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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **March 31, 2024**

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission **File Number**: 001-39290

WINDTREE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**94-3171943** (I.R.S. Employer Identification No.)
2600 Kelly Road, Suite 100 **Warrington, Pennsylvania** (Address of principal executive offices)	**18976-3622** (Zip Code)

Registrant's telephone number, including area code: **(215) 488-9300**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**WINT**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 15, 2024, there were 591,909 shares of the registrant's common stock outstanding, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc., and its consolidated subsidiaries.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of such risks and uncertainties, which potentially could have a material adverse effect on our development programs, business and/or operations, include, but are not limited to the following:

- our estimates regarding future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- how long we can continue to fund our operations with our existing cash and cash equivalents;
- changes in market conditions, general economic conditions, and the banking sector, and potential constraints in accessing capital or credit if and when needed with favorable terms, if at all;
- the potential impairment of our intangible assets on our condensed consolidated balance sheet, which could lead to material impairment charges in the future;
- our ability to repay indebtedness;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the COVID-19 pandemic and the evolving events in Israel and Gaza on our clinical trial operations;
- the costs, timing, and results, of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States, or U.S., and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- risks related to manufacturing active pharmaceutical ingredients, drug product, and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the plans of our AEROSURF and KL4 licensee, Lee's Pharmaceutical (HK) Ltd., and its affiliate, Zhaoke Pharmaceutical (Hefei) Co. Ltd., and their ability to successfully source materials, execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialization of the licensed product candidates;
- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contract laboratories, and independent contractors;
- the size and growth of the potential markets for our product candidates, the regulatory requirements in such markets, the rate and degree of market acceptance of our product candidates, and our ability to serve those markets;
- the success of competing therapies and products that are or may become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;

- recently enacted and future legislation, including but not limited to, the Inflation Reduction Act of 2022, regarding the healthcare system in the U.S. or the healthcare systems in foreign jurisdictions;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to secure electronically stored work product, including clinical data, analyses, research, communications, and other materials necessary to gain regulatory approval of our product candidates, including those acquired from third parties, and assure the integrity, proper functionality, and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, security incidents, data privacy violations, or other significant disruption;
- economic uncertainty resulting from inflation and the rapid increase in interest rates, including concerns involving liquidity, defaults or other non-performance by financial institutions; and
- economic uncertainty resulting from geopolitical instability, including the ongoing military 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.

Pharmaceutical, biotechnology, and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. In addition, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products and may never become profitable.

The forward-looking statements contained in this Quarterly Report on Form 10-Q, or the documents incorporated by reference herein, speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

You should also read carefully the factors described in the "Risk Factors" included in Part II, Item 1A of this Quarterly Report on Form 10-Q in conjunction with Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, to better understand the significant risks and uncertainties inherent in our business and underlying any forward-looking statements.

Trademark Notice
AEROSURF®, **AFECTAIR®**, **SURFAXIN®**, **SURFAXIN LS™**, **WINDTREE THERAPEUTICS® (logo)**, **WINDTREE THERAPEUTICS™**, and **WINDTREE™** are registered and common law trademarks of Windtree Therapeutics, Inc. (Warrington, PA).

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	March 31, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,547	$ 4,319
Prepaid expenses and other current assets	792	1,060
Total current assets	3,339	5,379
Property and equipment, net	162	183
Restricted cash	9	150
Operating lease right-of-use assets	1,343	1,444
Intangible assets	25,250	25,250
Total assets	$ 30,103	$ 32,406
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,689	$ 809
Accrued expenses	2,125	1,618
Operating lease liabilities - current portion	446	436
Loans payable	-	233
Other current liabilities	725	900
Total current liabilities	4,985	3,996
Operating lease liabilities - non-current portion	1,038	1,161
Restructured debt liability - contingent milestone payments	-	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	4,859	5,058
Total liabilities	14,682	29,015
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized; 510,181 and 333,145 shares issued at March 31, 2024 and December 31, 2023, respectively; 510,180 and 333,144 shares outstanding at March 31, 2024 and December 31, 2023, respectively	1	-
Additional paid-in capital	853,078	851,268
Accumulated deficit	(834,604)	(844,823)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	15,421	3,391
Total liabilities & stockholders' equity	$ 30,103	$ 32,406

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
Expenses:		
Research and development	$ 2,253	$ 1,415
General and administrative	2,152	2,292
Loss on impairment of goodwill	-	484
Total operating expenses	4,405	4,191
Operating loss	(4,405)	(4,191)
Other income (expense):		
Gain on debt extinguishment	14,520	-
Interest income	30	44
Interest expense	(13)	(12)
Other income, net	201	48
Total other income, net	14,738	80
Income (loss) before income taxes	10,333	(4,111)
Income tax expense	(114)	-
Net income (loss)	$ 10,219	$ (4,111)
Net income (loss) per common share		
Basic and diluted	$ 21.98	$ (85.65)
Weighted average number of common shares outstanding		
Basic and diluted	465	48

See notes to condensed consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

(in thousands)

	Mezzanine Equity		Stockholders' Equity						
	Series A Preferred Stock		Common Stock				Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Shares	Amount	Total
Balance - December 31, 2022	**3**	**$ -**	**43**	**$ -**	**$ 837,598**	**$ (824,532)**	**-**	**$ (3,054)**	**$ 10,012**
Net loss	-	-	-	-	-	(4,111)	-	-	(4,111)
Redemption of Series A Preferred Stock	(3)	-	-	-	-	-	-	-	-
Exercise of common stock warrants, net of expenses of $276	-	-	7	-	843	-	-	-	843
Reverse split adjustments - fractional share round ups	-	-	1	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	285	-	-	-	285
Balance - March 31, 2023	**-**	**$ -**	**51**	**$ -**	**$ 838,726**	**$ (828,643)**	**-**	**$ (3,054)**	**$ 7,029**

	Mezzanine Equity		Stockholders' Equity						
	Series A Preferred Stock		Common Stock				Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Shares	Amount	Total
Balance - December 31, 2023	**-**	**$ -**	**333**	**$ -**	**$ 851,268**	**$ (844,823)**	**-**	**$ (3,054)**	**$ 3,391**
Net income	-	-	-	-	-	10,219	-	-	10,219
Issuance of common stock, ATM Program, net of issuance costs of $44	-	-	143	1	1,366	-	-	-	1,367
Issuance of common stock, equity consideration in debt extinguishment	-	-	34	-	280	-	-	-	280
Stock-based compensation expense	-	-	-	-	164	-	-	-	164
Balance - March 31, 2024	**-**	**$ -**	**510**	**$ 1**	**$ 853,078**	**$ (834,604)**	**-**	**$ (3,054)**	**$ 15,421**

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net income (loss)	$ 10,219	$ (4,111)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	21	23
Stock-based compensation	251	285
Non-cash lease expense	101	116
Loss on impairment of goodwill	-	484
Gain on debt extinguishment	(14,520)	-
Unrealized (gain) loss on foreign exchange rate changes	(209)	21
Changes in assets and liabilities:		
Prepaid expenses and other current assets	270	218
Accounts payable	880	504
Accrued expenses	328	68
Operating lease liabilities	(113)	(127)
Other current liabilities	(175)	-
Net cash used in operating activities	(2,947)	(2,519)
Cash flows from financing activities:		
Proceeds from ATM Program, net of issuance costs	1,367	-
Principal payments on loans payable	(233)	(252)
Payments on debt extinguishment	(100)	-
Proceeds from exercise of common stock warrants, net of expenses	-	843
Net cash provided by financing activities	1,034	591
Net decrease in cash, cash equivalents, and restricted cash	(1,913)	(1,928)
Cash, cash equivalents, and restricted cash - beginning of period	4,469	6,326
Cash, cash equivalents, and restricted cash - end of period	$ 2,556	$ 4,398
Supplementary disclosure of non-cash activity:		
Fair value of common stock consideration related to debt extinguishment	$ 280	$ -
Fair value of January 2023 warrant modifications related to the January 2023 warrant exercise inducement	-	1,238
Fair value of February 2023 warrant modifications related to the February 2023 warrant exercise inducement	-	274

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

We are a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Our portfolio of product candidates includes istaroxime, a Phase 2 candidate with sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activating properties for acute heart failure and associated cardiogenic shock; preclinical SERCA2a activators for heart failure; rostafuroxin for the treatment of hypertension in patients with a specific genetic profile; and a preclinical atypical protein kinase C iota, or aPKCi, inhibitor (topical and oral formulations), being developed for potential application in rare and broad oncology indications. We also have a licensing business model with partnership out-licenses currently in place.

Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. Istaroxime demonstrated significant improvement in both systolic and diastolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure, or SBP, in acute decompensated heart failure patients and had a favorable renal profile, we initiated a Phase 2 global clinical study, or the SEISMiC Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. In April 2022, we announced our observations in the SEISMiC Study that istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. We believe that istaroxime has the potential to fulfill an unmet need in early and potentially more severe cardiogenic shock. We further believe that the data from the SEISMiC Study supports continued development in both cardiogenic shock and AHF. In the fourth quarter of 2023, we initiated an extension to the SEISMiC Study, or the SEISMiC Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of SERCA2a. The SEISMiC Extension study is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in the second half of 2024. Additionally, we have recently initiated a small study in more severe SCAI Stage C cardiogenic shock, or the SEISMiC C Study, to evaluate the safety and efficacy of istaroxime in cardiogenic shock patients who are also receiving standard of care rescue therapy for shock. The SEISMiC C Study is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock with enrollment anticipated to be completed in late 2024. Our ability to complete both of these studies with their intended sample size is dependent upon our ability to secure adequate resourcing for the program through financing efforts or business development activities.

Our heart failure cardiovascular portfolio also includes SERCA2a activators. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. These candidates would potentially be developed for both acute decompensated and chronic out-patient heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance the development of rostafuroxin without securing such an arrangement or partnership.

Our cardiovascular assets and programs are associated with a regional licensed partnership with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), for the development and commercialization of our product candidate, istaroxime, in Greater China. In addition to istaroxime, the agreement also licenses our preclinical next-generation dual mechanism SERCA2a activators, and rostafuroxin, a Phase 2 product candidate for hypertension associated with specific genotypes. In addition, we are supporting the efforts of Lee's (HK) in starting a Phase 3 trial in AHF with istaroxime. Further, we are engaged in discussions regarding potential global licensing partnerships outside of Lee's (HK) territory.

On April 2, 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with a licence agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. The Transferred Assets include a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations (topical and oral) of an aPKCi inhibitor. We plan to advance investigational new drug enabling activities and are in the process of determining the expected clinical development plan for the platform.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations.

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2023 that we filed with the Securities and Exchange Commission, or the SEC, on April 16, 2024, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Note 2 – Basis of Presentation

The interim unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., or US GAAP, for interim financial information in accordance with the instructions to Form 10-Q and include accounts of Windtree Therapeutics, Inc. and its wholly owned subsidiaries. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. Intercompany balances and transactions have been eliminated in consolidation. All adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. The consolidated balance sheet at December 31, 2023 has been derived from the Company's audited consolidated financial statements. There have been no changes to our significant accounting policies since December 31, 2023. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with our annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2023 contained in our Annual Report on Form 10-K for the year ended December 31, 2023.

The accompanying condensed consolidated financial statements reflect the 1-for-18 reverse split of our common stock that was approved by our Board of Directors and stockholders and made effective on April 19, 2024. All share and per share information herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Note 3 – Going Concern and Management's Plans

We are subject to risks common to companies in the biotechnology industry, including but not limited to the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international operations in Taiwan and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

With the exception of certain non-recurring items such as debt extinguishment, we have incurred net losses since inception. We had net income of $10.2 million for the three months ended March 31, 2024 due to a $14.5 million gain on debt extinguishment and $0.2 million of other income, partially offset by a $4.4 million operating loss and $0.1 million of income tax expense. For the three months ended March 31, 2023, our net loss was $4.1 million, which included a $0.5 million loss on impairment of goodwill (See the section titled, "Note 4 – Summary of Significant Accounting Policies"). We expect to continue to incur operating losses for at least the next several years. As of March 31, 2024, we had an accumulated deficit of $834.6 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development expense and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

As of March 31, 2024, we had cash and cash equivalents of $2.5 million and current liabilities of $5.0 million. On April 2, 2024, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the buyers named therein, or the Buyers. Pursuant to the Purchase Agreement, we agreed to sell senior convertible notes, or the Notes, for $1.4 million of net proceeds. As a result, we believe that we have sufficient resources available to fund our business operations through mid-May 2024. We do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we have filed a registration statement to raise additional capital in a follow-on public offering but cannot guarantee that such offering will be consummated in a timely manner, on acceptable terms or at all. Further, management plans to secure additional capital, potentially through a combination of public or private securities offerings, convertible debt financings, and/or strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Note 4 – Summary of Significant Accounting Policies

Principles of Consolidation

The interim unaudited condensed consolidated financial statements are prepared in accordance with US GAAP and include accounts of Windtree Therapeutics, Inc. and its wholly owned subsidiaries, CVie Investments Limited and its wholly owned subsidiary, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

Intangible Assets and Goodwill

We record acquired intangible assets and goodwill based on estimated fair value. The identifiable intangible assets resulting from the CVie Therapeutics acquisition in December 2018 relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin. The IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three months ended March 31, 2024, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired.

During the first quarter of 2023, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. Based on an interim goodwill impairment test, we determined that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, we recorded a loss on impairment of goodwill of $0.5 million for the three months ended March 31, 2023, recognized within operating expenses in our condensed consolidated statements of operations. As of March 31, 2024 and December 31, 2023, goodwill was zero on our condensed consolidated balance sheet.

The following table represents identifiable intangible assets as of March 31, 2024 and December 31, 2023:

(in thousands)	**March 31, 2024**	**December 31, 2023**
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	2,910	2,910
Intangible assets	25,250	25,250

Foreign Currency Transactions

The functional currency for our foreign subsidiary is U.S. Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income, net. Foreign currency transactions resulted in net gains of approximately $0.2 million and $0.1 million for the three-month periods ended March 31, 2024 and 2023, respectively.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including intangible assets and goodwill, at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are held at domestic and foreign financial institutions and consist of liquid investments and money market funds that are readily convertible into cash.

Concentration of Credit Risk

Financial instruments, which potentially subject us to credit risk, consist principally of cash and cash equivalents. All cash and cash equivalents are held in U.S. financial institutions and money market funds. At times, we may maintain cash balances in excess of the federally insured amount of $250,000 per depositor, per insured bank, for each account ownership category. Although we currently believe that the financial institutions with whom we do business will be able to fulfill their commitments to us, there is no assurance that those institutions will be able to continue to do so. We have not experienced any credit losses associated with our balances in such accounts.

Severance

In July 2023, we entered into a separation agreement with an executive, which provides that the former employee will be entitled to receive (i) a severance amount equal to the sum of the employee's base salary then in effect and (ii) subject to certain exceptions, a pro rata bonus commensurate with the bonus awarded to other contract executives for the year 2023, prorated for the number of days of the employee's employment during 2023, and payable at the time that other contract executives are paid bonuses with respect to 2023. The severance amount related to the departure of this executive is approximately $0.5 million, which was accrued in general and administrative expense at the date of the separation, and will be paid ratably through July 2024. As of March 31, 2024, approximately $0.3 million was paid. The remaining liability as of March 31, 2024 is approximately $0.2 million and is included in accrued expenses.

