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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 **June 30, 2022**

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 000-26422

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 August 11, 2022, there were 30,627,878 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;
- we received written notice from The Nasdaq Stock Market LLC, or Nasdaq, that we have failed to comply with Nasdaq’s continued listing standards; if we fail to regain compliance within the allowed grace periods or other processes provided under the Nasdaq listing requirements, our common stock may be delisted and the value of our common stock may decrease;
- delays in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the novel coronavirus, or COVID-19, pandemic 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;
- our plans and the plans of our licensee, Lee’s Pharmaceutical (HK) Ltd., or Lee’s (HK), in Asia and our respective abilities to successfully execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialize our product candidates;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices, and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contractor 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 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 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, loss of data privacy, or other significant disruption;
- the potential impairment of our intangible assets and goodwill on our condensed consolidated balance sheet, which could lead to material impairment charges in the future; and
- economic uncertainty resulting from inflation or geopolitical instability, including the ongoing military conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan).

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, medical device or combination drug/device 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, 2021, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements.

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,378	$ 22,348
Prepaid expenses and other current assets	1,784	1,143
Total current assets	13,162	23,491
Property and equipment, net	307	1,011
Restricted cash	154	154
Operating lease right-of-use assets	2,074	2,381
Intangible assets	32,070	32,070
Goodwill	4,046	15,682
Total assets	$ 51,813	$ 74,789
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,072	$ 693
Accrued expenses	2,823	3,408
Operating lease liabilities - current portion	432	528
Loans payable - current portion	1,007	294
Total current liabilities	5,334	4,923
Operating lease liabilities - non-current portion	1,839	2,071
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	6,643	7,114
Total liabilities	32,616	32,908
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2022 and December 31, 2021	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2022 and December 31, 2021; 29,406,196 and 28,268,950 shares issued at June 30, 2022 and December 31, 2021, respectively; 29,406,172 and 28,268,926 shares outstanding at June 30, 2022 and December 31, 2021, respectively	29	28
Additional paid-in capital	833,006	830,231
Accumulated deficit	(810,784)	(785,324)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	19,197	41,881
Total liabilities & stockholders' equity	$ 51,813	$ 74,789

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expenses:				
Research and development	$ 2,995	$ 4,221	$ 8,340	$ 8,631
General and administrative	2,907	3,371	5,895	8,040
Loss on impairment of goodwill	11,636	-	11,636	-
Loss on impairment of intangible assets	-	37,770	-	37,770
Total operating expenses	17,538	45,362	25,871	54,441
Operating loss	(17,538)	(45,362)	(25,871)	(54,441)
Other income (expense):				
Interest income	17	39	18	89
Interest expense	(13)	(46)	(26)	(87)
Other income (expense), net	201	(352)	419	(243)
Total other income (expense), net	205	(359)	411	(241)
Loss before income taxes	(17,333)	(45,721)	(25,460)	(54,682)
Deferred income tax benefit	-	8,332	-	8,332
Net loss	$ (17,333)	$ (37,389)	$ (25,460)	$ (46,350)
Net loss per common share				
Basic and diluted	$ (0.59)	$ (1.42)	$ (0.87)	$ (2.10)
Weighted average number of common shares outstanding				
Basic and diluted	29,200	26,350	29,236	22,047

See notes to condensed consolidated financial statements

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

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance - December 31, 2020	**16,922**	**$ 17**	**$ 790,277**	**$ (717,688)**	**-**	**$ (3,054)**	**$ 69,552**
Net loss	-	-	-	(8,961)	-	-	(8,961)
Issuance of common stock and common stock warrants, net of issuance costs	9,230	9	27,381	-	-	-	27,390
Stock-based compensation expense	-	-	2,443	-	-	-	2,443
Issuance of common stock, ATM Program, net of issuance costs	105	-	570	-	-	-	570
Issuance of common stock warrants, equity consideration for service agreement	-	-	494	-	-	-	494
Balance - March 31, 2021	**26,257**	**$ 26**	**$ 821,165**	**$ (726,649)**	**-**	**$ (3,054)**	**$ 91,488**
Net loss	-	-	-	(37,389)	-	-	(37,389)
Stock-based compensation expense	-	-	1,544	-	-	-	1,544
Issuance of common stock, ATM Program, net of issuance costs	447	1	1,119	-	-	-	1,120
Balance - June 30, 2021	**26,704**	**$ 27**	**$ 823,828**	**$ (764,038)**	**-**	**$ (3,054)**	**$ 56,763**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance - December 31, 2021	**28,269**	**$ 28**	**$ 830,231**	**$ (785,324)**	**-**	**$ (3,054)**	**$ 41,881**
Net loss	-	-	-	(8,127)	-	-	(8,127)
Stock-based compensation expense	-	-	770	-	-	-	770
Issuance of common stock, ATM Program, net of issuance costs	200	-	205	-	-	-	205
Balance - March 31, 2022	**28,469**	**$ 28**	**$ 831,206**	**$ (793,451)**	**-**	**$ (3,054)**	**$ 34,729**
Net loss	-	-	-	(17,333)	-	-	(17,333)
Stock-based compensation expense	-	-	781	-	-	-	781
Issuance of common stock, ATM Program, net of issuance costs	937	1	1,019	-	-	-	1,020
Balance - June 30, 2022	**29,406**	**$ 29**	**$ 833,006**	**$ (810,784)**	**-**	**$ (3,054)**	**$ 19,197**

