Windtree Therapeutics Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Key Business Updates

March 31, 2022

WARRINGTON, Pa., March 31, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today reported financial results for the fourth quarter and year ended December 31, 2021 and provided key business updates.

“This past quarter caps a very productive year for Windtree with progress towards multiple value-creating milestones, making for an exciting 2022. We are pleased to have successfully completed enrollment in our phase 2 study of istaroxime, our lead clinical program in early cardiogenic shock, and plan to announce topline data in April 2022. Cardiogenic shock represents a great opportunity for Windtree. It has significant unmet need, a potentially supportive scale and a regulatory pathway for development,” said Craig Fraser, President and Chief Executive Officer of Windtree. “We also continued with study preparations for additional development with istaroxime, including a planned extension to the early cardiogenic shock study and start-up activities for the next acute heart failure (AHF) trial that will build upon previous, positive phase 2 data.”

Key Business and Financial Updates

- Completed enrollment in the Company’s phase 2 study of istaroxime in early cardiogenic shock. The study is an international, randomized, double-blind, placebo-controlled study in 60 patients designed to assess the efficacy and safety of istaroxime in patients in early cardiogenic shock caused by heart failure and to support an intended pathway for development to an indication for use in cardiogenic shock. Topline data from the study is expected to be announced in April.

- Advanced plans and preparation for an extension study to the early cardiogenic shock trial to characterize the physiology associated with longer and titrated istaroxime dosing as well as to increase understanding of the effects and potential benefits associated with SERCA2a activation, one of the key mechanisms of action for istaroxime.

- Initiated and progressed study start-up activities to continue the development of istaroxime for the treatment of AHF with an additional phase 2b clinical trial that builds upon previous positive phase 2a and phase 2b results. Once fully funded, the study will focus on treating AHF patients with low blood pressure (who also tend to be diuretic resistant) as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and blood pressure while maintaining or improving renal function. This trial will also collect data on measures that may serve as primary endpoints in a phase 3 clinical trial, and will optimize the dosing regimen, potentially extending the infusion time beyond 24 hours.

- Completed enrollment and announced results for the Company’s phase 2 single-arm study of lucinactant (KL4 surfactant) designed to evaluate the safety and tolerability of lucinactant delivered as a liquid via the endotracheal tube in 20 patients who were mechanically ventilated due to COVID-19 associated lung injury and severe ARDS. The study demonstrated that intratracheal administration of reconstituted lyophilized lucinactant was generally safe and well tolerated with stable to improved oxygenation and other physiological parameters after dosing, supporting the feasibility of this approach to develop a potential treatment for critically ill patients with ARDS due to COVID-19 and other causes.

- Announced U.S. Patent and Trademark Office issuance of istaroxime patent (U.S. Patent No. 1197869), covering the intravenous delivery of istaroxime for the treatment of AHF. The patent, titled “Istaroxime-Containing Intravenous Formulation for the Treatment of Acute Heart Failure,” covers longer infusion durations of istaroxime for improved outcomes in the treatment of AHF. The patent provides intellectual property protection through late 2039.

Select Financial Results for the Fourth Quarter ended December 31, 2021

For the fourth quarter ended December 31, 2021, the Company reported an operating loss of $14.7 million, which includes non-cash expense of $7.2 million related to the impairment of our rostafuroxin intangible asset, compared to an operating loss of $7.0 million in the fourth quarter of 2020.

Research and development expenses were $4.5 million for the fourth quarter of 2021, compared to $3.5 million for the fourth quarter of 2020. The increase in research and development expenses is primarily due to an increase of $0.9 million for the clinical activity and development of istaroxime in early cardiogenic shock and acute heart failure.

General and administrative expenses for the fourth quarter of 2021 were $3.0 million, compared to $3.4 million for the fourth quarter of 2020. The

decrease in general and administrative expenses is primarily due to a decrease of $0.6 million in professional fees.

The Company reported a net loss of $13.1 million ($0.46 per basic share) on 28.2 million weighted-average common shares outstanding for the quarter ended December 31, 2021, compared to a net loss of $7.5 million ($0.44 per basic share) on 16.9 million weighted average common shares outstanding for the comparable period in 2020.

