeline; and (v) a decrease of \$0.1 million in non-cash stock-based compensation expense.

General and administrative expenses for the third quarter of 2023 were \$2.6 million, compared to \$2.7 million for the third 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 due to the timing of equity grants during 2023 compared to 2022; (ii) a decrease of \$0.2 million in personnel costs due to headcount reductions; (iii) a decrease of \$0.2 million in incentive bonus expense; and (iv) a decrease of \$0.1 million in insurance costs; partially offset by (v) an increase of \$0.4 million in severance expense related to a former executive; and (vi) an increase of \$0.3 million in professional fees.

The Company reported a net loss of \$4.4 million (\$0.86 per basic share) on 5.1 million weighted-average common shares outstanding for the quarter ended September 30, 2023, compared to a net loss of \$4.1 million (\$6.51 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2022.

As of September 30, 2023, the Company reported cash and cash equivalents of \$7.4 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 September 30, 2023, which will be filed with the Securities and Exchange Commission on November 9, 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 and the evolving events in Israel and Gaza, 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 the evolving events in Israel and Gaza, 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](http://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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### WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES Consolidated Balance Sheets

*(in thousands, except share and per share data)*

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 7,365	\$ 6,172
Prepaid expenses and other current assets	<u>1,543</u>	<u>1,205</u>
Total current assets	8,908	7,377
Property and equipment, net	205	262
Restricted cash	150	154
Operating lease right-of-use assets	1,544	1,853
Intangible assets	25,250	25,250
Goodwill	<u>-</u>	<u>3,058</u>
Total assets	\$ 36,057	\$ 37,954
<b>LIABILITIES, MEZZANINE EQUITY &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 944	\$ 249
Accrued expenses	1,859	1,552

Operating lease liabilities - current portion	439	404
Loans payable	467	252
Total current liabilities	3,709	2,457
Operating lease liabilities - non-current portion	1,251	1,624
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	4,813	5,061
Total liabilities	28,573	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 September 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 September 30, 2023 and December 31, 2022, respectively	-	-
Common stock, \$0.001 par value; 120,000,000 shares authorized at September 30, 2023 and December 31, 2022; 5,148,220 and 772,203 shares issued at September 30, 2023 and December 31, 2022, respectively; 5,148,219 and 772,202 shares outstanding at September 30, 2023 and December 31, 2022, respectively	5	-
Additional paid-in capital	850,202	837,598
Accumulated deficit	(839,669)	(824,532)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	7,484	10,012
Total liabilities, mezzanine equity & stockholders' equity	\$ 36,057	\$ 37,954

**WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Operations**

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expenses:				
Research and development	\$ 2,110	\$ 1,543	\$ 5,288	\$ 9,883
General and administrative	2,580	2,653	7,292	8,548
Loss on impairment of goodwill	-	454	3,058	12,090
Total operating expenses	4,690	4,650	15,638	30,521
Operating loss	(4,690)	(4,650)	(15,638)	(30,521)
Other income (expense):				
Interest income	112	39	264	57
Interest expense	(13)	(14)	(38)	(40)
Other income, net	166	569	275	988
Total other income, net	265	594	501	1,005
Net loss	\$ (4,425)	\$ (4,056)	\$ (15,137)	\$ (29,516)
Net loss per common share				
Basic and diluted	\$ (0.86)	\$ (6.51)	\$ (4.50)	\$ (49.94)
Weighted average number of common shares outstanding				
Basic and diluted	5,148	623	3,363	591



Source: Windtree Therapeutics