In June 2023, we implemented certain reductions in headcount. The total severance cost for impacted employees was approximately $0.2 million, which was accrued in research and development expense at the date of the separations and was paid ratably through December 2023.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt, we established a $15.0 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017, or the Milestone Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability was recorded at the full value of the contingent milestones and was to be carried at full value until the milestones were achieved and paid or the milestones were not achieved and the liability was written off as a gain on debt extinguishment.

On January 24, 2024, we and Deerfield entered into an Exchange and Termination Agreement, or the Exchange and Termination Agreement, wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share (See the section titled, “Note 8 – Restructured Debt Liability”).

Research and Development

We account for research and development expense by the following categories: (a) direct clinical and preclinical development programs, (b) product development and manufacturing, and (c) clinical, medical, and regulatory operations. Research and development expense includes personnel, facilities, manufacturing and quality, pharmaceutical development, research, clinical, regulatory, and other preclinical and clinical activities. Research and development costs are charged to operations as incurred in accordance with Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Accounting for Income Taxes*, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities.

We use a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Because we have never realized a profit, management has fully reserved the net deferred tax asset as there can be no assurance of realization.

Net Income (Loss) per Common Share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of March 31, 2024 and 2023, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants, as well as the vesting of restricted stock units, was 0.3 million and approximately 30,000 shares, respectively. For the three months ended March 31, 2024, all potentially dilutive securities were out-of-the-money and therefore have been excluded from the computation of diluted net income per share.

We do not have any components of other comprehensive (loss) income.

Note 5 – Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Fair Value on a Recurring Basis

The tables below categorize assets measured at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value March 31, 2024	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 1,561	$ 1,561	$ -	$ -
Total Assets	$ 1,561	$ 1,561	$ -	$ -

(in thousands)	Fair Value December 31, 2023	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 3,532	$ 3,532	$ -	$ -
Total Assets	$ 3,532	$ 3,532	$ -	$ -

Fair Value on a Non-Recurring Basis

Certain of our assets were measured at fair value on a non-recurring basis during the three months ended March 31, 2024 and the year ended December 31, 2023. Our goodwill was recorded at its estimated fair value as a result of the impairment tests performed in 2023, which resulted in the goodwill being written down to zero as of June 30, 2023 (See the section titled, “Note 4 – Summary of Significant Accounting Policies – Intangible Assets and Goodwill”).

In order to perform the goodwill impairment test, we compared the estimated fair value of our reporting unit to its carrying value. Significant factors considered in estimating the fair value of our reporting unit included the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies. Quantitative information about the significant unobservable inputs used in the fair value measurement of the reporting unit included an estimated control premium of 50% for both periods.

Note 6 – Loans Payable

In June 2023, we entered into an insurance premium financing and security agreement with IPFS Corporation. Under the agreement, we financed $0.8 million of certain premiums at a 7.24% fixed annual interest rate. Payments of approximately $77,000 were due monthly from July 2023 through April 2024. As of December 31, 2023, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the first quarter of 2024.

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% fixed annual interest rate. Payments of approximately $126,000 were due monthly from July 2022 through March 2023. As of December 31, 2022, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2023.

Note 7 - Other Current Liabilities

In 2008, we entered into an Amended and Restated License Agreement with Philip Morris USA, Inc., or PMUSA, with respect to the U.S., or the U.S. License Agreement, and, as PMUSA had assigned its ex-U.S. rights to Philip Morris Products S.A., or PMPSA, effective on the same date and on substantially the same terms and conditions, we entered into a license agreement with PMPSA with respect to rights outside of the U.S., which we refer to, together with the U.S. License Agreement, as the PM License Agreements.

Amendment No. 1 to the Amended and Restated License Agreement with Philip Morris USA for Aerosolization Technology

On January 16, 2024, we entered into Amendment No. 1 to the U.S. License Agreement, effective as of January 17, 2024, or the U.S. License Agreement Amendment, which amended the U.S. License Agreement. The U.S. License Agreement licenses U.S. intellectual property rights to us in respect of our former acute pulmonary care platform that was globally outlicensed to the Licensee in August 2022. Pursuant to the U.S. License Agreement Amendment, we agreed to pay PMUSA (i) $100,000 by January 18, 2024, or the PMUSA Upfront Payment, (ii) $400,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 and (iii) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from the Licensee. Additionally, under the U.S. License Agreement Amendment, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 7.3 of the U.S. License Agreement as in effect immediately prior to January 17, 2024. The U.S. License Agreement Amendment also grants PMUSA the right to terminate the U.S. License Agreement upon 30 days prior written notice to us if we have not paid a milestone payment to PMUSA by January 1, 2028.

Amendment No. 1 to the License Agreement with Philip Morris Products for Aerosolization Technology

On January 16, 2024, we also entered into Amendment No. 1 to the License Agreement with PMPSA, effective as of January 17, 2024, or the PMPSA License Amendment, which amended the License Agreement, dated March 28, 2008, between us and PMPSA, or the PMPSA License Agreement. The PMPSA License Agreement licenses ex-U.S. intellectual property to us in respect of our former acute pulmonary care platform that was globally outlicensed to the Licensee in August 2022. Pursuant to the PMPSA License Amendment, we agreed to pay PMPSA (i) $75,000 by January 19, 2024, or the PMPSA Upfront Payment, (ii) $325,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 (together with the PMPSA Upfront Payment, the Fixed Payments) and (iii) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from the Licensee. Additionally, but contingent upon our timely payment of the Fixed Payments, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 6.2 of the PMPSA License Agreement as in effect immediately prior to January 17, 2024.

Accounting for the PMUSA and PMPSA Payments

We accounted for these payments as a recognized subsequent event for 2023 in accordance with applicable accounting guidance provided in ASC Topic 855, *Subsequent Events*. For the year ended December 31, 2023, we accrued $0.9 million for payments to PMUSA and PMPSA to be paid in 2024. During the first quarter of 2024, the PMUSA Upfront Payment and the PMPSA Upfront Payment were both paid. As of March 31, 2024, the remaining liability related to PMUSA and PMPSA is $0.7 million and is recorded in other current liabilities.

Note 8 – Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into the Milestone Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 10 shares of our common stock at an exercise price of $2,124,360 per share held by Deerfield were cancelled in consideration for (x) a cash payment in the aggregate amount of $2.5 million, (y) 27 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Milestone Agreement) on the closing date, and (z) the right to receive certain milestone payments, or Milestone Payments, based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15.0 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. We established a $15.0 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Milestone Agreement. The liability was recorded at the full value of the contingent milestones and was to be carried at full value until the milestones were achieved and paid or the milestones were not achieved and the liability was written off as a gain on debt extinguishment. As of December 31, 2023, the restructured debt liability balance was $15.0 million.

On January 24, 2024, we and Deerfield entered into an Exchange and Termination Agreement wherein Deerfield agreed to terminate its rights to receive the Milestone Payments.

Pursuant to the Exchange and Termination Agreement, Deerfield agreed to terminate its rights to receive the Milestone Payments and all related rights and obligations in respect of such Milestone Payments in exchange for (i) cash in the aggregate amount of $0.2 million, $0.1 million of which was paid on January 24, 2024 and $0.1 million of which is included in accrued expenses and will be paid no later than the earlier to occur of (a) January 24, 2025 and (b) us receiving a specified amount of gross proceeds from debt or equity financings occurring on or after January 24, 2024, and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share. The shares of the common stock were issued to Deerfield in a transaction exempt from registration pursuant Section 4(a)(2) of the Securities Act of 1933.

Contemporaneously with the execution of the Exchange and Termination Agreement, we and Deerfield entered into a Registration Rights Agreement pursuant to which we have agreed to, among other matters, register for resale with the SEC the shares of the common stock issued to Deerfield pursuant to the Exchange and Termination Agreement. On February 14, 2024, we filed a resale registration statement on Form S-3 (File No. 333-277073) with respect to 33,793 shares of our common stock, which was amended on April 17, 2024. Such resale registration statement was declared effective by the SEC on April 19, 2024.

The Exchange and Termination Agreement was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and, as a result, we recognized a $14.5 million non-cash gain on debt extinguishment during the three months ended March 31, 2024 consisting of the difference between the $15.0 million of the extinguished Milestone Payments and the consideration to Deerfield under the Exchange and Termination Agreement, which includes $0.2 million in cash and $0.3 million in fair value of common stock issued to Deerfield.

Note 9 – Stockholders' Equity

January 2023 Warrant Exercise Inducement Offer Letters

On January 20, 2023, we entered into warrant exercise inducement offer letters with certain holders of certain of our: (i) warrants issued in December 2019 to purchase 88 shares of common stock with an exercise price of $10,881.00 per share; (ii) warrants issued in May 2020 to purchase 311 shares of common stock with an exercise price of $7,177.50 per share, and (iii) warrants issued in March 2021 to purchase 4,945 shares of common stock with an exercise price of $3,240.00 per share (collectively, the January 2023 Existing Warrants).

Pursuant to the terms of the inducement letters, we agreed to amend the January 2023 Existing Warrants by lowering the exercise price of the January 2023 Existing Warrants to $180.00 per share. Additionally, the exercising holders agreed to exercise for cash all of their January 2023 Existing Warrants to purchase an aggregate of 5,343 shares of common stock in exchange for our agreement to issue to such exercising holders new warrants, or the January 2023 New Warrants, to purchase up to an aggregate of 10,686 shares of common stock. We received aggregate gross and net proceeds of approximately $1.0 million and $0.7 million, respectively, from the exercise of the January 2023 Existing Warrants by the exercising holders.

Each January 2023 New Warrant is exercisable into shares of common stock at a price per share of $193.68, was exercisable six months following its date of issuance, or the January 2023 Initial Exercise Date, and will expire on the fifth anniversary of the January 2023 Initial Exercise Date.

February 2023 Warrant Exercise Inducement Offer Letter

On February 21, 2023, we entered into a warrant exercise inducement offer letter with Panacea Venture Healthcare Fund I, L.P., a holder of certain of our: (i) warrants issued in July 2018 to purchase 70 shares of common stock with an exercise price of $10,800.00 per share; (ii) warrants issued in December 2018 to purchase 554 shares of common stock with an exercise price of $10,935.00 per share; (iii) warrants issued in December 2019 to purchase 307 shares of common stock with an exercise price of $10,881.00 per share; and (iv) warrants issued in May 2020 to purchase 307 shares of common stock with an exercise price of $7,177.50 per share (collectively, the February 2023 Existing Warrants).

Pursuant to the terms of the inducement letter, we agreed to amend the February 2023 Existing Warrants by lowering the exercise price of the February 2023 Existing Warrants to $127.08 per share. Additionally, Panacea agreed to exercise for cash all of their February 2023 Existing Warrants to purchase an aggregate of 1,236 shares of common stock in exchange for our agreement to issue to Panacea new warrants, or the February 2023 New Warrants, to purchase up to an aggregate of 2,472 shares of common stock. We received aggregate gross and net proceeds of approximately $0.2 million and $0.1 million, respectively, from the exercise of the February 2023 Existing Warrants by Panacea.

Each February 2023 New Warrant is exercisable into shares of common stock at a price per share of $193.68, was exercisable six months following its date of issuance, or the February 2023 Initial Exercise Date, and will expire on the fifth anniversary of the February 2023 Initial Exercise Date.

Accounting for the January 2023 and February 2023 Warrant Exercise Inducement Offer Letters

The amendment of the January 2023 Existing Warrants and the February 2023 Existing Warrants by lowering the exercise prices and issuing the January 2023 New Warrants and the February 2023 New Warrants is considered a modification of the January 2023 Existing Warrants and the February 2023 Existing Warrants under the guidance of ASU 2021-04. The modification is consistent with the “Equity Issuance” classification under that guidance as the reason for the modification was to induce the holders to cash exercise their warrants, resulting in the imminent exercise of the January 2023 Existing Warrants and the February 2023 Existing Warrants, which raised equity capital and generated net proceeds for us of approximately $0.7 million and $0.1 million, respectively. The total fair value of the consideration of the modification includes the incremental fair value of the January 2023 Existing Warrants and the February 2023 Existing Warrants (determined by comparing the fair values immediately prior to and immediately after the modification) and the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants. The fair values were calculated using the Black-Scholes model and we determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants and the February 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants, was $1.2 million and $0.3 million, respectively.

At-The-Market Program

On November 9, 2023, we entered into the 2023 ATM Program with Ladenburg. We are not obligated to make any sales under the 2023 ATM Program. When we issue sale notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

Sales under the 2023 ATM Program will be made pursuant to our “shelf” registration statement on Form S-3 (No. 333-261878) filed with the SEC on December 23, 2021, and declared effective on January 3, 2022, and a prospectus supplement related thereto. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and, as of May 15, 2024, we had sold substantially all that we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. However, there can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

Either party may suspend the offering under the 2023 ATM Program by notice to the other party. The 2023 ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the 2023 ATM Program or (ii) termination of the 2023 ATM Program in accordance with its terms. Either party may terminate the 2023 ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the 2023 ATM Program. The rate of compensation will not apply when Ladenburg acts as principal, in which case such rate shall be separately negotiated. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $60,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

During the three months ended March 31, 2024, we sold 143,120 shares of our common stock under the 2023 ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.4 million.

Note 10 – Stock-Based Compensation

We recognize expense in our interim unaudited condensed consolidated financial statements related to all stock-based awards granted to employees and non-employee directors based on their fair value on the date of grant. Compensation expense related to stock options is calculated using the Black-Scholes option-pricing model and is recognized ratably over the vesting period, which is typically three years. Compensation expense related to restricted stock unit, or RSU, awards is also recognized ratably over the vesting period, which is typically between one to three years.

A summary of activity under our long-term incentive plans is presented below:

(in whole numbers)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2024	15,400	$ 1,664.00	
Granted	-	-	
Forfeited or expired	-	-	
Outstanding at March 31, 2024	15,400	$ 1,664.00	8.6
Vested and exercisable at March 31, 2024	3,336	$ 7,539.07	5.7
Vested and expected to vest at March 31, 2024	14,118	$ 1,678.09	8.6

(in whole numbers)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2024	8,180	$ 52.49
Awarded	-	-
Vested	(139)	918.00
Cancelled	-	-
Outstanding at March 31, 2024	8,041	$ 37.51

The table below summarizes the total stock-based compensation expense included in the interim unaudited condensed consolidated statements of operations for the periods presented:

(in thousands)	Three Months Ended March 31, 2024	2023
Research and development	$ 51	$ 129
General and administrative	200	156
Total	$ 251	$ 285

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the historical volatility of our common stock and other factors. We also use historical data and other factors to estimate option exercises and forfeiture rates. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

Note 11 – Licensing and Research Funding Agreements

Term Sheet and Project Financing Agreement with Lee's (HK)

In March 2020, we entered into a Term Sheet with Lee's (HK), pursuant to which Lee's (HK) provided financing for the development of AEROSURF. In August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, formalizing the terms of the Term Sheet, and under which we received payments totaling $2.8 million through October 2020. In November 2020, Lee's (HK) provided notice of termination of additional funding under the PF Agreement, and we and Lee's (HK) revised our plans for the continued development of AEROSURF. Lee's (HK) agreed to continue the development of AEROSURF in Asia at its own cost. Lee's (HK) agreed to fund an additional $1.0 million to us in 2021 for certain transition and analytical services to be provided by us with respect to the development of AEROSURF, which will be considered "Project Expenses" under the terms of the PF Agreement. In 2021, we received payments totaling $1.0 million from Lee's (HK) and no further amounts were due under the PF Agreement.

