Windtree Therapeutics Reports First Quarter 2023 Financial Results and Provides Key Business Updates

May 15, 2023

WARRINGTON, Pa., May 15, 2023 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or “the Company”) (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for cardiovascular disorders, today reported financial results for the first quarter ended March 31, 2023 and provided key business updates.

“We are excited with the progress made during the first quarter, particularly related to the strengthening of our balance sheet by securing additional capital and moving forward with our plans to begin our SEISMiC extension study to advance istaroxime in cardiogenic shock,” said Craig Fraser, President and Chief Executive Officer of Windtree. “In addition, we are realizing the financial benefits of the portfolio prioritization undertaken in 2022, which along with other cost-cutting measures, resulted in a 58% reduction in average monthly cash burn for the first quarter of 2023 compared to the first quarter of 2022. We plan to leverage the cost savings and successful financing to build on the positive Phase 2 data for istaroxime with significant development activity to deliver meaningful milestones over the next several quarters. We look forward to planned events and communication to keep our shareholders and the market updated on our progress with istaroxime and potential opportunities with the next generation SERCA2a activators.”

Key Business Update

- Raised $12.4 million in gross proceeds, before deducting underwriting discounts, commissions and other estimated offering expenses, in an April 2023 underwritten public offering of 4,238,906 shares of its common stock and warrants to purchase up to 4,238,906 shares of common stock including full exercise of the underwriter overallotment option. Net proceeds from the offering were approximately $10.8 million. Cash and cash equivalents as of March 31, 2023 were $4.2 million.

- Announced that the European Patent Office had granted patent coverage for its dual mechanism SERCA2a Activator class of drug candidates. Windtree has preclinical drug candidates with dual mechanisms of action (inhibition of the Na+/K+ pump and activation of SERCA2a) as well as pure SERCA2a activators (devoid of action on the Na+/K+ pump). The new patent, titled: “17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE,” provides patent protection until July 2038 for a family of compounds with a dual mechanism of action.

- Announced publication of a paper entitled: “*Safety and Efficacy of Istaroxime 1.0 and 1.5 µg/kg/min for Patients with Pre Cardiogenic Shock*,” in the Journal of Cardiac Failure. The paper describes additional dose-response analysis from the SEISMiC Study on the primary endpoint systolic blood pressure (SBP) area under the curve and on biomarkers and other clinical endpoints. This analysis indicated that for the endpoints measured in this study, the desired effects of istaroxime can be achieved at a dose less than 1.5 µg/kg/min.

- Announced it received a Bid Price Compliance Letter from the Nasdaq Stock Market LLC informing the company that it regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

Select First Quarter 2023 Financial Results

- Research and development expenses were $1.4 million for the first quarter of 2023, compared to $5.3 million for the first quarter of 2022. The decrease in research and development expenses is primarily due to (i) a decrease of $2.4 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 $0.8 million following the completion of enrollment in the SEISMiC study in March 2022; (iii) a decrease of $0.6 million for expenditures related to the development of istaroxime for AHF primarily due to toxicology studies that were completed in 2022; and (iv) a decrease of $0.1 million in non-cash stock-based compensation expense.

- General and administrative expenses for the first quarter of 2023 were $2.3 million, compared to $3.0 million for the first quarter of 2022. The decrease in general and administrative expenses is primarily due to (i) a decrease of $0.4 million in non-cash stock-based compensation expense; and (ii) a decrease of $0.3 million in personnel costs.

- For the first quarter ended March 31, 2023, the Company reported an operating loss of $4.2 million, compared to an operating loss of $8.3 million in the first quarter of 2022. Included in the operating loss for the first quarter of 2023 is non-cash expense of $0.5 million related to the impairment of goodwill.

- The Company reported a net loss of $4.1 million ($4.76 per basic share) on 0.9 million weighted-average common shares

outstanding for the quarter ended March 31, 2023, compared to a net loss of $8.1 million ($14.36 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2022.

- As of March 31, 2023, the Company reported cash and cash equivalents of $4.2 million which, along with the $10.8 million of proceeds received from the April 2023 underwritten public offering, is expected to be sufficient to fund our business operations through the first quarter of 2024.

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, 2023, which will be filed with the Securities and Exchange Commission on May 15, 2023, and includes detailed discussions about the Company's business plans and operations, financial condition, and results of operations.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is advancing 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 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: risks and uncertainties associated with the 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 and the Company's other product candidates; 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; 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, and other materials on a timely basis and in sufficient amounts; 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 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 its 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.

Contact Information:

Monique Kosse
LifeSci Advisors
212.915.3820 or monique@lifesciadvisors.com

Media:
Katie Larch / Robert Flamm, Ph.D.
Burns McClellan, Inc.
klarch@burnsmc.com / Rflamm@burnsmc.com

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
	Unaudited	

ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,235	$ 6,172
Prepaid expenses and other current assets	987	1,205
Total current assets	5,222	7,377
Property and equipment, net	239	262
Restricted cash	163	154
Operating lease right-of-use assets	1,737	1,853
Intangible assets	25,250	25,250
Goodwill	2,574	3,058
Total assets	$ 35,185	$ 37,954
LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 753	$ 249
Accrued expenses	1,621	1,552
Operating lease liabilities - current portion	389	404
Loans payable - current portion	-	252
Total current liabilities	2,763	2,457
Operating lease liabilities - non-current portion	1,512	1,624
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	5,081	5,061
Total liabilities	28,156	27,942
Mezzanine Equity:		
Series A redeemable preferred stock, $0.001 par value; 0 and 40,000 shares authorized; 0 and 38,610.119 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	-	-
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 and 4,960,000 shares authorized; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at March 31, 2023 and December 31, 2022; 909,014 and 772,203 shares issued at March 31, 2023 and December 31, 2022, respectively; 909,013 and 772,202 shares outstanding at March 31, 2023 and December 31, 2022, respectively	1	-
Additional paid-in capital	838,725	837,598
Accumulated deficit	(828,643)	(824,532)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	7,029	10,012
Total liabilities, mezzanine equity & stockholders' equity	$ 35,185	$ 37,954

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended March 31,	
	2023	**2022**
Expenses:		
Research and development	$ 1,415	$ 5,345
General and administrative	2,292	2,988
Loss on impairment of goodwill	484	-
Total operating expenses	4,191	8,333
Operating loss	(4,191)	(8,333)

Other income (expense):		
Interest income	44	1
Interest expense	(12)	(13)
Other income, net	48	218
Total other income, net	80	206
Net loss	$ (4,111)	$ (8,127)
Net loss per common share		
Basic and diluted	$ (4.76)	$ (14.36)
Weighted average number of common shares outstanding		
Basic and diluted	863	566

Source: Windtree Therapeutics