Windtree Therapeutics Reports Fourth Quarter and Year-End 2022 Financial Results and Provides Key Business Updates

April 3, 2023

WARRINGTON, Pa., April 03, 2023 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for cardiovascular disorders, today reported financial results for the fourth quarter and fiscal year ended December 31, 2022 and provided key business updates.

"We continued to advance our cardiovascular platform during the fourth quarter of 2022 and early 2023 with study start up preparations for the istaroxime SEISMiC extension study in early cardiogenic shock, new patent issuances for istaroxime, new publications, and data presentations at scientific conferences," said Craig Fraser, President and Chief Executive Officer of Windtree. "We believe all these activities reflect the quality of the science, data, and opportunity with istaroxime and our next generation SERCA2a activators. We look forward to executing the extension study and planning for a potential Phase 3 study. Additionally, we have significantly reduced our company expenses and cash burn to create a leaner, capital-efficient organization while supporting our development programs. We remain focused on addressing our capital needs by exploring options for financing, as well as actively engaging in business development activities, including both licensing and strategic."

Key Business Update

- Issued a new patent for istaroxime that provides expanded patent coverage for istaroxime administration. The new U.S. patent, entitled: "*Istaroxime-Containing intravenous formulation for the treatment of acute heart failure (AHF)*," is a continuing patent following the expedited U.S. Track One filing by Windtree. The claims of the newly issued patent cover longer durations of istaroxime infusion for improved outcomes in treatment of acute heart failure. In particular, the claims are directed to an improvement in diastolic heart function following administration of istaroxime by intravenous infusion for 6 hours or more, which the Company attributes to the SERCA2a mechanism of action of istaroxime and its metabolites. Istaroxime is the Company's investigational drug candidate being studied in early cardiogenic shock and acute heart failure.

- Announced the publication of "*Istaroxime Metabolite PST3093 Selectively Stimulates SERCA2a and Reverses Disease-induced Changes in Cardiac Function*," in the Journal of Pharmacology and Experimental Therapeutics. The paper characterizes the pharmacokinetic and pharmacodynamic effects of PST3093, a pure SERCA2a activator and terminal metabolite of istaroxime. The paper describes pathophysiologic changes in SERCA2a activity and calcium distribution that occur in heart failure and how SERCA2a activation may reverse those effects and improve calcium handling in cardiac cells. Calcium abnormalities contribute to risk for arrhythmias and impaired cardiac muscle contractility/relaxation. The paper also explains why the effects of istaroxime may persist beyond the duration of the infusion because of the SERCA2a effect from PST3093. This data provides a foundation for the Company's preclinical family of assets that are selective for activation of SERCA2a.

- Presented two istaroxime presentations at the 2023 Technology and Heart Failure Therapeutics (THT) Conference held on March 20-22, 2023, in Boston, MA. The first presentation was on the istaroxime Phase 2 data in decompensated heart failure and early cardiogenic shock by Professor Alex Mebazaa, MD, PhD, FESC, Hôpital Lariboisière, Paris, France. The second presentation was an abstract and scientific presentation entitled: "*Safety and Efficacy of Istaroxime 1.0 and 1.5 mg/kg/min for Patients with Pre Cardiogenic Shock*." The data presented are from the Company's Phase 2 SEISMiC study, an international randomized, double-blind, placebo-controlled study that enrolled 60 patients to evaluate istaroxime for the treatment of early cardiogenic shock due to severe heart failure with SBP between 75-90 mmHg. The study met its primary endpoint, which was the difference in SBP area under the curve over six hours after initiating the infusion, with the pooled istaroxime treated group performing significantly better compared to the control group ($p=0.017$) and persisted through the 24-hour SBP profile measurement. Two target doses of istaroxime were studied compared to placebo. The data presented characterized the differences between doses and highlighted the favorable profile of the 1.0 µg/kg/min dose group on cardiovascular physiology, biomarkers and safety.

- Announced the results from a recently completed market study demonstrating the need and opportunity to address the very high costs associated with cardiogenic shock. The research showed that in 2020 the U.S. average cardiogenic shock patient length of stay in the hospital was 19.6 days with a median of 10 days. Additionally, the resources required to take care of these patients are substantial, with patients frequently requiring costly ICU or CCU care. The istaroxime program will be collecting and analyzing both clinical and pharmacoeconomic related data in the pursuit of addressing this significant need.

- Raised approximately $1.0 million in gross proceeds from the exercise of previously issued warrants in connection with warrant inducement offer letters with certain of the Company's warrant holders, and the issuance of new warrants to such warrant holders.

Select Fourth Quarter 2022 Financial Results

- Research and development expenses were $1.2 million for the fourth quarter of 2022, compared to $4.5 million for the fourth quarter of 2021. The decrease in research and development expenses was primarily due to (i) a decrease of $2.1 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 $0.5 million following the completion of enrollment in the SEISMiC study in March 2022; (iii) a decrease of $0.4 million for expenditures related to the development of istaroxime for AHF primarily due to toxicology studies performed in 2021; and (iv) a decrease of $0.3 million in non-cash stock-based compensation expense due to granting two option grants to employees during 2021 compared to one option grant in 2022.

- General and administrative expenses for the fourth quarter of 2022 were $2.2 million, compared to $3.0 million for the fourth quarter of 2021. The decrease in general and administrative expenses is primarily due to (i) a decrease of $0.5 million in personnel costs and (ii) a decrease of $0.4 million in non-cash, stock-based compensation expense due to granting two option grants to employees during 2021 compared to one option grant in 2022.

