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

August 5, 2021

WARRINGTON, Pa., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today reported financial results for the second quarter ended June 30, 2021 and provided key business updates.

“I am pleased with the progress we have made this quarter across multiple fronts. We are on track with istaroxime, our lead clinical product candidate, as we continue to enroll patients in our phase 2 global study for the treatment of early cardiogenic shock. We are also advancing study start up activities for the next trial with istaroxime in acute heart failure that will build upon our two previous successful phase 2 trials. Our second current active clinical program is a phase 2 study of lucinactant in patients with COVID-19 associated lung injury and Acute Respiratory Distress Syndrome,” said Craig Fraser, President and Chief Executive Officer of Windtree. “With data in both phase 2 trials expected later this year, we are preparing for these important potential value inflection readouts. In addition, we are actively engaging with potential partners and remain opportunistic about business development prospects. Our balance sheet is strong and leaves us well-capitalized to execute on our ongoing clinical and regulatory milestones.”

Key Business and Financial Updates

- Progressed in the Company’s lead program for istaroxime in the treatment of early cardiogenic shock due to heart failure characterized by very low blood pressure and risk for hypo-perfusion to critical organs. This study is designed to build upon the phase 2 program where data showed istaroxime to improve cardiac function and dose related increases in systolic blood pressure. The Company currently has 12 participating trial sites, with data anticipated in the fourth quarter of 2021.

- Continued advancement of clinical trial of lucinactant for the treatment of COVID-19 associated lung injury (COVID-19 ARDS, acute respiratory distress syndrome). Given the changing patterns of COVID-19 due to both vaccines and variants, the Company is expanding the study to include select sites in Argentina where case counts and the number of severe COVID-19 patients in respiratory failure are high. Data in this phase 2 study is anticipated in the fourth quarter of 2021.

- Continued to advance multiple business development activities, including exploring regional based licensing with istaroxime, specifically in Asia, to support clinical development costs and activities as well as with the SERCA2a activators globally for development in chronic heart failure.

- Through the process of engaging with potential licensees, the Company recognized that to secure an out-licensing deal for rostafuroxin, an additional small clinical study would need to be conducted. Given that rostafuroxin is outside the current focus for development and investment, the Company is seeking a partner to conduct the additional clinical trial in addition to out-licensing opportunities for this program. Consequently, the Company lowered its rostafuroxin intangible asset value as described below.

- Filed a Track One prioritized patent application with the U.S. Patent and Trademark Office for istaroxime, which was previously filed under the Patent Cooperation Treaty. Under the Track One program, the new istaroxime patent is expected to receive review and final disposition within a year of priority status being granted, rather than the customary three-year examination for non-prioritized examinations.

- Announced Diane Carman, Esq. as Senior Vice President and General Counsel. A veteran senior executive, Ms. Carman brings over two decades of successful experience working in the life sciences and other highly regulated industries.

- Presented at the Ladenburg Thalmann 2021 Healthcare Conference and Access to Giving Virtual Investor Conference.

Select Financial Results for the Second Quarter ended June 30, 2021

For the second quarter ended June 30, 2021, the Company reported an operating loss of $45.4 million, which includes a non-cash expense of $37.8 million on impairment of our rostafuroxin intangible asset, compared to an operating loss of $7.9 million in the second quarter of 2020.

Research and development expenses were $4.2 million for the second quarter of 2021, compared to $4.5 million for the second quarter of 2020. The decrease in research and development expenses is primarily due to active pharmaceutical ingredient costs incurred in the second quarter of 2020.

General and administrative expenses for the second quarter of 2021 were $3.4 million, compared to $3.5 million for the second quarter of 2020.

The Company reported a net loss of $37.4 million ($1.42 per basic share) on 26.4 million weighted-average common shares outstanding for the quarter ended June 30, 2021, compared to a net loss of $9.6 million ($0.63 per basic share) on 15.1 million weighted average common shares outstanding for the comparable period in 2020.

As of June 30, 2021, the Company reported cash and cash equivalents of $30.0 million, which is 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 June 30, 2021. The Form 10-Q which includes detailed discussions about the Company's business plans and operations, financial condition and results of operations will be filed with the Securities and Exchange Commission on August 5, 2021.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to treat patients in moments of crisis. Using new 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 early cardiogenic shock in heart failure. Windtree has also focused on developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, and is facilitating transfer of clinical development of AEROSURF® to its licensee in Asia, Lee's HK, while Windtree evaluates other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions including lung injury due to viral, chemical and radiation induced insults. Also, in its 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 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)

	June 30, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,965	$ 16,930
Prepaid expenses and other current assets	2,329	1,188
Total current assets	32,294	18,118

Property and equipment, net	834	924
Restricted cash	154	154
Operating lease right-of-use assets	2,581	917
Intangible assets	39,320	77,090
Goodwill	15,682	15,682
Total assets	$ 90,865	$ 112,885
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 288	$ 1,161
Accrued expenses	3,111	3,813
Operating lease liabilities - current portion	336	805
Loans payable - current portion	1,175	352
Total current liabilities	4,910	6,131
Operating lease liabilities - non-current portion	2,318	201
Loans payable - non-current portion	-	2,423
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,200	2,800
Deferred tax liabilities	8,674	16,778
Total liabilities	34,102	43,333
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2021 and December 31, 2020; 26,704,480 and 16,921,506 shares issued at June 30, 2021 and December 31, 2020, respectively; 26,704,456 and 16,921,482 shares outstanding at June 30, 2021 and December 31, 2020, respectively	27	17
Additional paid-in capital	823,828	790,277
Accumulated deficit	(764,038)	(717,688)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	56,763	69,552
Total liabilities & stockholders' equity	$ 90,865	$ 112,885

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Expenses:				
Research and development	$ 4,221	$ 4,495	$ 8,631	$ 7,956
General and administrative	3,371	3,453	8,040	6,695
Loss on impairment of intangible assets	37,770	-	37,770	-
Total operating expenses	45,362	7,948	54,441	14,651
Operating loss	(45,362)	(7,948)	(54,441)	(14,651)
Other income (expense):				
Interest income	39	5	89	94
Interest expense	(46)	(31)	(87)	(75)
Other (expense), net	(352)	(1,584)	(243)	(1,460)
Total other (expense), net	(359)	(1,610)	(241)	(1,441)
Loss before income taxes	(45,721)	(9,558)	(54,682)	(16,092)
Income tax benefit	8,332	-	8,332	-
Net loss	$ (37,389)	$ (9,558)	$ (46,350)	$ (16,092)
Net loss per common share				

Basic and diluted	$ (1.42)	$ (0.63)	$ (2.10)	$ (1.12)
Weighted average number of common shares outstanding				
Basic and diluted	26,350	15,091	22,047	14,394

Source: Windtree Therapeutics