Windtree Therapeutics Reports Third Quarter 2024 Financial Results and Provides Key Business Updates

November 27, 2024

WARRINGTON, Pa., Nov. 27, 2024 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or “the Company”) (NasdaqCM: WINT), a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions, today reported financial results for the third quarter ended September 30, 2024 and provided key business updates.

“The third quarter of 2024 was marked with significant progress. We were very pleased with the SEISMiC B study results in early cardiogenic shock showing significant improvement in many measures of cardiac function and blood pressure along with a favorable safety profile in patients with heart failure and cardiogenic shock. There have been four positive Phase 2 studies with over 300 patients treated with istaroxime resulting in a consistent, unique and attractive drug profile across a wide range of severities,” said Craig Fraser, Chairman and CEO. “With trial execution and active operations comes the need for capital and we successfully completed transactions providing resources for our near-term needs as well as secured an equity line of credit to potentially support future requirements,” Mr. Fraser added. “Looking forward, we plan to accelerate enrollments in the istaroxime SCAI Stage C cardiogenic shock study with a planned interim data read out in early Q2 2025 as well as providing guidance on our strategy and planned activities with our oncology preclinical aPKCi inhibitor assets. Given what we believe to be strong data and market need, the Company is turning attention to business development activities to secure additional licenses and partnerships for our multi-asset cardiovascular platform with the objective to secure non-dilutive capital and partner resources to advance the assets to potential commercialization.”

Key Business Updates

- Announced positive Phase 2b topline clinical results with istaroxime significantly improving cardiac function and blood pressure in heart failure patients with early cardiogenic shock. The study met its primary endpoint in significantly improving systolic blood pressure over six hours (SBP AUC) for the combined Part A and Part B SEISMiC istaroxime group compared to placebo as well as for SEISMiC Part B alone. The improvements in SBP AUC at 24 hours were also significantly increased by istaroxime and the improvements were sustained through 96 hours of measurement. Cardiac output (the amount of blood pumped by the heart over a minute) and filling pressures in the heart significantly improved as did measured kidney function. Heart failure severity as assessed by the NYHA classification decreased significantly up to 72 hours compared to placebo. A favorable safety and tolerability profile, including risk for cardiac arrythmias, was also observed. The clinical study data was presented in a late-breaker session at the Heart Failure Society of America conference and the Company reviewed the clinical results along with the program strategy and plans at a virtual Investor Meeting which has been posted to the Company website.

- Completed two private placements in July 2024 for aggregate proceeds of approximately $13.9 million, which consisted of approximately $4.4 million of new funding (with $2.3 million of net proceeds) and a $9.5 million payment through the full cancellation and extinguishment of certain holders outstanding senior notes, including secured notes, and shares of the Company’s Series B Convertible Preferred Stock.

- Entered into a Common Stock Purchase Agreement with an equity line investor, whereby the Company has the right, but not the obligation, to sell such investor, and, subject to limited exceptions, the investor is obligated to purchase for up to $35 million of newly issued shares of the Company’s common stock.

- Announced initiation of the SEISMiC C study of istaroxime in SCAI Stage C cardiogenic shock to complete Phase 2b and advance the transition to Phase 3. This is a global trial including sites in the U.S., Europe and Latin America. It is a placebo-controlled, double-blinded study with istaroxime being added to current standard of care with inotropes and/or vasopressors. The effect of istaroxime in addition to these therapies will be assessed for 6 hours and based on the patient’s condition, the ability to remove standard of care therapies while on istaroxime will also be assessed. The primary endpoint of the study is assessment of systolic blood pressure (SBP) profile over the first 6 hours of treatment.

- Expanded patent estate with new patents with istaroxime in cardiogenic shock and acute heart failure. Cardiogenic shock national phase filings were completed for patent applications around the world, including in the United States, Germany, France, Italy, Japan and China. A patent was issued for istaroxime for Japan entitled, “Istaroxime-containing intravenous formulation for the treatment of heart failure and it has been accorded Patent No. 7560134. A patent was issued for istaroxime for Hong Kong, and it is entitled, “Istaroxime-containing intravenous formulation for the treatment of heart failure (AHF).” The claims are directed formulations comprising istaroxime, pharmaceutically acceptable salts thereof, and methods of use, alone, or in combination with other agents useful for the treatment and management of acute heart failure.

Select Third Quarter 2024 Financial Results

For the third quarter ended September 30, 2024, the Company reported an operating loss of $4.7 million, which was comparable to an operating loss of $4.7 million in the third quarter of 2023. Included in our operating loss for the third quarter of 2024 is $2.2 million related to the change in fair value of our common stock warrant liability and $0.7 million in expenses related to the two private placements completed in July 2024 which were allocated to the warrants issued in those transactions and expensed immediately.

Research and development expenses were $2.0 million for the third quarter of 2024, compared to $2.1 million for the third quarter of 2023. Research and development expenses for both periods primarily relate to the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock which completed enrollment during the third quarter of 2024.

General and administrative expenses for the third quarter of 2024 were $2.8 million, compared to $2.6 million for the third quarter of 2023. For the third quarter of 2024, general and administrative expenses include $0.7 million in expenses related to the two private placements completed in July 2024 which were allocated to the warrants issued in those transactions and expensed immediately.

The Company reported a net loss attributable to common stockholders of $3.8 million ($4.23 per basic share) on 0.9 million weighted-average common shares outstanding for the quarter ended September 30, 2024, compared to a net loss of $4.4 million ($15.47 per basic share) on 0.3 million weighted average common shares outstanding for the comparable period in 2023.