- For the fourth quarter ended December 31, 2022, the Company reported an operating loss of $10.8 million, compared to an operating loss of $14.7 million in the fourth quarter of 2021. Included in operating loss for the fourth quarter of 2022 is non-cash expense of $6.8 million related to the impairment of the Company's rostafuroxin intangible asset and non-cash expense of $0.5 million related to the impairment of goodwill. Included in operating loss for the fourth quarter of 2021 is non-cash expense of $7.3 million related to the impairment of our rostafuroxin intangible asset.

- The Company reported a net loss of $9.7 million ($13.01 per basic share) on 0.7 million weighted-average common shares outstanding for the quarter ended December 31, 2022, compared to a net loss of $13.1 million ($23.22 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2021.

Select 2022 Year-End Financial Results

- Research and development expenses were $11.1 million for the year ended December 31, 2022, compared to $17.8 million for the year ended December 31, 2021. The decrease in research and development expenses is primarily due to (i) a decrease of $4.0 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 $2.0 million in non-cash stock-based compensation expense due to granting two option grants to employees during 2021 compared to one option grant in 2022; and (iii) a decrease of $0.8 million for expenditures related to the development of istaroxime for AHF primarily due to toxicology studies performed in 2021.

- General and administrative expenses for the year ended December 31, 2022 were $10.8 million, compared to $14.5 million for the year ended December 31, 2021. The decrease in general and administrative expenses is primarily due to (i) a decrease of $2.0 million in non-cash, stock-based compensation expense due to granting two option grants to employees during 2021 compared to one option grant in 2022 and (ii) a decrease of $1.6 million in professional fees.

- For the year ended December 31, 2022, the Company reported an operating loss of $41.3 million, compared to an operating loss of $77.3 million for the year ended December 31, 2021. Included in operating loss for the year ended December 31, 2022 is non-cash expense of $12.6 million related to the impairment of goodwill and non-cash expense of $6.8 million related to the impairment of our rostafuroxin intangible asset. Included in operating loss for the year ended December 31, 2021 is non-cash expense of $45.0 million related to the impairment of our rostafuroxin intangible asset.

- The Company reported a net loss of $39.2 million ($62.23 per basic share) on 0.6 million weighted-average common shares outstanding for the year ended December 31, 2022, compared to a net loss of $67.6 million ($136.64 per basic share) on 0.5 million weighted average common shares outstanding for the comparable period in 2021.

- As of December 31, 2022, the Company reported cash and cash equivalents of $6.2 million, which is expected to be sufficient to fund operations into the second quarter of 2023.

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, 2022, which will be filed with the Securities and Exchange Commission on March 31, 2023, and 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 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 oral 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: changes in market conditions, general economic conditions, and the banking sector, and potential constraints in the Company's ability to access capital or credit if and when needed with favorable terms, if at all; 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 related to the plans of our AEROSURF and KL4 licensees and their ability to successfully execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialize the licensed product candidates; 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 or result in the need for additional clinical trials, 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 goodwill 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; and the rate and degree of market acceptance of the Company's product candidates, if approved; 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 and subsequent 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:
Monique Kosse
LifeSci Advisors
212.915.3820 or monique@lifesciadvisors.com

+++++ Tables to Follow +++++

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,172	$ 22,348
Prepaid expenses and other current assets	1,205	1,143
Total current assets	7,377	23,491
Property and equipment, net	262	1,011
Restricted cash	154	154
Operating lease right-of-use assets	1,853	2,381
Intangible assets	25,250	32,070
Goodwill	3,058	15,682
Total assets	$ 37,954	$ 74,789

LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable	$ 249	$ 693
Accrued expenses	1,552	3,408
Operating lease liabilities - current portion	404	528
Loans payable - current portion	252	294
Total current liabilities	2,457	4,923
Operating lease liabilities - non-current portion	1,624	2,071
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	5,061	7,114
Total liabilities	27,942	32,908
Mezzanine Equity:		
Series A redeemable preferred stock, $0.001 par value; 40,000 and 0 shares authorized; 38,610.119 and 0 shares issued and outstanding at December 31, 2022 and 2021, respectively	-	-
Stockholders' Equity:		
Preferred stock, $0.001 par value; 4,960,000 and 5,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2022 and 2021, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized; 772,203 and 565,379 shares issued at December 31, 2022 and 2021, respectively; 772,202 and 565,378 shares outstanding at December 31, 2022 and 2021, respectively	-	-
Additional paid-in capital	837,598	830,259
Accumulated deficit	(824,532)	(785,324)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	10,012	41,881
Total liabilities, mezzanine equity & stockholders' equity	$ 37,954	$ 74,789

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Expenses:				
Research and development	$ 1,216	$ 4,476	$ 11,099	$ 17,787
General and administrative	2,242	2,966	10,790	14,473
Loss on impairment of goodwill	534	-	12,624	-
Loss on impairment of intangible assets	6,820	7,250	6,820	45,020
Total operating expenses	10,812	14,692	41,333	77,280
Operating loss	(10,812)	(14,692)	(41,333)	(77,280)
Other income (expense):				
Interest income	52	1	109	91
Interest expense	(13)	(13)	(53)	(114)
Other expense, net	(286)	(24)	702	(320)
Total other income (expense), net	(247)	(36)	758	(343)
Loss before income taxes	(11,059)	(14,728)	(40,575)	(77,623)
Deferred income tax benefit	1,367	1,655	1,367	9,987
Net loss	$ (9,692)	$ (13,073)	$ (39,208)	$ (67,636)
Net loss per common share				

Basic and diluted	$ (13.01)	$ (23.22)	$ (62.23)	$ (136.64)
Weighted average number of common shares outstanding				
Basic and diluted	745	563	630	495

Source: Windtree Therapeutics