Select Financial Results for the Year ended December 31, 2021

For the year ended December 31, 2021, the Company reported an operating loss of $77.3 million, which includes non-cash expense of $45.0 million related to the impairment of our rostafuroxin intangible asset, compared to an operating loss of $30.3 million for the year ended December 31, 2020.

Research and development expenses were $17.8 million for the year ended December 31, 2021, compared to $15.4 million for the year ended December 31, 2020. The increase in research and development expenses is primarily due to (i) an increase of $2.0 million for the recently completed clinical study of istaroxime for early cardiogenic shock and the continued development of istaroxime for AHF; and (ii) an increase of $1.1 million related to personnel and non-cash, stock compensation expense; partially offset by (iii) a decrease of $0.5 million related to the KL4 surfactant platform.

General and administrative expenses for the year ended December 31, 2021 were $14.5 million, compared to $14.9 million for the year ended December 31, 2020. The decrease in general and administrative expenses is primarily due to a decrease of $0.8 million in severance costs and a decrease of $0.4 million in professional fees, partially offset by an increase of $0.7 million in non-cash, stock compensation expense.

The Company reported a net loss of $67.6 million ($2.73 per basic share) on 24.8 million weighted-average common shares outstanding for the year ended December 31, 2021, compared to a net loss of $32.6 million ($2.08 per basic share) on 15.7 million weighted average common shares outstanding for the comparable period in 2020.

As of December 31, 2021, the Company reported cash and cash equivalents of $22.3 million. As of March 31, 2022, we believe that we have sufficient cash resources to provide runway into the first 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, 2021, which will be filed with the Securities and Exchange Commission on March 31, 2021, 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 acute pulmonary 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 clinical development of AEROSURF®, to its licensee in Asia, Lee's HK. 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 ongoing 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, KL4 surfactant and the Company's other product candidates; the impacts of political unrest, including as a result geopolitical tension, including escalation in the conflict between Russia and Ukraine and any additional resulting 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; 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 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; 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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WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,348	$ 16,930
Prepaid expenses and other current assets	1,143	1,188
Total current assets	23,491	18,118
Property and equipment, net	1,011	924
Restricted cash	154	154
Operating lease right-of-use assets	2,381	917
Intangible assets	32,070	77,090
Goodwill	15,682	15,682
Total assets	$ 74,789	$ 112,885
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 693	$ 1,161
Accrued expenses	3,408	3,813
Operating lease liabilities - current portion	528	805
Loans payable - current portion	294	352
Total current liabilities	4,923	6,131
Operating lease liabilities - non-current portion	2,071	201
Loans payable - non-current portion	-	2,423
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	2,800
Deferred tax liabilities	7,114	16,778
Total liabilities	32,908	43,333
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2021 and 2020	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at December 31, 2021 and 2020; 28,268,950 and 16,921,506 shares issued at December 31, 2021 and 2020, respectively; 28,268,926 and 16,921,482 shares outstanding at December 31, 2021 and 2020, respectively	28	17
Additional paid-in capital	830,231	790,277
Accumulated deficit	(785,324)	(717,688)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	41,881	69,552
Total liabilities & stockholders' equity	$ 74,789	$ 112,885

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except per share data)

	Year Ended December 31,	
	2021	2020
Expenses:		
Research and development	17,787	15,373
General and administrative	14,473	14,944
Loss on impairment of intangible assets	45,020	-
Total operating expenses	77,280	30,317
Operating loss	(77,280)	(30,317)
Other income (expense):		
Interest income	91	122
Interest expense	(114)	(125)
Other (expense), net	(320)	(2,246)
Total other (expense), net	(343)	(2,249)
Loss before income taxes	(77,623)	(32,566)
Deferred income tax benefit	9,987	-
Net loss	$ (67,636)	$ (32,566)
Net loss per common share		
Basic and diluted	$ (2.73)	$ (2.08)
Weighted average number of common shares outstanding		
Basic and diluted	24,760	15,654

Source: Windtree Therapeutics