Since the 2018 acquisition of CVie Investments Limited and CVie Therapeutics, istaroxime has become our primary focus for investment and execution due to what we believe represents a greater potential value opportunity for us and our stockholders. Since completing our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury in January 2022, in order to preserve resources for the highest priority programs, we have begun to reduce costs not already being performed by our licensee, Lee's (HK) and Zhaoke, under the terms of our Original License Agreement. These costs include certain reductions in headcount dedicated to KL4 surfactant and the decommissioning of both our analytical and technical support laboratory, which previously conducted release testing of APIs and supportive research for our lyophilized and aerosolized KL4 surfactant, and our medical device development laboratory, which was previously used to conduct development activities and testing for our ADS technologies. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing one or more licensing transactions.

To repay the funds provided under the terms of the PF Agreement, until such time as we have repaid 125% of the amounts funded by Lee's (HK) for the development of AEROSURF, we will pay to Lee's (HK) 50% of all revenue amounts and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, excluding (i) payments for bona fide research and development services; (ii) reimbursement of patent expenses and (iii) all amounts paid to us under the Original License Agreement, minus certain deductions and certain reductions for any payments made by us with respect to third party intellectual property not previously funded by Lee's (HK).

As of March 31, 2024, the liability balance related to the payments under the PF Agreement was $3.8 million and is recorded in other liabilities.

A&R License Agreement with Lee's (HK)

Previously, we were developing a KL4 surfactant platform, including AEROSURF (lucinactant for inhalation), to address a range of serious respiratory conditions in children and adults. In order to focus our resources on the development of our istaroxime pipeline, we suspended all internal AEROSURF clinical activities in November 2020, and, in January 2022 we began to reduce all other costs related to the KL4 surfactant platform that were not already being performed by our licensee, Lee's (HK) and Zhaoke, under the terms of the Original License Agreement.

On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A&R License Agreement, with Lee's (HK) and Zhaoke effective as of August 9, 2022. We refer to Zhaoke and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes the Original License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A., or Esteve. If and when the exclusive license granted to Esteve terminates as to any country, such country automatically becomes part of the Licensed Territory of Licensee.

Under the Original License Agreement, Lee's (HK) previously made an upfront payment to us of $1.0 million. Pursuant to the terms of the A&R License Agreement, we may also receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income. We are also eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the A&R License Agreement) that ranges from low single digit to low teen percentages, depending on the product. Royalties are payable on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid patent claim covering the product in the country of sale, (ii) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (iii) ten years after the first commercial sale of the product in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each product but at substantially reduced rates. In addition, the royalty rates are subject to reduction by as much as 50% in a given country based on generic competition in such country.

The A&R License Agreement is considered to be a contract modification in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. No additional performance obligations were identified in the contract modification, and no future material performance obligations are due.

All revenue related to the $1.0 million upfront payment under the Original License Agreement was appropriately recognized as of the second quarter of 2019. Regulatory and commercialization milestones under the A&R License Agreement were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. Consideration related to sales-based milestones and royalties under the A&R License Agreement will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Licensee and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each future reporting period and as uncertain events are resolved or other changes in circumstances occur.

License, Development and Commercialization Agreement with Lee's (HK)

On January 12, 2024, we entered into a License, Development and Commercialization Agreement with Lee's (HK) effective as of January 7, 2024, or the Lee's (HK) License Agreement. Under the Lee's (HK) License Agreement, we granted an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute and otherwise commercialize products that incorporate istaroxime for intravenous administration, rostafuroxin for oral administration, and our proprietary dual-mechanism SERCA2a activators for intravenous or oral administration (collectively, the Products and each, a Product), in each case for the prevention, mitigation and/or treatment of any disease, disorder or condition in humans including acute decompensated heart failure, cardiogenic shock, and chronic use following discharge of an individual hospitalized for acute decompensated heart failure, or Field, in the People's Republic of China, Hong Kong, Macau, Taiwan, Singapore, South Korea, Thailand, Vietnam, Brunei, Myanmar, Cambodia, East Timor, Indonesia, Laos, Malaysia, and the Philippines, or the New Licensed Territory.

Under the Lee's (HK) License Agreement, we may receive up to $3.1 million in potential upfront pre-development, development, clinical, and regulatory milestone payments and up to $135.25 million in sales milestone payments. We are also entitled to receive a low double-digit percentage of Lee's (HK) non-royalty sublicense income.

We are eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the Lee's (HK) License Agreement) that ranges from low single-digit to low double-digit percentages, depending on the Product. Royalties are payable on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid patent claim covering the Product in the country of sale, (ii) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (iii) ten years after the first commercial sale of the Product in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each Product but at substantially reduced rates. In addition, the royalty rates are subject to reduction by as much as 50% in a given country based on generic competition in such country.

Under the Lee's (HK) License Agreement, Lee's (HK) will be solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of Products in the New Licensed Territory, with the exception of certain costs in connection with filing fees payable to regulatory authorities in the New Licensed Territory relative to a Product for which we hold the applicable marketing authorization. Lee's (HK) may sublicense its rights to its affiliates and may grant sublicenses to third-party subcontractors to perform certain activities under the Lee's (HK) License Agreement on behalf of Lee's (HK) or its affiliates but may not otherwise grant sublicenses to unaffiliated third parties without our prior consent. A sublicensee and a subcontractor may not be a competitor identified by us. Sublicenses granted under the Lee's (HK) License Agreement may not include the right to further sublicense. The Lee's (HK) License Agreement establishes a joint steering committee and a joint development committee to oversee the regional development (with us retaining final decision rights over clinical protocols) and a joint commercialization committee.

During the term of the Lee's (HK) License Agreement, we receive an exclusive (even as to Lee's (HK)), sublicensable license under any Lee's (HK) and its affiliate's intellectual property that covers a Product (including its manufacture and use) and any improvements to the licensed technology developed solely by or on behalf of Lee's (HK) or jointly with us, to (i) develop Product in the Field to obtain or maintain regulatory approval outside of the New Licensed Territory, and (ii) use, sell, offer for sale, import, export, make, have made, distribute, warehouse, market, promote, apply for and submit applications for drug approval and reimbursement approval and otherwise commercialize Product in the Field outside of the New Licensed Territory. After the term of the Lee's (HK) License Agreement, or in the event that we wish to obtain an exclusive license under certain patent rights during or after the term, we have the option to negotiate an exclusive royalty-bearing license under any such intellectual property, provided that such royalties shall not exceed specified low single-digit caps.

Under the Lee's (HK) License Agreement, each party is responsible for prosecution and maintenance of its respective solely-owned patents, and the parties shall decide on a case-by-case basis the appropriate allocation of costs and control concerning matters regarding the prosecution, maintenance, defense and infringement of any jointly-owned patents. The Lee's (HK) License Agreement provides for cooperation between the parties with respect to enforcement of patent rights. As between the parties, we have the first right to enforce patent rights against third parties at our own expense. If we decline to enforce such rights, Lee's (HK) has the right to enforce such rights at its own expense. In the event that a third party claims that a Product used or sold by Lee's (HK) (or its affiliate or sublicensee) is infringing on a patent in the New Licensed Territory, Lee's (HK) is responsible for defending against such third party claim at its cost and expense, with the exception of certain counterclaims that we may bring.

The term of the Lee's (HK) License Agreement will continue on a country-by-country basis for the commercial life of the Products. Either party may terminate the Lee's (HK) License Agreement in the event of bankruptcy or a material breach of the Lee's (HK) License Agreement by the other party that remains uncured for a period of sixty days (or within 30 days after delivery of a Default Notice (as defined in the Lee's (HK) License Agreement) if such material breach is solely based on the breaching party's failure to pay amount due under the Lee's (HK) License Agreement). In addition, either party may terminate the Lee's (HK) License Agreement with respect to any individual Product in a country if a regulatory authority in such country terminates, suspends or discontinues development of such Product and such termination, suspension or discontinuance persists for a period in excess of 18 months. Upon termination of the Lee's (HK) License Agreement in its entirety or with respect to a particular Product or country, generally all related rights and licenses granted to Lee's (HK) will terminate, all rights under our technology will revert to us, and Lee's (HK) will cease all use of our technology, in each case in relation to the terminated Product(s) and country(ies), as applicable.

The Lee's (HK) License Agreement constitutes a contract with a customer accounted for in accordance with ASC Topic 606. The promise of the istaroxime product, dual mechanism SERCA2a activator products, and rostafuroxin product license is the sole performance obligation provided in the Lee's (HK) License Agreement. The performance obligation was fully satisfied as of the effective date of the Lee's (HK) License Agreement, and no future material performance obligations are due.

No revenue has been recognized under the Lee's (HK) License Agreement. Clinical, regulatory and commercialization milestones under the Lee's (HK) License Agreement were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. Consideration related to sales-based milestones and royalties under the Lee's (HK) License Agreement will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Lee's (HK) and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each future reporting period and as uncertain events are resolved or other changes in circumstances occur.

Note 12 – Income Taxes

During the three months ended March 31, 2024, we recorded an income tax provision of $0.1 million related to the state tax on our estimated taxable income for the year, primarily due to the gain on debt extinguishment (See the section titled, "Note 8 – Restructured Debt Liability").

We have evaluated the positive and negative evidence bearing upon our ability to realize our deferred tax assets, which primarily consist of net operating losses, or NOLs. We considered the history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies, and have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets. As such, we recorded a full valuation allowance against net deferred tax assets as of March 31, 2024 and December 31, 2023.

Under Internal Revenue Code of 1986, or IRC, Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple ownership changes since we became a "loss corporation" as defined in Section 382.

Utilization of NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the IRC due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and income tax liabilities, respectively. We are currently performing a Section 382 analysis and will continue to monitor any limitations on our ability to use NOLs and R&D credits in the future.

Note 13 – Subsequent Event

Asset Purchase Agreement with Varian Biopharmaceuticals

On April 2, 2024, we entered into the Asset Purchase Agreement with Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. We also assumed all liabilities arising on or after April 2, 2024, relating to the research, development, manufacturing, registration, commercialization, use, handling, supply, storage, import, export or other disposition or exploitation of any and all products associated with the Transferred Assets.

In consideration of the purchase of the Transferred Assets, (i) on April 2, 2024, we issued a total of 5,500 shares of our Series B Convertible Preferred Stock, par value $0.001 per share, or the Series B Preferred Stock, to certain creditors of Varian and (ii) agreed to pay up to $2.3 million in milestone payments upon the achievement of certain regulatory and clinical development milestones with our option to pay such milestone payments either in cash or our common stock.

The Asset Purchase Agreement contains customary representations and warranties, covenants, closing conditions and indemnification provisions for a transaction of this nature, including, without limitation, confidentiality and non-compete undertakings by Varian.

Series B Preferred Stock

The terms of the Series B Preferred Stock are as set forth in the Series B Certificate of Designation of Series B Preferred Stock, as filed with the Delaware Secretary of State and effective on April 3, 2024. The Series B Certificate of Designation authorizes a total of 5,500 shares of Series B Preferred Stock, or the Series B Preferred Stock, with an initial conversion price of $6.4854, or the Preferred Conversion Price, which is subject to adjustment as provided in the Series B Certificate of Designation to no lower than $1.2978. The Series B Preferred Stock has a stated value of $1,000 per share, or the Stated Value, which equal to an aggregate Stated Value of $5,500,000 as of April 2, 2024. Each share of Series B Preferred Stock is initially convertible into 155 shares of our common stock, subject to adjustment as provided in the Series B Certificate of Designation. No fractional shares will be issued upon conversion; rather any fractional share will be rounded up to the nearest whole share.

From and after April 2, 2024, each holder of a share of Series B Preferred Stock is entitled to receive dividends, or Dividends, which are computed on the basis of a 360-day year and twelve 30-day months and will increase the Stated Value of the Series B Preferred Stock on each dividend date (as defined in the Series B Certificate of Designation).

Dividends on the Series B Preferred Stock will accrue at 10.0% per annum, or the Dividend Rate, and be payable by way of inclusion of the Dividends in the Conversion Amount (as defined in the Series B Certificate of Designation) on each Conversion Date (as defined in the Series B Certificate of Designation) in accordance with the Series B Certificate of Designation or upon any redemption in accordance with the Series B Certificate of Designation or upon any required payment upon any Bankruptcy Triggering Event (as defined in the Series B Certificate of Designation). From and after the occurrence and during the continuance of any Triggering Event (as defined in the Series B Certificate of Designation), the Dividend Rate will automatically be increased to 18.0% per annum.

The Preferred Conversion Price is subject to adjustment upon the occurrence of specified events and subject to price-based adjustment in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock at a price below the then-applicable Preferred Conversion Price, as described in further detail in the Series B Certificate of Designation.

Securities Purchase Agreement and Convertible Notes

On April 2, 2024, we entered into the Purchase Agreement with the Buyers. Pursuant to the Purchase Agreement, we agreed to sell the Notes for $1.4 million of net proceeds. The Notes have an initial conversion price of $6.4854, which is subject to adjustment upon the occurrence of specified events to no lower than $1.2978, subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock.

The Notes will be senior obligations of the Company. The Notes will accrue interest at a rate of 10.0% per annum, payable in arrears on the first calendar day of each calendar month, beginning on May 2, 2024, unless an event of default has occurred, upon which interest will accrue at 18.0% per annum. The Notes mature on January 2, 2025 unless earlier converted or redeemed (upon the satisfaction of certain conditions).

We may, subject to certain conditions, redeem all, but not less than all, of the amount then remaining under the Notes in cash at a premium of 20% of the greater of (i) the amount then outstanding under the Notes, and (ii) the equity value of our common stock underlying the Notes, which is calculated using the greatest closing sale price of our common stock on any trading day during the period commencing on the date of notice of such redemption and ending on the date we make the entire payment required pursuant to the Purchase Agreement. The Notes can also be redeemed by us under various other circumstances, such as a change of control, events of default, or at the option of the Buyer under limited circumstances, with any such redemption subject to the terms and conditions as set forth in the Notes.

The Notes contain certain conversion limitations, providing that no conversion may be made if, after giving effect to the conversion, the holder, together with any of its affiliates, would own in excess of 4.99% of our outstanding shares of common stock.

