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

May 14, 2021

WARRINGTON, Pa., May 13, 2021 /PRNewswire/ -- 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 first quarter ended March 31, 2021 and provided key business updates.

Key Business and Financial Updates

- Expanded the participating countries and sites in the Company's Phase 2 global clinical study of istaroxime for the treatment of Early Cardiogenic Shock in severe acute heart failure patients. Cardiogenic shock is a severe form of heart failure marked by critically low blood pressure. This study builds upon observations from the acute heart failure program and will assess the ability of istaroxime to improve blood pressure in these patients and is expected to be completed in the second half of 2021.

- Dosed the first patient in its Phase 2 clinical trial studying lucinactant, the Company's KL4 surfactant, in acute lung injury in adults with COVID-19 associated acute respiratory distress syndrome (ARDS). The study is designed to evaluate key safety and physiological measures and is expected to be completed in Q3 2021.

- Completed an equity financing raising approximately $30.0 million in gross proceeds during the first quarter of 2021, before deducting underwriting discounts and commissions and other estimated offering expenses. Net proceeds from the offering were approximately $27.4 million.

- Announced pursuit of additional expedited patent protection for our lead asset istaroxime with the filing of a Track One prioritized patent application with the U.S. Patent and Trademark Office for a patent stemming from an application 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.

- Extended the scientific collaboration with the University of Milan-Bicocca for further characterization and development of the Company's oral SERCA2a compounds for the potential treatment of chronic and acute human heart failure.

"With additional countries and sites opening and dosing patients in our Phase 2 global clinical study of istaroxime for the treatment of Early Cardiogenic Shock in severe acute heart failure patients and the first patient dosed in our Phase 2 study of lucinactant in acute lung injury in adults with COVID-19 associated ARDS, our first quarter was off to a very productive start," said Craig Fraser, President and Chief Executive Officer of Windtree. "As we look to the rest of the year, we see several potential value-creating milestones with data readouts anticipated in both Phase 2 trials. Additionally, we are actively engaged on the business development front, and are encouraged by the level of interest. Importantly, with the successful completion of a financing this quarter, our balance sheet provides the runway to continue to help fuel these current and planned development activities. We are focused on execution and a year of important milestones."

Select Financial Results for the First Quarter ended March 31, 2021

For the first quarter ended March 31, 2021, the Company reported an operating loss of $9.1 million, compared to an operating loss of $6.7 million in the first quarter of 2020.

Research and development expenses were $4.4 million for the first quarter of 2021, compared to $3.5 million for the first quarter of 2020. The increase in research and development expenses is primarily due to costs related to the clinical development of istaroxime.

General and administrative expenses for the first quarter of 2021 were $4.7 million, compared to $3.2 million for the first quarter of 2020.

The Company reported a net loss of $9.0 million ($0.51 per basic share) on 17.7 million weighted-average common shares outstanding for the first quarter ended March 31, 2021, compared to a net loss of $6.5 million ($0.48 per basic share) on 13.7 million weighted average common shares outstanding for the comparable period in 2020.

As of March 31, 2021, the Company reported cash and cash equivalents of $38.5 million.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, which will be filed with the Securities and Exchange Commission on May 13, 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 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, AEROSURF®, 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 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.

Tables to Follow
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Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	***2020***
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	*$ 38,490*	*$ 16,930*
Prepaid expenses and other current assets	*851*	*1,188*
Total current assets	*39,341*	*18,118*
Property and equipment, net	*879*	*924*
Restricted cash	*154*	*154*
Operating lease right-of-use assets	*2,747*	*917*
Intangible assets	*77,090*	*77,090*
Goodwill	*15,682*	*15,682*
Total assets	*$ 135,893*	*$ 112,885*
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	*$ 939*	*$ 1,161*
Accrued expenses	*3,744*	*3,813*

Operating lease liabilities - current portion	*392*	*805*
Loans payable - current portion	*2,409*	*352*
Total current liabilities	*7,484*	*6,131*
Operating lease liabilities - non-current portion	*2,438*	*201*
Loans payable - non-current portion	*-*	*2,423*
Restructured debt liability - contingent milestone payments	*15,000*	*15,000*
Other liabilities	*2,800*	*2,800*
Deferred tax liabilities	*16,683*	*16,778*
Total liabilities	*44,405*	*43,333*
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2021 and December 31, 2020	*-*	*-*
Common stock, $0.001 par value; 120,000,000 shares authorized at March 31, 2021 and December 31, 2020; 26,257,089 and 16,921,506 shares issued at March 31, 2021 and December 31, 2020, respectively; 26,257,065 and 16,921,482 shares outstanding at March 31, 2021 and December 31, 2020, respectively	*26*	*17*
Additional paid-in capital	*821,165*	*790,277*
Accumulated deficit	*(726,649)*	*(717,688)*
Treasury stock (at cost); 24 shares	*(3,054)*	*(3,054)*
Total stockholders' equity	*91,488*	*69,552*
Total liabilities & stockholders' equity	*$ 135,893*	*$ 112,885*

Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended March 31,	
	2021	***2020***
Expenses:		
Research and development	*$ 4,410*	*$ 3,461*
General and administrative	*4,669*	*3,242*
Total operating expenses	*9,079*	*6,703*
Operating loss	*(9,079)*	*(6,703)*
Other (expense) income:		
Interest income	*50*	*89*
Interest expense	*(41)*	*(44)*
Other income, net	*109*	*124*
Total other (expense) income, net	*118*	*169*
Net loss	*$ (8,961)*	*$ (6,534)*
Net loss per common share		
Basic and diluted	*$ (0.51)*	*$ (0.48)*
Weighted average number of common shares outstanding		
Basic and diluted	*17,695*	*13,697*

SOURCE Windtree Therapeutics, Inc.