As of September 30, 2024, the Company reported cash and cash equivalents of $2.3 million and current liabilities of $14.4 million, which includes an $8.6 million warrant liability. Included in prepaid expenses and other assets as of September 30, 2024 is $0.7 million in receivables related to ELOC Purchase Agreement gross proceeds for sales made during the quarter for which we had not yet received the cash payment. The related net proceeds after the redemption of the Series C Preferred Stock was $0.5 million. In addition, subsequent to September 30, 2024 and through November 22, 2024, we sold an additional 4.3 million shares of Common Stock under the ELOC Purchase Agreement for net proceeds of $2.4 million following mandatory redemption payments on our Series C Preferred Stock. Following these financings, we believe that we have sufficient resources available to fund our business operations through January 2025.

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, 2024, which was filed with the Securities and Exchange Commission on November 26, 2024, and includes detailed discussions about the Company's business plans and operations, financial condition, and results of operations.

Nasdaq Update

On November 21, 2024, the Company received a letter from the Nasdaq Listing Qualifications Staff ("Staff") of The Nasdaq Stock Market LLC stating that it was not in compliance with Nasdaq Listing Rule 5250(c)(1) as a result of it not having timely filed its Quarterly Report on Form 10-Q ("Form 10-Q") for the quarter ended September 30, 2024 with the Securities and Exchange Commission. Based on the November 26, 2024 filing of the Company's Form 10-Q and a subsequent letter received from Nasdaq on November 27, 2024 stating the Staff has determined that the Company complies with Nasdaq Listing Rule 5250(c)(1), this matter is now closed.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Windtree's portfolio of product candidates includes istaroxime, a Phase 2 candidate with SERCA2a activating properties for acute heart failure and associated cardiogenic shock, preclinical SERCA2a activators for heart failure and preclinical precision aPKCi inhibitors that are being developed for potential in rare and broad oncology applications. Windtree also has a licensing business model with partnership out-licenses currently in place.

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, among other things: the Company's ability to secure significant additional capital as and when needed; the Company's ability to achieve the intended benefits of the aPKCi asset acquisition with Varian Biopharmaceuticals, Inc.; the Company's risks and uncertainties associated with the success and advancement of the clinical development programs for istaroxime and the Company's other product candidates, including preclinical oncology candidates; 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; the rate and degree of market acceptance of the Company's product candidates, if approved; the Company's ability to maintain compliance with the continued listing requirements of Nasdaq; the economic and social consequences of the COVID-19 pandemic and 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 the evolving events in the Middle East, 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. 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.

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WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,300	$ 4,319
Prepaid expenses and other current assets	1,628	1,060
Total current assets	3,928	5,379
Property and equipment, net	128	183
Restricted cash	9	150
Operating lease right-of-use assets	1,133	1,444
Intangible assets	25,250	25,250
Total assets	$ 30,448	$ 32,406
LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,054	$ 809
Accrued expenses	1,650	1,618
Operating lease liabilities - current portion	468	436
ELOC commitment note payable	317	-
Derivative liability - ELOC commitment note	347	-
Common stock warrant liability	8,621	-
Loans payable	444	233
Other current liabilities	525	900
Total current liabilities	14,426	3,996
Operating lease liabilities - non-current portion	784	1,161
Restructured debt liability - contingent milestone payments	-	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	4,887	5,058
Total liabilities	23,897	29,015
Mezzanine Equity:		
Series C redeemable preferred stock, $0.001 par value; 18,820 and 0 shares authorized; 15,719 and 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2,142	-
Series B redeemable preferred stock, $0.001 par value; 5,500 and 0 shares authorized; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	-	-
Total mezzanine equity	2,142	-
Stockholders' Equity:		
Preferred stock, $0.001 par value; 4,975,680 and 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized; 2,340,429 and 333,145 shares issued at September 30, 2024 and December 31, 2023, respectively; 2,340,428 and 333,144 shares outstanding at September 30, 2024 and December 31, 2023, respectively	2	-
Additional paid-in capital	856,267	851,268
Accumulated deficit	(848,806)	(844,823)

Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	4,409	3,391
Total liabilities, mezzanine equity & stockholders' equity	$ 30,448	$ 32,406

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Expenses:				
Research and development	$ 1,968	$ 2,110	$ 14,084	$ 5,288
General and administrative	2,773	2,580	6,514	7,292
Loss on impairment of goodwill	-	-	-	3,058
Total operating expenses	4,741	4,690	20,598	15,638
Operating loss	(4,741)	(4,690)	(20,598)	(15,638)
Other income (expense):				
Gain on debt extinguishment	71	-	14,591	-
Change in fair value of common stock warrant liability	2,166	-	2,166	-
Interest income	12	112	62	264
Interest expense	(51)	(13)	(174)	(38)
Other (expense) income, net	(446)	166	(530)	275
Total other income, net	1,752	265	16,115	501
Loss before income taxes	(2,989)	(4,425)	(4,483)	(15,137)
Income tax benefit (expense)	240	-	(71)	-
Net loss	$ (2,749)	$ (4,425)	$ (4,554)	$ (15,137)
Extinguishment of Series B Preferred Stock	572	-	572	-
Deemed dividend on Series C Preferred Stock	(1,573)	-	(1,573)	-
Net loss attributable to common stockholders	$ (3,750)	$ (4,425)	$ (5,555)	$ (15,137)
Net loss per share attributable to common stockholders				
Basic and diluted	$ (4.23)	$ (15.47)	$ (8.64)	$ (80.95)
Weighted average number of common shares outstanding				
Basic and diluted	887	286	643	187

Source: Windtree Therapeutics