The Notes contain certain customary affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends, distributions or redemptions and the transfer of assets, among other matters. The Notes also contain certain customary events of default, including, among other things, the failure to file and maintain an effective registration statement covering the certain registrable securities, subject to certain exceptions.

We agreed to seek stockholder approval for the issuance of all of the shares of common stock issuable upon conversion of the Notes and the Series B Preferred Stock in accordance with the rules and regulations of the Nasdaq Stock Market.

We additionally agreed that, subject to certain exceptions, without the consent of the holders holding at least a majority of our common stock underlying the Series B Preferred Stock and our common stock underlying the Notes for the period commencing on April 2, 2024 and ending on the date immediately following the 90th trading day after the Applicable Date (as defined in the Purchase Agreement), or the Restricted Period, neither we nor our subsidiaries shall directly or indirectly issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any equity security (as that term is defined under Rule 405 promulgated under the Securities Act of 1933, as amended), any Convertible Securities (as defined in the Purchase Agreement), any debt, any preferred stock or any purchase rights) (any such issuance, offer, sale, grant, disposition or announcement (whether occurring during the Restricted Period or at any time thereafter) is referred to as a Subsequent Placement).

Subject to the limitations described in the Purchase Agreement, for so long as the Notes are outstanding, we will be prohibited from effecting or entering into an agreement to effect any Subsequent Placement involving a Variable Rate Transaction (as defined in the Purchase Agreement). Additionally, the Purchase Agreement contains a participation right, which provides that, subject to certain exceptions, at any time on or prior to the fourth anniversary of April 2, 2024, neither we nor our subsidiaries shall, directly or indirectly, effect any Subsequent Placement unless we comply with the notice procedures as outlined in the Purchase Agreement with respect to each Buyer, providing the opportunity for such Buyer to participate in such Subsequent Placement on a pro rata basis as described in the Purchase Agreement.

Reverse Stock Split

On April 19, 2024, we filed an amendment to our Amended and Restated Certificate of Incorporation to implement a 1-for-18 reverse stock split of our issued and outstanding common stock. The reverse stock split of our outstanding common stock was effected at a ratio of 1 post-split share for every 18 pre-split shares as of 11:59 p.m. Eastern Time on April 19, 2024. The reverse stock split correspondingly adjusted the per share exercise price of all outstanding options and all shares underlying any of our outstanding warrants by reducing the conversion ratio for each outstanding warrant and increasing the applicable exercise price or conversion price in accordance with the terms of each outstanding warrant and based on the reverse stock split ratio. No fractional shares were issued in connection with the reverse stock split. The number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation is unchanged at 120 million shares. The accompanying interim unaudited condensed financial statements reflect the 1-for-18 reverse split of our common stock. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Continued Listing on The Nasdaq Capital Market

On January 22, 2024, we received a deficiency letter from the Staff of Nasdaq notifying us that, for the last 31 consecutive business days, the closing bid price for our common stock has been below the minimum $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Rule 5550(a)(2). The Nasdaq deficiency letter had no immediate effect on the listing of our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol "WINT". We were initially given 180 calendar days, or until July 22, 2024, to regain compliance with Rule 5550(a)(2).

As described above, on April 19, 2024, we effected a reverse stock split of our issued and outstanding shares of common stock, par value $0.001 per share, at a ratio of 1 post-split share for every 18 pre-split shares. On May 6, 2024, we received written confirmation from Nasdaq notifying us that we had regained compliance with Rule 5550(a)(2).

Entry into a Material Definitive Agreement

In order to reduce expected costs with our contract research organization, Momentum Research, Inc., or MRI, on May 9, 2024, or the Effective Date, we entered into Amendment No. 1 to the Master Services Agreement and Work Order Nos. 11 and 12, or the Amendment, with MRI. The Amendment amends the Master Services Agreement we entered into with MRI on February 13, 2020, or the Original MSA, and the original Work Order Nos. 11 and 12 we entered into with MRI on June 1, 2023, collectively, the Original Work Orders.

Under the Original MSA, we agreed to, among other things, engage MRI to provide non-exclusive research and development services, by executing individual work orders to be negotiated and specified in writing on terms agreed to by both parties on a later date.

Under the terms of the Amendment, we agreed to, among other things, be responsible for certain management, regulatory strategy, and reporting obligations in connection with our SEISMiC Extension study and MRI agreed to fully perform its obligations under the Original Work Orders with respect to the SEISMiC Extension study, including performance of all services and delivery of all deliverables required by the Original Work Orders. Additionally, with respect to the SEISMiC C Study, MRI agreed to be responsible for certain regulatory submissions, as provided in the Amendment.

Additionally, in consideration of and conditioned upon the payments described below, we and MRI each agreed to cancel and extinguish any and all amounts owed to MRI or us, respectively, each subject to the terms of the Amendment. The parties agreed that such cancellation and extinguishment shall not be construed as a waiver of claims by each party for breach of the Original MSA or either or both of the Original Work Orders other than for non-payment, nor a waiver of each party's respective indemnification rights under the Original MSA.

In consideration of MRI's full performance of the Original Work Orders and cancellation of accrued expenses as described above, we agreed to, among other things, pay MRI $1.2 million in a series of scheduled payments through September 20, 2024, subject to the terms of the Amendment. If services are not completed by October 31, 2024, the parties agree that MRI will continue its services until fully completed with no further compensation. In case of delayed payments, we agreed to pay MRI interest on any overdue amount from the due date until the date paid in full at a rate equal to 18% per annum. If the SEISMiC Extension study and the SEISMiC C Study are terminated prior to September 20, 2024, then the next payment due after termination will be made to MRI and remaining payments that would have become due automatically become no longer payable.

Additionally, we agreed that, for a transaction consummated by December 31, 2027, we shall pay MRI an amount equal to 2% of istaroxime license fees, milestone payments, royalties, securities or other property that we actually collect in respect of any license of istaroxime that we grant to any unaffiliated third party on or after the Effective Date; net of all legal and financial advisory fees and expenses actually paid by us in respect of the associated license transaction. Further, we agreed that if we commercialize istaroxime ourselves in the United States or another region, we shall also pay MRI an amount equal to 2% of our net profit derived from direct sales of istaroxime to clients in our territory where sales occurred, as determined in our US GAAP financial statements. Pursuant to the Amendment, such payments on istaroxime sales will end when data and market exclusivity protection expires for istaroxime.

Further, in connection with the first to occur of either a Change of Control (as defined in the Amendment) or the sale of all or substantially all of our rights in istaroxime not in the context of a Change of Control, we agree to pay MRI an amount equal to 2% of the sum of any cash and the fair market value of any securities or other property that we actually collect or receive that is attributable to our rights in istaroxime (subject to the terms of the Amendment), net of a ratable portion of certain fees and expenses as provided by the Amendment.

After December 1, 2025, we have the right to buy out the amounts due under certain provisions of the Amendment.

The foregoing descriptions of the Original MSA and Amendment are general descriptions only, do not purport to be complete descriptions of the rights and obligations of the parties thereunder, and are qualified in their entirety by reference to the terms of such agreements, which are filed as Exhibit 10.1 and 10.2, respectively, to this Quarterly Report on Form 10-Q.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the section titled "Forward-Looking Statements" and any risk factors discussed elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2023 that we filed with the Securities and Exchange Commission, or SEC, on April 16, 2024, as supplemented by our other filings with the SEC and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

This Management's Discussion and Analysis, or MD&A, is provided as a supplement to the accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) to help provide an understanding of our financial condition and changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) and our Annual Report on Form 10-K for the year ended December 31, 2023. Unless otherwise specified, references to Notes in this MD&A refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

We are a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Our portfolio of product candidates includes istaroxime, a Phase 2 candidate with sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activating properties for acute heart failure and associated cardiogenic shock; preclinical SERCA2a activators for heart failure; rostafuroxin for the treatment of hypertension in patients with a specific genetic profile; and a preclinical atypical protein kinase C iota, or aPKCi, inhibitor (topical and oral formulations), being developed for potential application in rare and broad oncology indications. We also have a licensing business model with partnership out-licenses currently in place.

Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. Istaroxime demonstrated significant improvement in both systolic and diastolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure, or SBP, in acute decompensated heart failure patients and had a favorable renal profile, we initiated a Phase 2 global clinical study, or the SEISMiC Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. In April 2022, we announced our observations in the SEISMiC Study that istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. We believe that istaroxime has the potential to fulfill an unmet need in early and potentially more severe cardiogenic shock. We further believe that the data from the SEISMiC Study supports continued development in both cardiogenic shock and AHF. In the fourth quarter of 2023, we initiated an extension to the SEISMiC Study, or the SEISMiC Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of SERCA2a. The SEISMiC Extension study is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in the second half of 2024. Additionally, we have recently initiated a small study in more severe SCAI Stage C cardiogenic shock, or the SEISMiC C Study, to evaluate the safety and efficacy of istaroxime in cardiogenic shock patients who are also receiving standard of care rescue therapy for shock. The SEISMiC C Study is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock with enrollment anticipated to be completed in late 2024. Our ability to complete both of these studies with their intended sample size is dependent upon our ability to secure adequate resourcing for the program through financing efforts or business development activities.

Our heart failure cardiovascular portfolio also includes SERCA2a activators. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. These candidates would potentially be developed for both acute decompensated and chronic out-patient heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance the development of rostafuroxin without securing such an arrangement or partnership.

Our cardiovascular assets and programs are associated with a regional licensed partnership with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), for the development and commercialization of our product candidate, istaroxime, in Greater China. In addition to istaroxime, the agreement also licenses our preclinical next-generation dual mechanism SERCA2a activators, and rostafuroxin, a Phase 2 product candidate for hypertension associated with specific genotypes. In addition, we are supporting the efforts of Lee's (HK) in starting a Phase 3 trial in AHF with istaroxime. Further, we are engaged in discussions regarding potential global licensing partnerships outside of Lee's (HK) territory.

On April 2, 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with a licence agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. The Transferred Assets include a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations (topical and oral) of an aPKCi inhibitor. We plan to advance investigational new drug enabling activities and are in the process of determining the expected clinical development plan for the platform.

With the exception of certain non-recurring items such as debt extinguishment, we have incurred net losses since inception. We had net income of $10.2 million for the three months ended March 31, 2024 due to a $14.5 million gain on debt extinguishment and $0.2 million of other income, partially offset by a $4.4 million operating loss and $0.1 million of income tax expense. For the three months ended March 31, 2023, our net loss was $4.1 million, which included a $0.5 million loss on impairment of goodwill. As of March 31, 2024, we had an accumulated deficit of $834.6 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock, warrants to purchase common stock, and borrowings from investors and financial institutions.

We expect to continue to incur significant research and clinical development, regulatory, and other expenses as we (i) continue to develop our product candidates; (ii) seek regulatory clearances or approvals for our product candidates; (iii) conduct clinical trials on our product candidates; and (iv) manufacture, market, and sell any product candidates for which we may obtain regulatory approval.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations.

Business and Program Updates

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2023 that we filed with the SEC on April 16, 2024, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Istaroxime (Cardiogenic Shock)

In September 2020, we initiated a Phase 2 clinical study of istaroxime for the acute treatment of cardiogenic shock in more severe heart failure patients than previously studied to evaluate the potential to improve blood pressure (primary measure) and cardiac function (secondary measure). The study also evaluated the safety and side effect profile of istaroxime in this patient population. In April 2022, we announced positive topline results with istaroxime in rapidly and significantly raising SBP. In May 2022, we presented data from our positive Phase 2 study of istaroxime in early cardiogenic shock in a late-breaker presentation at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. There is a significant unmet medical need in the area of early cardiogenic shock and severe heart failure. Istaroxime demonstrated a meaningful increase in blood pressure while simultaneously increasing cardiac output and preserving renal function in clinical trials of this condition.

In order to continue our development of istaroxime for the acute treatment of cardiogenic shock, during the third quarter of 2023, we initiated the SEISMiC Extension study, which is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock. We believe that this extension will advance the characterization of the physiology associated with longer dosing as well as enhancing dose optimization. Additionally, in the fourth quarter of 2023, we commenced with study start up activities for the SEISMiC C study, which is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock. We also believe that the SEISMiC Extension and SEISMiC C studies will further characterize the effects associated with SERCA2a activation and will support our clinical and regulatory strategy for istaroxime. We currently do not have sufficient capital to fully complete these clinical trials.

Istaroxime (AHF)

There is substantial potential synergy between our clinical trial program in early cardiogenic shock and our development program in acute decompensated heart failure. Both programs are focused on treating heart failure patients with acute congestion and low blood pressure requiring hospitalization. We believe that this category of heart failure patients (whether they are in shock or not) could particularly benefit from the unique profile and potential ability of istaroxime to improve cardiac function and increase blood pressure while maintaining or improving renal function. Our strategy is to advance istaroxime in cardiogenic shock as the lead indication and utilize this data and experience, along with the positive Phase 2a and 2b AHF studies, already completed, to potentially enter Phase 3 for acute decompensated heart failure in the normal to low SBP population. We currently do not have sufficient capital to execute our clinical trial in AHF and are seeking partnership opportunities to advance the program. We believe the Phase 3 AHF program being planned by our licensing partner in China may provide supportive data for potential AHF programs initiated in the future.

SERCA2a Activators – Preclinical Oral, Chronic, and Acute Heart Failure Product Candidates

We are pursuing several early exploratory research programs to assess potential product candidates, including oral and intravenous SERCA2a activator heart failure compounds, and believe that we can add value to our cardiovascular portfolio by advancing these SERCA2a activator candidates through preclinical studies. In April 2023, we announced that the European Patent Office has granted Patent No. 3599243, providing patent coverage for the dual mechanism SERCA2a Activator class of drug candidates. This patent provides protection until July 2038 for the family of compounds with a dual mechanism of action. To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements, or other strategic opportunities. Additionally, the United States Patent and Trademark Office has issued US Patent No. 11,730,746 covering our dual mechanism SERCA2a activators. The new composition of matter patent titled: "17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE," provides patent protection through late 2039.

Rostafuroxin

Rostafuroxin has demonstrated efficacy in Caucasian patients in treatment naïve hypertension in a Phase 2b trial. During the second quarter of 2021, we concluded an initial process to test the industry's interest in investing in our product candidate. We currently have not been able to secure a licensing transaction or other strategic opportunity. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional Phase 2 clinical trial to demonstrate efficacy in African American patients in treatment resistant hypertension. We are continuing to pursue licensing arrangements and/or other strategic partnerships for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement or partnership.

aPKCi inhibitor (topical formulation previously designated as VAR-101)

The topical (cutaneous) formulation is a small molecule that may have potential for the treatment of basal cell carcinoma, or BCC. The active pharmaceutical ingredient, or API, in aPKCi inhibitor (topical) has demonstrated dose dependent anti-tumor activity in murine and human BCC cell lines, in studies performed at Cancer Research UK, or CRUK, a charity registered in England and Scotland, and based in London, United Kingdom. CRUK collaborators, including Stanford University under a sponsored research agreement with CRUK, completed the preclinical tumor cell line data and the BCC cell line data that formed the basis for additional "method of use" patents that are included in the License Agreement. These types of in vitro studies in tumor cell lines are typical early-stage models of activity or efficacy when testing a new chemical compound, the data from which is used in regulatory filings for first-in-man clinical trials. These mouse models of BCC and lung cancer were performed by CRUK and their collaborators.

aPKCi inhibitor (oral formulation previously designated as VAR-102)

The oral formulation is a small molecule that may have potential for the treatment of solid tumors. The API in the aPKCi inhibitor (oral)is the same as the API in aPKCi inhibitor (topical). In the scientific literature, the presence and activation of aPKCi has been implicated in the growth of multiple human cancers including non-small cell lung cancer, or NSCLC, pancreatic, and ovarian cancer. The API in aPKCi inhibitor (oral) has demonstrated dose dependent anti-tumor activity in a mouse model of NSCLC (squamous cell lung carcinoma), in studies performed at CRUK and with its collaborators. Preclinical experiments of the API in aPKCi inhibitor (oral), appears to show dose dependent anti-tumor activity in a xenograft NSCLC model.

