Windtree Therapeutics Reports Fourth Quarter and Year-End 2023 Financial Results and Provides Key Business Updates

April 17, 2024

WARRINGTON, Pa., April 17, 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 fourth quarter and fiscal year ended December 31, 2023 and provided key business updates.

“The end of 2023 and the past few months have been very productive at Windtree as we advanced clinical programs, executed a license for cardiovascular assets, took actions to strengthen our balance sheet and, most recently, acquired a novel oncology preclinical atypical protein kinase C iota inhibitor (aPKCi inhibitor) platform from Varian Biopharmaceuticals. These actions represent the first part of a portfolio optimization strategy and a potentially transformative next step for Windtree,” said Craig Fraser, CEO. “Later this year, we plan to read out data from both of our ongoing Phase 2 istaroxime trials in cardiogenic shock while we are also supporting our regional partner, Lee’s Pharmaceutical, in starting a Phase 3 program in acute heart failure. In addition, we are actively engaged in global partnership discussions for istaroxime, with the objective of partnering to help advance istaroxime through existing and future clinical trials and gaining potential deal revenue. Given the intent to have the resource intensive, late stage istaroxime program advanced by a larger company, by adding the innovative aPKCi inhibitor platform to our early-stage pipeline, we plan to strengthen our focus on advancing our preclinical programs, including our selective SERCA2a activators. We believe partnering our istaroxime program both regionally and globally, has the potential to allow us to better advance our other pipeline assets and help us to significantly reduce our cash burn, extend runway and leverage our experienced team to advance our innovative early-stage platforms.” Mr. Fraser further added, “Mid to longer term, we believe there could be opportunity to leverage our internal programs, partner deal revenue, a strengthened balance sheet and public company liquidity to selectively execute other potential acquisitions and/or strategic transactions to grow the business and its value.”

“The R&D and clinical team has been busy this period. We advanced the istaroxime program in cardiogenic shock with two clinical trials. First, we progressed clinical execution of the SEISMiC Extension Study in the U.S., Europe and Latin America. We also initiated a study of istaroxime in more severe SCAI Stage C cardiogenic shock patients. Earlier this year, we announced preclinical data describing a reduction in arrythmias with both istaroxime and a pure SERCA2a activator in a rat heart ischemia-reperfusion model,” said Dr. Steve Simonson, Chief Medical Officer of Windtree. “Next, we intend to integrate our newly acquired aPKCi inhibitor into our preclinical portfolio, which we believe has an exciting preclinical data package with two formulations in development. We plan to progress the IND-enabling activities for a topical and oral formulation while we create a comprehensive development plan focused on malignancies with unmet needs that are targets for this mechanism of action. While there is scientific rationale for potential broad application of this mechanism of action, we believe there will be options for targeted disease selection and differentiation due to the potential for high target specificity and the opportunity for a topical formulation to treat various cutaneous malignancies. We are assessing our new asset platform and look forward to communicating our future development plans later this year.”

Key Business Update

- Entered into an asset purchase agreement with Varian Biopharmaceuticals, Inc. (“Varian”) on April 2, 2024 to acquire certain of its assets, including a proprietary aPKCi inhibitor. The Company also completed a $1.5 million convertible note bridge financing. The acquired Varian asset platform is a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology and certain rare malignant diseases. The asset platform includes both a topical and oral formulation in development.

- Announced the enrollment of the first subject in its Phase 2 SEISMiC Extension Study of istaroxime in the treatment of early cardiogenic shock in December 2023 as well as initiated a parallel study in more severe, SCAI Stage C cardiogenic shock patients. Study results are expected in the second half of 2024.

- Entered into a license agreement with Lee’s Pharmaceutical (HK) Limited in January 2024 for the development and commercialization of istaroxime in Greater China, including for acute heart failure and cardiogenic shock. In addition to istaroxime, the agreement also licenses preclinical next-generation SERCA2a activators, known as dual mechanism SERCA2a activators, and rostafuroxin, a Phase 2 product candidate for hypertension associated with specific genotypes. We are eligible to receive up to approximately $138 million in milestone payments, plus low double-digit percentage royalties on certain sales.

