Windtree Therapeutics Reports Third Quarter 2021 Financial Results and Provides Key Business Updates

November 10, 2021

WARRINGTON, Pa., Nov. 10, 2021 (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 third quarter ended September 30, 2021 and provided key business updates.

"I am very pleased to report on another productive quarter for Windtree. We continue to make progress with istaroxime, our lead clinical product candidate, and are focused on completing our phase 2 global study for the treatment of early cardiogenic shock, where we plan to announce topline data in Q1 2022. The need for new critical care cardiovascular therapies was clearly articulated during our KOL event held in October as well as in market research, and we believe istaroxime has the potential to be a meaningful new therapeutic innovation. The team is also busy preparing for the next study in our foundational program, acute heart failure with istaroxime. Concurrently, we are advancing an open-label phase 2 study of lucinactant (KL4) in patients with COVID-19 associated acute respiratory distress syndrome (ARDS) and anticipate topline data from this study in Q1 2022," said Craig Fraser, President and Chief Executive Officer of Windtree. "Our business development group continues to be very active as we explore opportunities and engage with potential partners. Our balance sheet provides sufficient support of our upcoming clinical and regulatory milestones as well as company operations through 2022."

Key Business and Financial Updates

- Hosted Key Opinion Leader (KOL) webinar on istaroxime for the treatment of acute heart failure and the upcoming data in early cardiogenic shock, featuring a presentation by John Teerlink, M.D., University of California, San Francisco. Dr. Teerlink presented the current treatment landscape, highlighted the unmet medical need in treating patients with acute heart failure, and discussed the potential role for istaroxime based on clinical data he presented. Management followed with a presentation covering the clinical development program for istaroxime in early cardiogenic shock, which is currently in a phase 2 global study with data expected in the first quarter of 2022.

- Continued executing the Company's lead program for istaroxime in the treatment of patients in early cardiogenic shock due to heart failure. These patients are characterized by very low blood pressure and risk for hypo-perfusion to critical organs. The ongoing phase 2 global study is designed to build upon data which showed istaroxime improved cardiac function and dose-related increases in systolic blood pressure in acute heart failure patients.

- Shared results from a U.S. physician survey and market research estimating that the worldwide total market value of cardiogenic shock is $1.25 billion. In the survey results, 99 out of 100 U.S.-based cardiologists responded that there was high need for pharmacologic (drug) treatment for early cardiogenic shock patients. Additionally, 84% of the cardiologists responded that for early cardiogenic shock patients they would be "likely to extremely likely" to use a drug with the observed characteristics of istaroxime.

- Announced that the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance of new patent claims for istaroxime administration. A notice of allowance is issued by the USPTO to indicate that the application has passed examination. When the new patent is issued by the USPTO, it will provide new intellectual property protection for istaroxime until late 2039.

- Presented a corporate overview at the Oppenheimer Fall Healthcare Life Sciences and MedTech Summit.

Select Financial Results for the Third Quarter ended September 30, 2021

For the third quarter ended September 30, 2021, the Company reported an operating loss of $8.1 million, compared to an operating loss of $8.7 million in the third quarter of 2020.

Research and development expenses were $4.7 million for the third quarter of 2021, compared to $3.9 million for the third quarter of 2020. The increase in research and development expenses is primarily due to an increase of $0.6 million for the clinical activity and development of istaroxime in early cardiogenic shock and acute heart failure.

General and administrative expenses for the third quarter of 2021 were $3.5 million, compared to $4.8 million for the third quarter of 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 $0.6 million in professional fees.

The Company reported a net loss of $8.2 million ($0.31 per basic share) on 26.7 million weighted-average common shares outstanding for the quarter ended September 30, 2021, compared to a net loss of $9.0 million ($0.54 per basic share) on 16.6 million weighted average common shares outstanding for the comparable period in 2020.

As of September 30, 2021, the Company reported cash and cash equivalents of $24.5 million. During October 2021, the Company raised an additional $3.2 million through its At-The-Market (ATM) program. The Company's cash and cash equivalents as of September 30, 2021 and the additional funding from the ATM program are expected to be sufficient to fund operations through at least the next twelve months.

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, 2021, which will be filed with the Securities and Exchange Commission on November 10, 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. Windtree is also evaluating KL4 surfactant for the treatment of acute respiratory distress syndrome in COVID-19 patients. Included in Windtree's portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

For more information, please visit the Company's website at www.windtreetx.com.

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 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
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 24,541	$ 16,930
Prepaid expenses and other current assets	1,826	1,188
Total current assets	26,367	18,118

Property and equipment, net	890	924
Restricted cash	154	154
Operating lease right-of-use assets	2,412	917
Intangible assets	39,320	77,090
Goodwill	15,682	15,682
Total assets	$ 84,825	$ 112,885
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 582	$ 1,161
Accrued expenses	3,549	3,813
Operating lease liabilities - current portion	278	805
Loans payable - current portion	734	352
Total current liabilities	5,143	6,131
Operating lease liabilities - non-current portion	2,196	201
Loans payable - non-current portion	-	2,423
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,600	2,800
Deferred tax liabilities	8,707	16,778
Total liabilities	34,646	43,333
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at September 30, 2021 and December 31, 2020; 26,704,480 and 16,921,506 shares issued at September 30, 2021 and December 31, 2020, respectively; 26,704,456 and 16,921,482 shares outstanding at September 30, 2021 and December 31, 2020, respectively	27	17
Additional paid-in capital	825,457	790,277
Accumulated deficit	(772,251)	(717,688)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	50,179	69,552
Total liabilities & stockholders' equity	$ 84,825	$ 112,885

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expenses:				
Research and development	$ 4,680	$ 3,882	$ 13,311	$ 11,838
General and administrative	3,467	4,823	11,507	11,518
Loss on impairment of intangible assets	-	-	37,770	-
Total operating expenses	8,147	8,705	62,588	23,356
Operating loss	(8,147)	(8,705)	(62,588)	(23,356)
Other income (expense):				
Interest income	1	21	90	115
Interest expense	(14)	(46)	(101)	(121)
Other (expense), net	(53)	(290)	(296)	(1,750)
Total other (expense), net	(66)	(315)	(307)	(1,756)

Loss before income taxes	(8,213)	(9,020)	(62,895)	(25,112)
Deferred income tax benefit	-	-	8,332	-
Net loss	$ (8,213)	$ (9,020)	$ (54,563)	$ (25,112)
Net loss per common share				
Basic and diluted	$ (0.31)	$ (0.54)	$ (2.31)	$ (1.65)
Weighted average number of common shares outstanding				
Basic and diluted	26,704	16,579	23,616	15,228

Source: Windtree Therapeutics