Reverse Stock Split

On April 19, 2024, we filed an amendment to our Amended and Restated Certificate of Incorporation to implement a 1-for-18 reverse stock split of our issued and outstanding common stock. The reverse stock split of our outstanding common stock was effected at a ratio of 1 post-split share for every 18 pre-split shares as of 11:59 p.m. Eastern Time on April 19, 2024. The reverse stock split correspondingly adjusted the per share exercise price of all outstanding options and all shares underlying any of our outstanding warrants by reducing the conversion ratio for each outstanding warrant and increasing the applicable exercise price or conversion price in accordance with the terms of each outstanding warrant and based on the reverse stock split ratio. No fractional shares were issued in connection with the reverse stock split. The number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation is unchanged at 120 million shares. The accompanying interim unaudited condensed financial statements reflect the 1-for-18 reverse split of our common stock. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Continued Listing on The Nasdaq Capital Market

On January 22, 2024, we received a deficiency letter from the Staff of Nasdaq notifying us that, for the last 31 consecutive business days, the closing bid price for our common stock has been below the minimum $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Rule 5550(a)(2). The Nasdaq deficiency letter had no immediate effect on the listing of our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol "WINT". We were initially given 180 calendar days, or until July 22, 2024, to regain compliance with Rule 5550(a)(2).

As described above, on April 19, 2024, we effected a reverse stock split of our issued and outstanding shares of common stock, par value $0.001 per share, at a ratio of 1 post-split share for every 18 pre-split shares. On May 6, 2024, we received written confirmation from Nasdaq notifying us that we had regained compliance with Rule 5550(a)(2).

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2023. For a discussion of our accounting policies, see the section titled, "Note 4 – Summary of Significant Accounting Policies" and, in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2023, Note 4 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Intangible Assets and Goodwill

We record acquired intangible assets and goodwill based on estimated fair value. The identifiable intangible assets resulting from the CVie Therapeutics acquisition in December 2018 relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin. The IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three months ended March 31, 2024, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired.

During the first quarter of 2023, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. Based on an interim goodwill impairment test, we determined that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, we recorded a loss on impairment of goodwill of $0.5 million for the three months ended March 31, 2023, recognized within operating expenses in our condensed consolidated statements of operations. As of March 31, 2024 and December 31, 2023, goodwill was zero on our condensed consolidated balance sheet.

The following table represents identifiable intangible assets as of March 31, 2024 and December 31, 2023:

(in thousands)	March 31, 2024	December 31, 2023
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	2,910	2,910
Intangible assets	25,250	25,250

RESULTS OF OPERATIONS

Comparison of the Three Months EndedMarch 31, 2024 and 2023

(in thousands)	Three Months Ended March 31, 2024	2023	Change
Expenses:			
Research and development	$ 2,253	$ 1,415	$ 838
General and administrative	2,152	2,292	(140)
Loss on impairment of goodwill	-	484	(484)
Total operating expenses	4,405	4,191	214
Operating loss	(4,405)	(4,191)	(214)
Other income (expense):			
Gain on debt extinguishment	14,520	-	14,520
Interest income	30	44	(14)
Interest expense	(13)	(12)	(1)
Other income, net	201	48	153
Total other income, net	14,738	80	14,658
Income (loss) before income taxes	10,333	(4,111)	14,444
Income tax expense	(114)	-	(114)
Net income (loss)	$ 10,219	$ (4,111)	$ 14,330

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, contract manufacturing organizations, contract laboratories, consulting, and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical, and regulatory operations expenses, to specific programs. We also account for research and development and report annually by major expense category as follows: (i) contracted services; (ii) salaries and benefits; (iii) rents and utilities; (iv) stock-based compensation; (v) depreciation; and (vi) other. We expect that our research and development expenses related to istaroxime – cardiogenic shock program will continue to increase to the extent that we continue the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock and start-up procedures for a small study in more severe SCAI Stage C cardiogenic shock. We currently do not have sufficient capital to fully complete these clinical trials. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates.

Research and development expenses are as follows:

(in thousands)	Three Months Ended March 31, 2024	2023	Increase (Decrease)
Istaroxime – cardiogenic shock program	$ 1,475	$ 424	$ 1,051
Istaroxime – AHF	-	(20)	20
KL4 surfactant	-	(82)	82
Total direct clinical and preclinical programs	1,475	322	1,153
Product development and manufacturing	224	245	(21)
Clinical, medical, and regulatory operations	554	848	(294)
Total research and development expenses	$ 2,253	$ 1,415	$ 838

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.1 million for both the three months ended March 31, 2024 and 2023.

Direct Clinical and Preclinical Programs

Direct clinical and preclinical programs include: (i) activities associated with conducting clinical trials, including contract research organization costs, patient enrollment costs, clinical site costs, clinical drug supply, and related external costs, such as consultant fees and expenses; and (ii) development activities, toxicology studies, and other preclinical studies.

Total direct clinical and preclinical programs expenses increased $1.2 million for the three months ended March 31, 2024 compared to the same period in 2023 primarily due to increases in istaroxime – cardiogenic shock program costs as described below.

Istaroxime – cardiogenic shock program costs increased $1.1 million for the three months ended March 31, 2024 compared to the same period in 2023 due to (i) the trial execution costs for the SEISMiC Extension study, which began enrollment in the fourth quarter of 2023 and (ii) the start-up procedures for the small study in more severe SCAI Stage C cardiogenic shock.

Istaroxime – AHF costs have been limited as we focus our resources on the execution of the istaroxime – cardiogenic shock program.

Costs related to the KL4 surfactant platform are expected to be minimal as prior KL4 surfactant platform clinical trials have now been closed out.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations with our contract manufacturing organization, validation activities, quality assurance; and (ii) pharmaceutical and manufacturing development activities of our drug product candidates, including development of istaroxime. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality assurance activities, and expert consultants and outside services to support pharmaceutical development activities.

Product development and manufacturing expenses for the three months ended March 31, 2024 are comparable to the same period in 2023.

Clinical, Medical, and Regulatory Operations

Clinical, medical, and regulatory operations include medical, scientific, preclinical and clinical, regulatory, data management, and biostatistics activities in support of our research and development programs. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Clinical, medical, and regulatory operations expenses decreased $0.3 million for the three months ended March 31, 2024 compared to the same period in 2023 due to (i) a decrease of $0.2 million in personnel costs; and (ii) a decrease of $0.1 million in non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consist of costs for executive management, business development, intellectual property, finance and accounting, legal, insurance, human resources, information technology, facilities, and other administrative costs.

General and administrative expenses decreased $0.1 million for the three months ended March 31, 2024 compared to the same period in 2023 due to (i) a decrease of $0.2 million in insurance costs; partially offset by (ii) an increase of $0.1 million in professional fees.

Other Income, Net

On January 24, 2024, we and affiliates of Deerfield Management Company L.P., or Deerfield, entered into an Exchange and Termination Agreement, or the Exchange and Termination Agreement, wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share (See the section titled, "Note 8 – Restructured Debt Liability"). This transaction was accounted for as an extinguishment of debt in accordance with ASC 470, *Debt-Modifications and Extinguishments*, and as a result, we recognized a $14.5 million non-cash gain on debt extinguishment.

Interest income relates to interest on our money market account for the three months ended March 31, 2024 and 2023.

For the three months ended March 31, 2024 and 2023, interest expense consists of interest expense associated with loans payable.

For the three months ended March 31, 2024 and 2023, other income, net primarily consists of net gains on foreign currency translation. Foreign currency gains and losses are primarily due to changes in the New Taiwan dollar exchange rate related to activities of our wholly-owned subsidiary, CVie Therapeutics Limited, in Taiwan.

Income Tax Expense

During the three months ended March 31, 2024, we recorded an income tax provision of $0.1 million related to the state tax on our estimated taxable income for the year, primarily due to the gain on debt extinguishment (See the section titled, "Note 8 – Restructured Debt Liability"). For the three months ended March 31, 2023, there was no income tax expense due to losses incurred and forecasted for 2023 as well as a full valuation allowance against deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

We are subject to risks common to companies in the biotechnology industry, including but not limited to the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international operations in Taiwan and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

With the exception of certain non-recurring items such as debt extinguishment, we have incurred net losses since inception. We had net income of $10.2 million for the three months ended March 31, 2024 due to a $14.5 million gain on debt extinguishment and $0.2 million of other income, partially offset by a $4.4 million operating loss and $0.1 million of income tax expense. For the three months ended March 31, 2023, our net loss was $4.1 million, which included a $0.5 million loss on impairment of goodwill (See the section titled, "Note 4 – Summary of Significant Accounting Policies"). We expect to continue to incur operating losses for at least the next several years. As of March 31, 2024, we had an accumulated deficit of $834.6 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development expense and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

As of March 31, 2024, we had cash and cash equivalents of $2.5 million and current liabilities of $5.0 million. On April 2, 2024, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the buyers named therein. Pursuant to the Purchase Agreement, we agreed to sell senior convertible notes for $1.4 million of net proceeds. As a result, we believe that we have sufficient resources available to fund our business operations through mid-May 2024. We do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we have filed a registration statement to raise additional capital in a follow-on public offering but cannot guarantee that such offering will be consummated in a timely manner, on acceptable terms or at all. Further, management plans to secure additional capital, potentially through a combination of public or private securities offerings, convertible debt financings, and/or strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying financial statements.

Cash Flows

Cash flows for the three months ended March 31, 2024 consist of $2.9 million of net cash used in operating activities and $1.0 million of net cash provided by financing activities. Cash flows for the three months ended March 31, 2023 consist of $2.5 million of net cash used in operating activities and $0.6 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $2.9 million for the three months ended March 31, 2024 and consisted primarily of (i) a $14.5 million gain on debt extinguishment; and (ii) an unrealized gain on foreign exchange rate changes of $0.2 million; partially offset by (iii) net income of $10.2 million; (iv) changes in operating assets and liabilities of $1.2 million; (v) non-cash stock-based compensation of $0.3 million; and (vi) non-cash lease expense of $0.1 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in operating activities was $2.5 million for the three months ended March 31, 2023 and consisted primarily of (i) a net loss of $4.1 million; partially offset by (ii) changes in operating assets and liabilities of $0.7 million; (iii) a non-cash loss on impairment of goodwill of $0.5 million; (iv) non-cash stock-based compensation of $0.3 million; and (v) non-cash lease expense of $0.1 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 was $1.0 million and includes (i) $1.4 million in net proceeds from the 2023 ATM Program; partially offset by (ii) $0.2 million of principal payments on loans payable; and (iii) $0.1 million in payments related to the debt extinguishment.

Net cash provided by financing activities for the three months ended March 31, 2023 was $0.6 million and includes (i) $0.8 million in proceeds from the exercise of common stock warrants, net of expenses; partially offset by (ii) $0.2 million of principal payments on loans payable.

The following sections provide a more detailed discussion of our available financing facilities.

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings.

At-The-Market Program

On November 9, 2023, we entered into the 2023 ATM Program with Ladenburg. We are not obligated to make any sales under the 2023 ATM Program. When we issue sale notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

Sales under the 2023 ATM Program will be made pursuant to our “shelf” registration statement on Form S-3 (No. 333-261878) filed with the SEC on December 23, 2021, and declared effective on January 3, 2022, and a prospectus supplement related thereto. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and, as of May 15, 2024, we had sold substantially all that we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. However, there can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

Either party may suspend the offering under the 2023 ATM Program by notice to the other party. The 2023 ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the 2023 ATM Program or (ii) termination of the 2023 ATM Program in accordance with its terms. Either party may terminate the 2023 ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the 2023 ATM Program. The rate of compensation will not apply when Ladenburg acts as principal, in which case such rate shall be separately negotiated. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $60,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

During the three months ended March 31, 2024, we sold 143,120 shares of our common stock under the 2023 ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.4 million.

Loans Payable

In June 2023, we entered into an insurance premium financing and security agreement with IPFS Corporation. Under the agreement, we financed $0.8 million of certain premiums at a 7.24% fixed annual interest rate. Payments of approximately $77,000 were due monthly from July 2023 through April 2024. As of December 31, 2023, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the first quarter of 2024.

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% fixed annual interest rate. Payments of approximately $126,000 were due monthly from July 2022 through March 2023. As of December 31, 2022, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2023.

Supplementary Disclosure of Non-Cash Activity

During the first quarter of 2024, we and Deerfield entered into the Exchange and Termination Agreement wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock. The Exchange and Termination Agreement was accounted for as an extinguishment of debt in accordance with *ASC Topic 470, Debt – Modifications and Extinguishments*, and, as a result, we recognized a $14.5 million non-cash gain on debt extinguishment during the three months ended March 31, 2024 consisting of the difference between the $15.0 million of the extinguished milestone payments and the consideration to Deerfield of $0.2 million in cash and $0.3 million in fair value of common stock issued to Deerfield (See the section titled, “Note 8 – Restructured Debt Liability”).

During the first quarter of 2023, we entered into amendments to the January 2023 Existing Warrants and the February 2023 Existing Warrants which were accounted for as “Equity Issuance” classification modifications under the guidance of ASU 2021-04. The total fair value of the consideration of each of the modifications includes the incremental fair value of the January 2023 Existing Warrants and the February 2023 Existing Warrants, respectively (determined by comparing the fair value immediately prior to and immediately after the modification), and the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants, respectively. The fair values were calculated using the Black-Scholes model. We determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants, was $1.2 million, and that the total fair value of the consideration related to the modification of the February 2023 Existing Warrants, including the initial fair value of the February 2023 New Warrants, was $0.3 million (See the section titled, “Note 9 – Stockholders’ Equity”).

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements as of March 31, 2024 or 2023 or during the periods then ended.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer and principal financial officer), does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms.

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

ITEM 1A. RISK FACTORS

Investing in our securities involves certain risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, investors should carefully consider the risks and uncertainties discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023. These risks are not the only risks that could materialize. Other than as set forth below, there have been no material changes in our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations and development activities. Should any of the risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2023, as supplemented by our subsequent filings with the SEC, actually materialize, our business, financial condition, and/or results of operations could be materially adversely affected, the trading price of our common stock could decline, and an investor could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in *Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources*.

Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations in the near term.

We do not have sufficient resources available to fund our business beyond mid-May 2024. To increase our cash runway, we have filed a registration statement to raise additional capital in a follow-on public offering but cannot guarantee that such offering will be consummated in a timely manner, on acceptable terms or at all. Further, management plans to secure additional capital, potentially through a combination of public or private securities offerings, convertible debt financings, and/or strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. These conditions raise substantial doubt regarding our ability to continue as a going concern.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

In order to reduce expected costs with our contract research organization, Momentum Research, Inc., or MRI, on May 9, 2024, or the Effective Date, we entered into Amendment No. 1 to the Master Services Agreement and Work Order Nos. 11 and 12, or the Amendment, with MRI. The Amendment amends the Master Services Agreement we entered into with MRI on February 13, 2020, or the Original MSA, and the original Work Order Nos. 11 and 12 we entered into with MRI on June 1, 2023, collectively, the Original Work Orders.

Under the Original MSA, we agreed to, among other things, engage MRI to provide non-exclusive research and development services, by executing individual work orders to be negotiated and specified in writing on terms agreed to by both parties on a later date.

Under the terms of the Amendment, we agreed to, among other things, be responsible for certain management, regulatory strategy, and reporting obligations in connection with our SEISMiC Extension study and MRI agreed to fully perform its obligations under the Original Work Orders with respect to the SEISMiC Extension study, including performance of all services and delivery of all deliverables required by the Original Work Orders. Additionally, with respect to the SEISMiC C Study, MRI agreed to be responsible for certain regulatory submissions, as provided in the Amendment.

Additionally, in consideration of and conditioned upon the payments described below, we and MRI each agreed to cancel and extinguish any and all amounts owed to MRI or us, respectively, each subject to the terms of the Amendment. The parties agreed that such cancellation and extinguishment shall not be construed as a waiver of claims by each party for breach of the Original MSA or either or both of the Original Work Orders other than for non-payment, nor a waiver of each party's respective indemnification rights under the Original MSA.

In consideration of MRI's full performance of the Original Work Orders and cancellation of accrued expenses as described above, we agreed to, among other things, pay MRI $1.2 million in a series of scheduled payments through September 20, 2024, subject to the terms of the Amendment. If services are not completed by October 31, 2024, the parties agree that MRI will continue its services until fully completed with no further compensation. In case of delayed payments, we agreed to pay MRI interest on any overdue amount from the due date until the date paid in full at a rate equal to 18% per annum. If the SEISMiC Extension study and the SEISMiC C Study are terminated prior to September 20, 2024, then the next payment due after termination will be made to MRI and remaining payments that would have become due automatically become no longer payable.

Additionally, we agreed that, for a transaction consummated by December 31, 2027, we shall pay MRI an amount equal to 2% of istaroxime license fees, milestone payments, royalties, securities or other property that we actually collect in respect of any license of istaroxime that we grant to any unaffiliated third party on or after the Effective Date; net of all legal and financial advisory fees and expenses actually paid by us in respect of the associated license transaction. Further, we agreed that if we commercialize istaroxime ourselves in the United States or another region, we shall also pay MRI an amount equal to 2% of our net profit derived from direct sales of istaroxime to clients in our territory where sales occurred, as determined in our US GAAP financial statements. Pursuant to the Amendment, such payments on istaroxime sales will end when data and market exclusivity protection expires for istaroxime.

Further, in connection with the first to occur of either a Change of Control (as defined in the Amendment) or the sale of all or substantially all of our rights in istaroxime not in the context of a Change of Control, we agree to pay MRI an amount equal to 2% of the sum of any cash and the fair market value of any securities or other property that we actually collect or receive that is attributable to our rights in istaroxime (subject to the terms of the Amendment), net of a ratable portion of certain fees and expenses as provided by the Amendment.

After December 1, 2025, we have the right to buy out the amounts due under certain provisions of the Amendment.

The foregoing descriptions of the Original MSA and Amendment are general descriptions only, do not purport to be complete descriptions of the rights and obligations of the parties thereunder, and are qualified in their entirety by reference to the terms of such agreements, which are filed as Exhibit 10.1 and 10.2, respectively, to this Quarterly Report on Form 10-Q.

ITEM 6. EXHIBITS

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report on Form 10-Q. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

INDEX TO EXHIBITS

The following exhibits are included with this Quarterly Report on Form 10-Q.

Exhibit No.	Description	Method of Filing
10.1†	Master Services Agreement and Work Orders Nos. 11 and 12, by and between the Company and Momentum Research, Inc., dated February 13, 2020.	Filed herewith.
10.2†	Amendment No. 1 to Master Services Agreement and Work Orders Nos. 11 and 12, by and between the Company and Momentum Research, Inc., effective upon May 9, 2024.	Filed herewith.
31.1	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101.1	The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of March 31, 2024 (unaudited) and December 31, 2023, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2024 and March 31, 2023, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2024 and March 31, 2023, and (iv) Notes to Condensed Consolidated Financial Statements.	
101.INS	Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) (1).	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1).	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1).	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1).	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1).	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1).	Filed herewith.
104	Cover Page Interactive Data File (formatted as Inline XBRL and combined in Exhibit 101.1)	Filed herewith.

† Certain confidential portions have been omitted from this exhibit pursuant to Item 601(b)(10)(iv) of Regulation S-K.
(1) These Interactive Data Files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Act of 1934, as amended, or otherwise subject to liability under those sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Windtree Therapeutics, Inc.
(Registrant)

Date: May 15, 2024

By: /s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer

Exhibit 10.1

MASTER SERVICES AGREEMENT

This Master Services Agreement ("Agreement") is made between Windtree Therapeutics Inc, a Delaware corporation having its principal place of business at 2600 Kelly Road, Warrington, PA 18976 (hereinafter "WINDTREE"), and Momentum Research Inc. a C corporation having its principal place of business at [***] (hereinafter "MRI"). When signed by both parties, this Agreement will set forth the terms and conditions under which MRI agrees to provide certain services to WINDTREE as set forth herein.

RECITALS:

A. WINDTREE is a clinical-stage biopharmaceutical and medical device company. MRI is in the business of providing clinical trial services, research, and other services for the pharmaceutical, medical device and biotechnology industries.

B. WINDTREE and MRI desire to enter into this Agreement to provide the terms and conditions upon which WINDTREE may engage MRI to provide non-exclusive services for projects by executing individual Work Orders (as defined below) specifying the details of the services and the related terms and conditions.

Now, therefore, in consideration of the mutual covenants and promises set forth below, and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereby agree as follow:

AGREEMENT:

1. SCOPE OF THE AGREEMENT; WORK ORDERS; NATURE OF SERVICES;

a) SCOPE OF AGREEMENT. As a "master" form of contract, this Agreement allows the parties to contract for multiple projects through the issuance of multiple Work Orders (as discussed in Section 1(b) below), without having to re-negotiate the basic terms and conditions contained herein. This Agreement covers the provision of services by MRI and MRI's corporate affiliates (see Section 17) and, accordingly, this Agreement represents a vehicle by which WINDTREE can efficiently contract with MRI and its corporate affiliates for a broad range of services.

b) WORK ORDERS. The specific details of each project under this Agreement (each "Project") shall be separately negotiated and specified in writing on terms and in a form agreed to in writing by both parties (each such writing, a "Work Order"). A sample Work Order is attached hereto as Exhibit A. Each Work Order will include, as appropriate, the scope of work, time line, budget and payment schedule. Each Work Order shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Work Order. To the extent any terms or provisions of a Work Order conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, except to the extent that the applicable Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter. All Work Orders and other exhibits hereto shall be deemed to be incorporated herein by reference.

c) NATURE OF SERVICES. The services covered by this Agreement may include strategic planning, expert consultation, clinical trial services, data processing, regulatory, clerical, project management, preclinical services, pharmaceutical sciences services, medical device services, and other research and development services requested by WINDTREE and agreed to by MRI as set forth in the relevant Work Order (collectively, the "Services"). MRI and WINDTREE, where appropriate, shall cooperate in the completion of a Transfer of Obligations Form in conjunction with the relevant Work Order. Any responsibilities not specifically transferred in the Transfer of Obligations Form shall remain the regulatory responsibility of WINDTREE. The obligations that have been transferred to MRI will be set forth in the FDA Form 1571.

2. PAYMENT OF FEES AND EXPENSES.

WINDTREE will pay MRI for fees, expenses and pass-through costs in accordance with the budget and payment schedule contained in each Work Order. WINDTREE agrees that the budget and payment schedule for each Work Order will be structured in an effort to maintain cash neutrality for MRI (with respect to the payment of professional fees, pass-through costs and otherwise). WINDTREE agrees that a prepayment may be necessary for MRI to maintain cash neutrality over the term of the Work Order, taking into account payment terms agreed upon between the parties. Any items to be prepaid shall be specified in the applicable Work Order. Unless otherwise agreed in a particular Work Order, the following shall apply: (a) MRI will invoice WINDTREE monthly for the fees, expenses and pass-through costs (with no administrative overhead) actually incurred in performing the Services; and, (b) WINDTREE shall pay each invoice within twenty five (25) days of WINDTREE's receipt of the invoice. If any portion of an invoice is disputed, then WINDTREE shall pay the undisputed amounts as set forth in the preceding sentence and the parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. WINDTREE shall pay MRI interest, on a per diem basis at a rate equal to one percent (1%) per annum, on all undisputed amounts owing hereunder and not paid within thirty (30) days of WINDTREE's receipt of the invoice. Invoices should be submitted to:

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3646
Attention: [***]
With a copy to [***]

MRI may be required to travel to such locations as reasonably requested by WINDTREE for performance of the Services. All such travel shall be in accordance with WINDTREE'S Travel Policy, a copy of which is attached hereto as Exhibit B.

3. TERM.

This Agreement shall commence on the date it has been signed by all parties and shall continue for a period of five (5) years from the date of execution, or until terminated by either party in accordance with Section 15 below. The Agreement will automatically renew each year thereafter for a period of one year, unless either party notifies the other party in writing at least 45 days prior to the renewal date that it does not want to renew the Agreement.

4. CHANGE ORDERS.

Any (a) change in the details of a Work Order, even if a fixed price Work Order, or (b) change in the assumptions upon which a Work Order is based (including, but not limited to, changes in an agreed starting date for a Project or suspension of the Project by WINDTREE) may require changes in the budget and/or time lines, and shall require a written amendment to the Work Order (a "Change Order"). Each Change Order shall detail the requested changes to the applicable task, responsibility, duty, budget, time line or other matter. The Change Order will become effective upon the execution of the Change Order by both parties, and will include a specified period of time (as agreed upon by the parties) within which MRI will implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order requested by the other party. MRI reserves the right to postpone effecting material changes in the Project's scope until such time as the parties agree to and execute the corresponding Change Order. If the parties cannot agree upon the terms of a Change Order within a reasonable period of time not to exceed thirty (30) days, then WINDTREE reserves the right to terminate the applicable Work Order immediately upon notice to MRI, paying for only those costs actually and necessarily incurred by MRI for Services performed on the Work Order through the termination date.

For any Change Order that affects the scope of the regulatory obligations that have been transferred to MRI, MRI and WINDTREE shall execute a corresponding amendment to the Transfer of Obligations Form. WINDTREE shall provide such changes to the FDA on the 1571 form and will file such amendment where appropriate, or as required by law or regulation.

5. CONFIDENTIALITY.

It is understood that during the course of this Agreement, all data and information provided by WINDTREE and its officers, employees, contractors, agents and affiliates to MRI or any of its officers, employees, contractors, agents or affiliates, except as otherwise expressly acknowledged in writing in each and every instance by WINDTREE, is confidential and proprietary to WINDTREE. All such data and information (hereinafter "WINDTREE Confidential Information"), whether written or verbal, tangible or intangible, made available, disclosed, or otherwise made known to MRI or its officers, employees, contractors, agents or affiliates as a result of Services under this Agreement shall be considered confidential and shall be considered the sole property of WINDTREE.

All information regarding MRI's operations, methods, and pricing and all MRI's Property (as defined in Section 6 below), disclosed by MRI to WINDTREE in connection with this Agreement is proprietary, confidential information belonging to MRI (the "MRI Confidential Information", and together with the "WINDTREE Confidential Information", the "Confidential Information"). The Confidential Information shall be used by the receiving party and its officers, employees, contractors, agents and affiliates only for purposes of performing the receiving party's obligations hereunder. Each party agrees that: (a) it will not (and will not permit its officers, employees, contractors, agents or affiliates to) reveal, publish or otherwise disclose the Confidential Information of the other party to any third party without the prior written consent of the disclosing party, and (b) it will not use or capitalize upon (or permit its officers, employees, contractors, agents or affiliates to use or capitalize upon) the Confidential Information. Each party agrees that it will not disclose the terms of this Agreement or any Work Order to any third party without the prior written consent of the other party, which shall not unreasonably be withheld. These obligations of confidentiality and nondisclosure shall remain in effect indefinitely and shall survive the termination of this Agreement and all Work Orders.

The foregoing obligations shall not apply to Confidential Information to the extent that it: (a) is or becomes generally available to the public other than as a result of a disclosure by the receiving party; (b) becomes available to the receiving party on a non-confidential basis from a source which is not prohibited from disclosing such information; (c) was developed independently of any disclosure by the disclosing party or was known to the receiving party prior to its receipt from the disclosing party, as shown by contemporaneous written evidence; or, (d) is required by law or regulation to be disclosed, provided however that the other party is promptly notified in writing of such requirement prior to, if practicable, disclosure and given an opportunity to obtain a suitable protective order.

6. OWNERSHIP AND INVENTIONS.

All data, information, inventions, improvements in know-how, new uses, processes and compounds relating to the study drug(s) and or products(s) covered by this Agreement and/or applicable Work Orders that are conceived, generated, derived, or reduced to practice as a result of the Services performed by MRI under this Agreement , whether developed independently by MRI or jointly with others shall be and remain the exclusive property of WINDTREE ("WINDTREE's Property"), and MRI agrees to assign its rights in all WINDTREE's Property to WINDTREE. For these purposes, MRI agrees to make, constitute and appoint WINDTREE, irrevocably and coupled with an interest, MRI's true and lawful attorney in fact, in MRI's name, place and stead, to sign, execute, acknowledge, deliver and record all documents and instruments, at any time and in any manner, which WINDTREE may deem necessary or desirable to grant and assign to WINDTREE all rights of any nature whatsoever (including, but not limited to the exclusive global copyrights, patents, trademarks and service marks) in and to WINDTREE's Property. Notwithstanding the foregoing, WINDTREE acknowledges that MRI possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by MRI and which relate to its business or operations (collectively "MRI'S Property"). WINDTREE and MRI agree that any of MRI's Property or improvements thereto which are used, improved, modified or developed by MRI under or during the term of this Agreement are the sole and exclusive property of MRI.