- Renewed its partnership with Chang Gung University in Taiwan to further research on SERCA2a, an important target for the Company’s cardiovascular portfolio. Windtree personnel from its offices in Taipei, Taiwan will participate in the collaboration.

- Entered into an Exchange and Termination Agreement with affiliates of Deerfield Management Company (collectively, “Deerfield”) in January 2024 pursuant to which Deerfield has agreed to terminate its rights under the Company’s 2017 Exchange and Termination Agreement to receive up to $15 million in development and commercial milestone payments associated with AEROSURF®, an acute pulmonary drug/device combination intended to treat premature infants with respiratory distress syndrome, in exchange for $200,000 and 608,272 shares of common stock. Windtree out-licensed global rights to AEROSURF® in 2022.

- Announced preclinical data on the Company’s lead product candidate, istaroxime, and a preclinical pipeline pure SERCA2a activator drug candidate, CVie-216, showing reductions in ventricular arrythmias in a rat heart model of diabetes with restricted and restored coronary blood flow induced injury.

- Announced that the European Patent Office granted Patent No. 3805243 composition of matter patent coverage for the pure SERCA2a Activator class of drug candidates. The new European patent, titled: “ANDROSTANE DERIVATIVES WITH ACTIVITY AS PURE OR PREDOMINANTLY PURE STIMULATORS OF SERCA2A FOR THE TREATMENT OF Heart Failure,” provides patent protection until October 9, 2039 for the family of compounds with the pure SERCA2a mechanism of action.

- As of December 31, 2023, cash and cash equivalents were $4.3 million and current liabilities were $4.0 million.

Select Fourth Quarter 2023 Financial Results

Research and development expenses were $3.1 million for the fourth quarter of 2023, compared to $1.2 million for the fourth quarter of 2022. The increase in research and development expenses was primarily due to costs related to the execution of the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock and to $0.9 million in accrued payments to Philip Morris USA Inc. and Philip Morris Products S.A. related to amendments to our license agreements.

General and administrative expenses for the fourth quarter of 2023 were $1.9 million, compared to $2.2 million for the fourth 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 related to headcount reductions and the timing of grants; (ii) a decrease of $0.3 million in insurance and professional fees; and (iii) a decrease of $0.1 million in personnel costs due to headcount reductions; partially offset by (iv) the reversal of $0.5 million in incentive bonus expense during the fourth quarter of 2022.

For the fourth quarter ended December 31, 2023, the Company reported an operating loss of $5.0 million, compared to an operating loss of $10.8 million in the fourth quarter of 2022. Included in operating loss for the fourth quarter of 2022 is a non-cash loss on impairment of intangible assets related to rostafuroxin of $6.8 million and a related $1.4 million deferred income tax benefit and a non-cash loss on impairment of goodwill of $0.5 million.

The Company reported a net loss of $5.2 million ($0.95 per basic share) on 5.4 million weighted-average common shares outstanding for the quarter ended December 31, 2023, compared to a net loss of $9.7 million ($13.01 per basic share) on 0.7 million weighted average common shares outstanding for the comparable period in 2022.

Select 2023 Year-End Financial Results

Research and development expenses were $8.3 million for the year ended December 31, 2023, compared to $11.1 million for the year ended December 31, 2022. The decrease in research and development expenses is primarily due to (i) a decrease of $3.0 million related to the KL4 surfactant platform, inclusive of $1.4 million in personnel cost reductions, as the Company continues to focus its resources on the development of its istaroxime pipeline; (ii) a decrease of $0.7 million for expenditures related to the development of istaroxime for AHF; and (iii) a decrease of $0.4 million in non-cash stock-based compensation expense related to headcount reductions and the timing of grants; partially offset by (iv) $0.9 million in accrued payments to Philip Morris USA Inc. and Philip Morris Products S.A. in 2023 related to amendments to our license agreements; and (v) an increase of $0.4 million as we continue the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock.