7. RECORDS AND MATERIALS.

At the completion of the Services by MRI, or earlier, at the request of WINDTREE, all materials, information and all other data owned by WINDTREE, regardless of the method of storage or retrieval, shall be delivered to WINDTREE in such form as is then currently in the possession of MRI. Alternatively, at WINDTREE's written request, such materials and data may be retained by MRI for WINDTREE for an agreed-upon time period, or disposed of pursuant to the written directions of WINDTREE. WINDTREE shall pay the costs associated with any of the above options and shall pay a to-be-determined fee for storage by MRI of records and materials after completion or termination of the Services. MRI, however, reserves the right to retain, at its own cost and subject to the confidentiality provisions herein and the requirements of applicable law, one copy of all materials for its corporate files. Nothing in this Agreement shall be construed to transfer from WINDTREE to MRI any FDA or regulatory record-keeping requirements unless such transfer is specifically provided for in the applicable Transfer of Obligations Form.

8. INDEPENDENT CONTRACTOR RELATIONSHIP.

Except as provided in Article 10 herein, for the purposes of this Agreement, the parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venture and neither party shall have the power or right to bind or obligate the other party or shall hold itself out as having such authority. If, however, WINDTREE desires to conduct clinical trials in one or more countries that require a local WINDTREE representative, and WINDTREE does not have an office in those countries, then the parties may agree, pursuant to a Work Order in each and every such instance, that MRI or its affiliate shall serve as its agent for that purpose, and the parties will include in the Work Order an attachment regarding local representative duties.

9. REGULATORY COMPLIANCE; INSPECTIONS.

MRI agrees that its Services will be conducted in compliance with ICH Guidelines, Good Clinical Practices, all applicable laws, rules and regulations, including but not limited to the Federal Food, Drug and Cosmetic Act and the regulations promulgated pursuant thereto, and with the standard of care customary in the contract research organization industry. MRI’s standard operating procedures will be used in performance of the Services, unless otherwise specifically stated in the Work Order. MRI certifies that it has not been debarred by the FDA pursuant to Section (a) or (b) of 21 U.S.C. Section 335a, and that it will not knowingly employ any person or entity that has been so debarred to perform any Services under this Agreement. WINDTREE represents and certifies that it will not require MRI to perform any assignments or tasks in a manner that would or potentially would violate any applicable law or regulation or scientific standard. WINDTREE further represents that it will cooperate with MRI in taking any actions that MRI reasonably believes are necessary to comply with the regulatory obligations that have been transferred to MRI.

Each party acknowledges that the other party may respond independently to any regulatory correspondence or inquiry in which such party or its affiliates is named. However, WINDTREE shall in each such instance have the right to review and approve MRI’s response with respect to WINDTREE's study or Project, but such approval shall not be unreasonably withheld. Each party shall: a) notify the other party promptly of any FDA or other governmental or regulatory inspection or inquiry concerning any study or Project of WINDTREE in which MRI is providing Services and such inspection or inquiry relates to or affects such Services, including but not limited to, inspections of investigational sites or laboratories; b) forward to the other party copies of any correspondence from any regulatory or governmental agency relating to such an inspection or inquiry, including, but not limited to, FDA Form 483 notices, and FDA refusal to file, rejection or warning letters, even if they do not specifically mention the other party; and, c) obtain the written consent of the other party, which will not unreasonably be withheld, before referring to the other party or any of its affiliates in any regulatory correspondence (provided, however, that the party may refer to the other party even in the absence of such written consent if the consent was appropriately requested, the consent was not timely received by the requesting party, and the reference was reasonably necessary for a proper response to the regulatory correspondence). Where reasonably practicable, each party will be given the opportunity to have a representative present during an FDA or regulatory inspection.

Each party acknowledges that it may not direct the manner in which the other party fulfills its obligations to permit inspection by governmental entities. Provided, however, that each party agrees that, during an inspection by the FDA or other regulatory authority concerning any study or Project of WINDTREE in which MRI is providing Services, it will not disclose information and materials that are not required to be disclosed to such agency, without the prior written consent of the other party, which consent shall not unreasonably be withheld. Such information and materials include, but are not limited to, the following: 1) financial data and pricing (including, but not limited to, the budget and payment sections of the Work Order); 2) sales data (other than shipment data); 3) personnel data (other than data as to qualification of technical and professional persons performing functions subject to regulatory requirements); and 4) Confidential Information of the other party.

During the term of this Agreement, MRI will permit WINDTREE's representatives (unless such representatives are competitors of MRI) to examine or audit the work performed hereunder and the facilities at which the work is conducted upon reasonable advance notice during regular business hours to determine that the Project assignment is being conducted in accordance with the agreed task and that the facilities are adequate. All information disclosed, revealed to or ascertained by WINDTREE in connection with any such audit or examination or in connection with any correspondence between MRI and any regulatory authorities (including any FDA Form 483 notices) shall be deemed to constitute MRI Confidential Information for purposes of this Agreement. WINDTREE shall reimburse MRI for its time and expenses (including reasonable attorney fees and the costs of responding to findings) associated with any inspection, audit or investigation relating to the Services ("Inspection") instigated by WINDTREE or by a governmental authority, unless such Investigation finds that MRI breached this Agreement or any applicable law or regulation.

10. RELATIONSHIP WITH INVESTIGATORS.

The parties acknowledge and agree that medical professionals who participate in WINDTREE's clinical trials ("Investigators") shall not be considered the employees, agents, or subcontractors of MRI or WINDTREE. MRI's responsibilities with respect to Investigators shall be limited to those responsibilities specifically set forth in this Agreement and the applicable Work Order.

If MRI will be paying Investigators on behalf of WINDTREE, the parties will agree in the applicable Work Orders as to a schedule of amounts to be paid to Investigators. WINDTREE acknowledges and agrees MRI will only pay Investigators from advances or pre-payments received from WINDTREE for Investigators' services, and that MRI will not make payments to Investigators prior to receipt of sufficient funds from WINDTREE. WINDTREE acknowledges and agrees that MRI will not be responsible for delays in a study or Project to the extent that such delays are caused by WINDTREE's failure to make adequate pre-payment for Investigators' services. WINDTREE further acknowledges and agrees that payments for Investigators' services are pass-through payments to third parties and are separate from payments for MRI's Services.

11. CONFLICT OF AGREEMENTS.

MRI represents to WINDTREE that it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement, and that during the term of this Agreement, MRI agrees that it will not enter into any agreement to provide services which would in any way prevent it from providing the Services contemplated under this Agreement. WINDTREE agrees that it will not enter into an agreement with a third party that would alter or affect the regulatory obligations delegated to MRI in any study or project without prior written notice to MRI.

12. RESTRICTIONS ON ANNOUNCEMENTS.

MRI shall not make any oral presentation or publications relating to any Project without WINDTREE's prior written consent except as required by law or by court or administrative order. Neither party shall employ or use the name of the other party in any announcement, publication or promotional material or in any form for public distribution, without the prior written consent of the other party, except as required by law or by court or administrative order. WINDTREE shall have the exclusive, unrestricted right to publish the results of a particular study.

13. INDEMNITY.

WINDTREE shall indemnify and hold MRI and its affiliates, and their respective directors, officers, employees, and agents (the "MRI Indemnified Parties") harmless and hereby forever releases and discharges the MRI Indemnified Parties from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) ("Losses") that the MRI Indemnified Parties may suffer or incur as a result of any claims, demands, actions or other proceedings made or instituted by a third party against any of them arising out of or relating to the Services performed under this Agreement or any Work Order, solely to the extent such Losses arise out of (a) any injury to or death of any person participating in any Project or study (unless caused in whole or in part by the intentional misconduct or negligent acts of the MRI Indemnified Parties, or any of them), (b) the negligence or intentional misconduct of WINDTREE or its affiliates, or their respective directors, officers, employees or agents, (c) any breach of this Agreement or any Work Order by WINDTREE or its affiliates, or its or their directors, officers, employees or agents; (d) any theory of product liability (including, without limitation, actions in the form of tort, warranty or strict liability), solely as it relates to medical products or drugs that are the subject of the applicable study or Project being conducted by WINDTREE for which MRI has provided Services pursuant to a Work Order hereunder; or e) any patent infringement action, solely as it relates to medical products, drugs or devices that are the subject of the applicable study or Project being conducted by WINDTREE for which MRI has provided Services pursuant to a Work Order hereunder.

Notwithstanding the foregoing, the MRI Indemnified Parties shall not be entitled to any indemnification hereunder to the extent that Losses result from (1) any material breach by MRI of its obligations under this Agreement, or (2) the negligence, recklessness or intentional acts or omissions in connection with the work performed by or on behalf of MRI hereunder. In no event shall WINDTREE indemnify MRI for any loss, liability, damage or expense suffered or incurred as a result of activity which is outside the scope of a Work Order hereunder.

MRI shall indemnify and hold WINDTREE and its affiliates, and their respective directors, officers, employees, and agents (the "WINDTREE Indemnified Parties") harmless and hereby forever releases and discharges the WINDTREE Indemnified Parties from and against all Losses that the WINDTREE Indemnified Parties may suffer or incur as a result of any claims, demands, actions or other proceedings made or instituted by a third party against any of them arising out of or relating to the Services performed under this Agreement or any Work Order to the extent that such claims, demands, actions or other proceedings result from (a) any material breach of MRI of its obligations under this Agreement, or (b) the negligence, recklessness or intentional acts or omissions in connection with the work performed by or on behalf of WINDTREE hereunder.

14. PROCEDURE.

The party that intends to claim indemnification under Article 13 (the "Indemnitee") shall promptly notify the indemnifying party (the "Indemnitor") for any loss, claim, damage, liability or action with respect to which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof with counsel mutually satisfactory to the Indemnitee whether or not such loss, claim, damage, liability or action is rightfully brought; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor if Indemnitor does not assume the defense, or, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other person represented by such counsel in such proceedings. The indemnity agreement in Article 13 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is affected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, only if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under Article 13 to the extent of such prejudicial impact, but the omission to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnitee otherwise under Article 13. The indemnitor shall not settle the action or otherwise consent to an adverse judgement in such action that diminishes the rights or interest of the Indemnitee without the express consent of the Indemnitee. The Indemnitee under this Article, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigations of any action, claim or liability covered by this indemnification. The Indemnitee shall keep the Indemnitor informed of any investigation and the Indemnitor shall have the right to review and comment on the conduct of the investigation.

15. TERMINATION.

Except as otherwise expressly provided in this Agreement:

WINDTREE may terminate this Agreement or any Work Order without cause at any time during the term of the Agreement on forty-five (45) days' prior written notice to MRI. Upon any material breach of this Agreement by either party, the non-breaching party may terminate this Agreement upon thirty (30) days written notice to the breaching party. For purposes of this Agreement, material breach includes, but is not limited to, nonperformance and breach of Confidential Information. Either party may terminate this Agreement or any Work Order for material breach upon thirty (30) days' written notice specifying the nature of the breach. The notice shall become effective at the end of the thirty (30) day period unless the breaching party cures such breach within such period. During the 30-day cure period for termination due to breach; each party will continue to perform its obligations under the Agreement. If the termination notice is not due to a breach, or if the cure period has expired without a substantial cure of the breach, then the parties shall promptly meet to prepare a close-out schedule, and MRI shall cease performing all work not necessary for the orderly close-out of the Services or required by laws or regulations. Either party may terminate this Agreement or any Work Orders immediately upon provision of written notice if the other party becomes insolvent or files for bankruptcy. Any written termination notice shall identify the specific Work Order or Work Orders that are being terminated.

If this Agreement or any Work Order is terminated, WINDTREE shall pay MRI for all Services performed in accordance with this Agreement and any applicable Work Order and reimburse MRI for all costs and expenses incurred in performing those Services, including all non-cancelable costs incurred prior to termination but paid after the termination date. WINDTREE shall pay for all the work actually performed in accordance with this Agreement and the applicable Work Order, even if the parties' original payment schedule spreads-out payments for certain services (examples are unit or milestone-based payments) or defers payments for certain services until the end of the study or Project.

16. RELATIONSHIP WITH AFFILIATES.

WINDTREE agrees that MRI may use the Services of MRI’s corporate affiliates, subject to prior written consent by WINDTREE, to fulfill MRI’s obligations under this Agreement and any Work Order. Any affiliate so used shall be subject to all of the terms and conditions applicable to MRI under this Agreement or any Work Order, entitled to all rights and protections afforded MRI under this Agreement or any Work Order. MRI agrees that WINDTREE's affiliates may use the services of MRI (and its affiliates) under this Agreement. In such event, such WINDTREE affiliates shall be bound by all the terms and conditions of this Agreement and any Work Order and entitled to all rights and protections afforded WINDTREE under this Agreement and any Work Order. The term "affiliate" shall mean all entities controlled by or under common control with WINDTREE or MRI, as the case may be. The term "control" shall mean the ability to vote fifty percent (50%) or more of the voting securities of any entity or otherwise having the ability to influence and direct the policies and direction of an entity.

17. COOPERATION; WINDTREE DELAYS; DISCLOSURE OF HAZARDS.

WINDTREE shall forward to MRI in a timely manner all documents, materials and information in WINDTREE's possession or control necessary for MRI to conduct the Services. MRI shall not be liable to WINDTREE nor be deemed to have breached this Agreement or any Work Order for errors, delays or other consequences arising from WINDTREE's failure to timely provide documents, materials or information or to otherwise cooperate with MRI in order for MRI to timely and properly perform its obligations. In the event WINDTREE provides notice to MRI that it plans to delay a Project from its agreed starting date or suspend performance of a Project for a period longer than 10 working days, then, at WINDTREE’s sole discretion,: a) WINDTREE will pay the standard daily rate of MRI’s personnel assigned to the Project, based on the percentage of their time allocated to the Project, for the period of the delay beginning on the eleventh working day, in order to keep the current team members; or, b) MRI may re-allocate the personnel at its discretion, and WINDTREE will pay the costs of retraining new personnel if and when the Project or study resumes. In addition, WINDTREE will pay all non-cancelable costs and expenses incurred by MRI due to the delay and will adjust all timelines to reflect additional time required due to the delay.

WINDTREE shall provide MRI with all information available to it regarding known or potential hazards associated with the use of any substances supplied to MRI by WINDTREE, and WINDTREE shall comply with all current legislation and regulations concerning the shipment of substances by the land, sea or air.

18. FORCE MAJEURE.

In the event either party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons beyond the reasonable control of the party, including strike, lockouts, labor troubles, inability to procure materials or services, failure of power, declaration of martial law, riots, insurrection, Acts of God, inclement weather or other reason or cause beyond that party's control, then performance of such act shall be excused for the period of such delay.

19. NOTICES AND DELIVERIES.

Any notice required or permitted to be given by either party hereunder shall be in writing and shall be deemed given on the date received if delivered personally or by a reputable overnight delivery service, three (3) days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid, or by electronic mail to the following addresses:

If to WINDTREE:

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976
Attention: Legal Department

(E) [***]

If to MRI:

Momentum Research Inc.
[***]

Attention: Gad Cotter
Title: C.E.O.
(E) [***]

If WINDTREE delivers, ships, or mails materials or documents to MRI, or requests that MRI deliver, ship, or mail materials or documents to WINDTREE or to third parties, then the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by WINDTREE, provided that MRI followed WINDTREE's written instructions for the materials that were delivered, shipped, or mailed. MRI disclaims any liability for the actions or omissions of reputable third-party delivery services or carriers.

20. INSURANCE.

Each party will maintain, for the duration of this Agreement, insurance in an amount reasonably adequate to cover its obligations hereunder, and, upon request, each party will provide to the other party a certificate of insurance showing that such insurance is in place.

21. INFLATION ADJUSTMENTS.

Over multiple calendar years, MRI may increase its fees at the beginning of each calendar year to reflect increases in MRI's business costs on a prospective basis only. MRI's overall cost increase for any twelve (12) month period shall not exceed the lesser of: (a) the percentage charge in the wages/earnings survey (or an equivalent inflation index), as published in the Economist (or as reported at WWW.ECONOMIST.COM), for the preceding twelve (12) month period for the country where services are to be performed; and (b) the percentage change in the consumer price index (CPI), as published in the Economist (or as reported at WWW.ECONOMIST.COM), during the preceding twelve (12) month period for the country where services are to be performed.

22. ASSIGNMENT.

Due to the specialized nature of the Services provided by MRI hereunder, MRI shall not assign, transfer or convey this Agreement or any moneys due or to become due hereunder without the prior written consent of WINDTREE. WINDTREE may assign its rights and obligations under this Agreement to a wholly-owned subsidiary, or in connection with the sale of all or substantially all of its assets or the merger, acquisition, or other consolidation of WINDTREE with or into another party, and MRI's consent shall not be required hereunder in connection therewith.

23. CHOICE OF LAW, WAIVER AND ENFORCEABILITY.

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of Delaware, exclusive of its conflicts of law provisions. The failure to enforce any right or provision herein shall not constitute a waiver of that right or provision. Any waiver of a breach of a provision shall not constitute a waiver of any subsequent breach of that provision. If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with applicable laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

24. SURVIVAL.

The rights and obligations of WINDTREE and MRI under this Agreement, which by intent or meaning have validity beyond such termination of this Agreement (including, but not limited to, rights with respect to inventions, confidentiality, discoveries and improvements, indemnification and liability limitations) shall survive the termination of this Agreement and any Work Order.

25. DISPUTE RESOLUTION.

Any controversy or claim arising out of or relating to this Agreement or the breach thereof shall be settled first by reasonable, good faith negotiations between the parties. If the parties cannot settle any such controversy or claim within a reasonable period of time, then the matter shall be settled by arbitration administered by the American Arbitration Association ("AAA") under its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator shall be binding and may be entered in any court having jurisdiction thereof. Any such arbitration shall take place in New York, New York. Such arbitration shall be conducted in English by one arbitrator mutually acceptable to the parties selected in accordance with AAA rules. The arbitrator shall not have the power to award any punitive damages or any damages excluded by this Agreement. The arbitrator shall have the power to award attorneys' fees and costs as the arbitrator may deem appropriate.

26. ENTIRE AGREEMENT, HEADINGS AND MODIFICATION.

This Agreement, together with the applicable Work Orders, contains the entire understandings of the parties with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions; *provided that* the parties acknowledge and agree that the obligations of confidentiality set forth in the Confidential Disclosure Agreements between them dated January 8, 2020 and January 29, 2020, respectively, remain in full force and effect. The descriptive headings of the sections of this Agreement are inserted for convenience of reference only and shall not control or affect the meaning or construction of any provision hereof. Any modifications to the provisions herein must be in writing and signed by the parties. This Agreement, as well as any amendments hereto, may be executed in separate counterparts, none of which need contain the signatures of all parties, each of which shall be deemed to be an original, and all of which taken together constitute one and the same instrument. Telecopied or scanned signatures will be deemed to have the same effect as an original.

IN WITNESS WHEREOF, THIS AGREEMENT has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

Windtree Therapeutics, Inc.		Momentum Research, Inc.	
By:	/s/Steven G. Simonson	By:	/s/Gad Cotter
Name:	Steven G. Simonson, MD	Name:	Gad Cotter
Title:	Senior Vice President and Chief Medical Officer	Title:	CEO
Date:	February 13, 2020	Date:	February 13, 2020

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [***], HAS BEEN EXCLUDED PURSUANT TO ITEM 601(b)(10)(iv) OF REGULATION S-K. SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1 TO MASTER SERVICES AGREEMENT AND WORK ORDER NOS. 11 AND 12

This AMENDMENT NO. 1 TO MASTER SERVICES AGREEMENT AND WORK ORDER NOS. 11 AND 12 (this "***Amendment***"), dated May 9, 2024 (the "***Effective Date***"), is made and entered into by and between Windtree Therapeutics, Inc., a Delaware corporation ("***Windtree***"), and Momentum Research, Inc., a Delaware corporation ("***MRI***"). Each of Windtree and MRI are sometimes referred to in this Agreement as a "***Party***" and collectively as the "***Parties***."

BACKGROUND

Windtree and MRI are parties to a Master Services Agreement dated February 13, 2020 (the "***MSA***") as well as Work Order Nos. 11 and 12 dated June 1, 2023 (the "***Work Orders***"). The Parties desire to amend the payment terms arising from MRI's performance of the Work Orders.

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the adequacy of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Performance of the Work Orders**.

(a) For the Seismic B extension (study 1904 covered under work order 11), MRI shall fully perform the Work Order through to completion including performance of all services and delivery of all deliverables required by the Work Order, including [***] (the "***Services***"). Windtree shall be responsible for [***].

(b) For the Seismic C study (2201 - covered under work order 12), MRI will be responsible for [***] until the [***] of the Seismic B extension/1904 study. Any additional work beyond that period, work to cover specific Seismic C/2201 [***] beyond the specified period as well as any extension of the Seismic C/2201 study beyond [***] will be paid separately and is not covered under this Agreement.

2. **Reconciliation of Amounts Due to MRI**. Effective on the Effective Date:

(a) In consideration of and conditioned upon the payments described in Section 3 below, MRI hereby cancels and extinguishes any and all amounts owed by Windtree in respect of the MSA and the Work Orders including fees and expenses due for periods ending on May 1, 2024, whether or not already invoiced to Windtree as of the Effective Date; provided that the foregoing shall not be construed as a waiver of claims by MRI for breach of the MSA or either or both of the Work Orders other than for non-payment, nor as a waiver of MRI's indemnification rights under the MSA; and

(b) Windtree hereby cancels and extinguishes any and all claims for amounts that may be due to Windtree from MRI under the MSA and the Work Orders such as refunds of advance payments for investigator grants or credits for unperformed services; provided that the foregoing shall not be construed as a waiver of claims by Windtree for breach of the MSA or either or both of the Work Orders other than for non-payment, nor a waiver of Windtree's indemnification rights under the MSA.

3. **Payments to MRI**. In consideration of MRI's full performance of the Work Orders and the cancellation of indebtedness set forth in Section 2(a):

(a) Payment of $100,000 will be made on May [***] and May [***] and payments of $200,000 will be made on May [***], June [***], July [***], August [***] and September [***], 2024. MRI shall issue to Windtree an invoice for each installment on or in advance of the applicable payment date (for a total amount under this Section 3(a) equal to $1,200,000) and Windtree shall pay each such invoice by the applicable date set forth in this Section 3(a). If the Services by MRI are not completed by October 31, 2024, the parties agree that MRI will continue the Services until fully completed with no further compensation. In case of delayed payments, Windtree shall pay MRI interest on the overdue amount from the due date until the date paid in full at a rate equal to eighteen percent (18%) per annum. Reasonable pass throughs will be added to these sums and will include regulatory or other submission fees or travel expenses. These will be reimbursed within 25 days of the invoice and be backed up by original documents to verify their accuracy.

(b) the amounts payable under Section 3(a) are in lieu of, and fully discharge, the amounts that would otherwise become payable by Windtree under the MSA, including the Work Orders other than investigator grants;

(c) [***] clinical sites will be paid as contractually due by Windtree in respect of investigator grants payable to the investigators located in [***] (or their respective employers or institution, as applicable) for the clinical studies that are the subject of the Work Orders;

(d) Windtree shall pay MRI in respect of all investigator grants related to the Seismic B 1904 and Seismic C/2202 payable to the investigators located outside of [***] (or their respective employers or institution, as applicable) for the clinical studies that are the subject of the Work Orders, with MRI invoicing Windtree for such investigator grants on a monthly basis (including providing Windtree with a monthly reconciliation of such investigator grants as against the approved budget for each clinical site) and Windtree paying each such invoice within 25 days after receipt;

(e) MRI shall use the amounts paid by Windtree under Section 3(d) solely to pay investigator grants;

(f) if Windtree terminates both the Seismic B and Seismic C studies prior to September 20, 2024, then the next payment due after termination will be made to MRI and remaining payments that would have become due under Section 3(a) automatically become no longer payable; provided that for the avoidance of doubt, the payments payable under Sections 3(g), 3(h) or 3(i), as applicable, will remain payable;

(g) for a transaction that is consummated by December 31, 2027, Windtree shall pay MRI an amount equal to two percent (2%) of istaroxime license fees, milestone payments, royalties, securities or other property that Windtree actually collects in respect of any license to istaroxime that it grants to any unaffiliated third party on or after the Effective Date; net of all legal and financial advisory fees and expenses actually paid by Windtree in respect of the associated license transaction;

(h) if Windtree commercializes istaroxime itself in the US or another region of the world, Windtree shall also pay MRI an amount equal to two percent (2%) of Windtree's net profit derived from direct sales of istaroxime to clients in the Windtree territory where sales occurred, as determined in Windtree's GAAP financial statements. Payments on istaroxime sales will end when data and market exclusivity protection expires for istaroxime;

(i) in connection with the first to occur of either a Change of Control (as defined in Section 3(p)) or the sale of all or substantially all of Windtree's rights in istaroxime not in the context of a Change of Control, Windtree shall pay MRI an amount equal to two percent (2%) of the sum of any cash and the fair market value of any securities or other property that Windtree actually collects or receives that is attributable to its rights in istaroxime (which attribution will be determined, in the case of a Change of Control, by Windtree's Board of Directors and a MRI representative acting in good faith or, in the case of sale of all or substantially all of Windtree's rights in istaroxime, be equal to the fair market value of any securities or other property that Windtree actually collects or receives specifically in respect of its rights in istaroxime), net of a ratable portion of all legal and financial advisory fees and expenses actually paid by Windtree in respect of such change of control or sale of assets;

(j) if, in the case of a Change of Control, Windtree's Board of Directors and an MRI representative are unable pursuant to Section 3(i) to agree on the fair market value of the securities and other property that Windtree actually collects or receives that is attributable to its rights in istaroxime, then the Parties will hire a mutually agreed appraiser to determine such fair market value and split the fees and expenses of the appraiser;

(k) if any payment is triggered under Section 3(i), the obligations under Section 3(g) and 3(h) shall immediately terminate except in respect of, in the case of Section 3(g), the license fees, milestone payments, royalties, securities or other property that Windtree actually collected prior to the closing of the transaction that triggered payment under Section 3(i) or, in the case of Section 3(h), the net profit earned prior to the closing of the of the transaction that triggered payment under Section 3(i);

(l) the fair market value of any securities or other property received by Windtree will be equal to the value that Windtree and the unaffiliated third party have determined as part of the relevant transaction;

(m) Windtree will pay MRI the amounts due under Sections 3(g), 3(h) or 3(i) within 15 days after receipt of the relevant license fees, milestone payments, royalties, securities or other property and at the same time provide to MRI an accounting that demonstrates the calculation of the applicable payment to MRI;

(n) for the avoidance of doubt, no consideration will be paid to MRI with respect to a license or sale of preclinical dual mechanism or pure SERCA2A activator compounds; and

(o) After December 1, 2025, Windtree shall have the right to buy out the amounts due under Sections 3(g), 3(h) or 3(i) for the higher of (i) [***], adjusted for the change in the US Consumer Price Index, All Urban Consumers, from and after December 1, 2025 or (ii) the risk adjusted net present value of the relevant payment(s) being bought out. If the parties cannot agree on the amount of the risk adjusted net present value within thirty (30) days after request by Windtree, the parties will hire a mutually agreed appraiser to determine risk adjusted net present value and such valuation shall be binding on the parties for the next six months. The parties shall split the fees and expenses of the appraiser unless Windtree decides not to proceed with the buyout following receipt of the appraisal report in which case Windtree shall bear all of the fees and costs of the appraiser.

(p) "***Change of Control***" means, in a single transaction or a series of related transactions: (a) the sale or disposition of all or substantially all of the assets of Windtree to an unaffiliated third party; (b) the direct or indirect acquisition by an unaffiliated third party of beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of Windtree or any direct or indirect entity which holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of Windtree (a "***Windtree's Parent***") other than in connection with a bona fide financing of Windtree or Windtree's Parent; or (c) the merger or consolidation of Windtree or Windtree's Parent with or into an unaffiliated third party, unless, following such merger or consolidation, the stockholders of Windtree or Windtree's Parent, as applicable, immediately prior to such merger or consolidation beneficially own directly or indirectly more than fifty percent (50%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation.

4. Representations and Warranties of Windtree. Windtree represents and warrants to MRI that as of the Effective Date:

(a) Windtree is a Delaware corporation duly organized, validly existing and in good standing under the laws of the State of Delaware.

(b) Windtree has the requisite corporate power and authority to execute, deliver and perform its obligations under this Amendment. The execution, delivery and performance of this Amendment, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary corporate action on the part of Windtree.

5. Representations and Warranties of MRI. MRI represents and warrants to Windtree that as of the Effective Date:

(a) MRI is a Delaware corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware.

(b) MRI has all requisite corporate power and authority to execute, deliver and perform its obligations under this Amendment. The execution, delivery and performance of this Amendment, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary corporate action on the part of MRI.

6. No Other Changes. Except as set forth in this Amendment, the MSA and the Work Orders remain in full force and effect and are hereby ratified and confirmed. The MSA and the Work Orders, as modified by this Amendment, constitute the entire agreement between the Parties with respect to the subject matter of the MSA and the Work Orders and supersedes all other discussions, negotiations and understandings with respect to such subject matter. Any reference to the MSA or the Work Orders from and after the date of this Amendment shall be deemed and construed as meaning the MSA or Work Orders, as applicable, as modified by this Amendment.

7. Execution in Counterparts. This Amendment may be executed in two (2) or more counterparts, each of which will be deemed an original but both of which together will constitute one and the same instrument. Delivery of a signed counterpart of this Amendment by electronic means such as facsimile or email transmission will have the same legal effect as delivery in hand of an original ink-signed copy.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives as of the Effective Date.

WINDTREE THERAPEUTICS, INC.

/s/Craig Fraser
Name: Craig Fraser
Title: Chief Executive Officer

MOMENTUM RESEARCH, INC.

/s/Gad Cotter
Name: Gad Cotter
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATION

I, Craig E. Fraser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Windtree Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2024

/s/ Craig E. Fraser

Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report of Windtree Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2024

/s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.