General and administrative expenses for the year ended December 31, 2023 were $9.2 million, compared to $10.8 million for the year ended December 31, 2022. The decrease in general and administrative expenses is primarily due to (i) a decrease of $1.4 million in non-cash stock-based compensation expense related to headcount reductions and the timing of grants; (ii) a decrease of $0.6 million in personnel costs due to headcount reductions; and (iii) a decrease of $0.4 million in insurance costs; partially offset by (iv) an increase of $0.4 million in professional fees; and (v) $0.4 million in severance expense related to a former executive.

For the year ended December 31, 2023, the Company reported an operating loss of $20.6 million, compared to an operating loss of $41.3 million for the year ended December 31, 2022. Included in operating loss for the year ended December 31, 2023 is a non-cash loss on impairment of goodwill of $3.1 million. Included in operating loss for the year ended December 31, 2022 is a non-cash loss on impairment of goodwill of $12.6 million and a non-cash loss on impairment of intangible assets related to rostafuroxin of $6.8 million and a related $1.4 million deferred income tax benefit.

The Company reported a net loss of $20.3 million ($5.24 per basic share) on 3.9 million weighted-average common shares outstanding for the year ended December 31, 2023, compared to a net loss of $39.2 million ($62.23 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2022.

As of December 31, 2023, the Company reported cash and cash equivalents of $4.3 million and current liabilities of $4.0 million. In April 2024, the Company completed a $1.5 million convertible note bridge financing. As a result, we believe that we have sufficient resources available to fund our operations through April 2024.

Readers are referred to, and encouraged to read in its entirety, the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, which will be filed with the Securities and Exchange Commission on April 16, 2024, and includes detailed discussions about the Company’s business plans and operations, financial condition, and results of operations.

About Windtree Therapeutics
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 II 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: 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; 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 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 Israel and Gaza, 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)

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,319	$ 6,172
Prepaid expenses and other current assets	1,060	1,205
Total current assets	5,379	7,377
Property and equipment, net	183	262
Restricted cash	150	154
Operating lease right-of-use assets	1,444	1,853
Intangible assets	25,250	25,250
Goodwill	-	3,058
Total assets	$ 32,406	$ 37,954
LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 809	$ 249
Accrued expenses	1,618	1,552
Operating lease liabilities - current portion	436	404
Loans payable - current portion	233	252
Other current liabilities	900	-
Total current liabilities	3,996	2,457
Operating lease liabilities - non-current portion	1,161	1,624

Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	5,058	5,061
Total liabilities	29,015	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 2023 and 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 2023 and 2022, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized; 5,996,587 and 772,203 shares issued at 2023 and 2022, respectively; 5,996,586 and 772,202 shares outstanding at 2023 and 2022, respectively	6	-
Additional paid-in capital	851,262	837,598
Accumulated deficit	(844,823)	(824,532)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	3,391	10,012
Total liabilities, mezzanine equity & stockholders' equity	$ 32,406	$ 37,954

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Expenses:				
Research and development	$ 3,053	$ 1,216	$ 8,341	$ 11,099
General and administrative	1,906	2,242	9,198	10,790
Loss on impairment of goodwill	-	534	3,058	12,624
Loss on impairment of intangible assets	-	6,820	-	6,820
Total operating expenses	4,959	10,812	20,597	41,333
Operating loss	(4,959)	(10,812)	(20,597)	(41,333)
Other (expense) income:				
Interest income	61	52	325	109
Interest expense	(12)	(13)	(50)	(53)
Other expense, net	(244)	(286)	31	702
Total other (expense) income, net	(195)	(247)	306	758
Loss before income taxes	(5,154)	(11,059)	(20,291)	(40,575)
Deferred income tax benefit	-	1,367	-	1,367
Net loss	$ (5,154)	$ (9,692)	$ (20, 291)	$ (39,208)
Net loss per common share				
Basic and diluted	$ (0.95)	$ (13.01)	$ (5.24)	$ (62.23)
Weighted average number of common shares outstanding				
Basic and diluted	5,399	745	3,876	630

Source: Windtree Therapeutics