See notes to condensed consolidated financial statements

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

(in thousands)

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (25,460)	$ (46,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	488	93
Stock-based compensation	1,551	3,987
Non-cash lease expense	307	336
Non-cash expense related to equity consideration for a service agreement	-	494
Loss on impairment of goodwill	11,636	-
Loss on impairment of intangible assets	-	37,770
Loss on sale and disposal of property and equipment	19	-
Deferred income tax benefit	-	(8,332)
Unrealized (gain) loss on foreign exchange rate changes	(485)	300
Changes in assets and liabilities:		
Prepaid expenses and other current assets	496	179
Accounts payable	379	(873)
Accrued expenses	(576)	(703)
Operating lease liabilities	(328)	(352)
Net cash used in operating activities	(11,973)	(13,451)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	210	-
Purchase of property and equipment	(13)	(3)
Net cash provided by (used in) investing activities	197	(3)
Cash flows from financing activities:		
Proceeds from ATM Program, net of issuance costs	1,225	1,690
Principal payments on loans payable	(419)	(2,991)
Proceeds from issuance of common stock and warrants, net of issuance costs	-	27,390
Proceeds from research and development funding arrangement	-	400
Net cash provided by financing activities	806	26,489
Net (decrease) increase in cash, cash equivalents, and restricted cash	(10,970)	13,035
Cash, cash equivalents, and restricted cash - beginning of period	22,502	17,084
Cash, cash equivalents, and restricted cash - end of period	$ 11,532	$ 30,119
Supplementary disclosure of non-cash activity:		
Prepayment of insurance through third-party financing	$ 1,132	$ 1,321
Operating lease liabilities arising from obtaining right-of-use assets	-	2,000

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 clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Our development programs are primarily focused on the treatment of acute cardiovascular diseases and secondarily on acute pulmonary diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic 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 in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs. We completed this Phase 2 global clinical study and, in April 2022, announced positive topline results with istaroxime in raising systolic blood pressure. In May 2022, we presented the study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activators which activate SERCA2a. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potential oral agents, these candidates would be developed for chronic 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 this product candidate without securing such an arrangement or partnership.

Our pulmonary product candidate portfolio consists of a KL4 surfactant platform to address a range of serious respiratory conditions in children and adults. In January 2022, we completed enrollment of 20 patients in our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe novel coronavirus, or COVID-19, associated acute respiratory distress syndrome, or ARDS. The study demonstrated that intratracheal administration of reconstituted lyophilized lucinactant was generally safe and well tolerated. Oxygenation and other physiological parameters were stable to improved after dosing, supporting the feasibility of this treatment approach to develop a potential treatment for critically ill patients with ARDS due to COVID-19 or other causes.

Previously, we were also developing AEROSURF (lucinactant for inhalation), a novel drug/medical device combination product for noninvasive delivery of aerosolized KL4 surfactant using our aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome in premature infants. 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 transferred to our licensee in Asia, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Asia License Agreement. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing a potential licensing transaction.

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, and 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, 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, 2021 that we filed with the Securities and Exchange Commission, or the SEC, on March 31, 2022, 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 and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The consolidated balance sheet at December 31, 2021 has been derived from the Company's audited consolidated financial statements. There have been no changes to our significant accounting policies since December 31, 2021. 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, 2021 contained in our Annual Report on Form 10-K for the year ended December 31, 2021.

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 locations and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $17.3 million and $37.4 million, respectively, for the three-month periods ended June 30, 2022 and 2021. Our net loss was $25.5 million and $46.4 million, respectively, for the six-month periods ended June 30, 2022 and 2021. Included in our net loss for the three and six months ended June 30, 2022 is an $11.6 million loss on impairment of goodwill, and included in our net loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 – Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2022, we had an accumulated deficit of $810.8 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 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.

We are party to an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the six months ended June 30, 2022, we sold 1,137,246 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.3 million and net proceeds of approximately $1.2 million. During July and August 2022, we sold 1,221,706 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million (*see*, Note 8 – Stockholders' Equity).

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited in 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. If our public float increases to $75 million or more, we will no longer be subject to such limitations.

As of June 30, 2022, we had cash and cash equivalents of $11.4 million and current liabilities of $5.3 million. We believe that we have sufficient resources available to support our development activities and fund our business operations into the first quarter of 2023. However, 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 through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, 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. Further, on June 3, 2022, we received a deficiency letter from the Nasdaq Stock Market LLC, or Nasdaq, notifying us that the closing bid price of our common stock had been below the minimum $1.00 per share for 30 consecutive business days, we are out of compliance with the requirements for continued listing on Nasdaq, and are subject to potential delisting. If we are unable to re-achieve compliance with the Nasdaq listing requirements within 180 days, or November 30, 2022, after receipt of a delisting notice, and if we are unable to obtain an extension therefore, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition.

The accompanying condensed consolidated 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.).

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or 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 and six months ended June 30, 2022, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

During the second quarter of 2021, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not impaired and we performed the required quantitative impairment assessment of the related intangible asset. We recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2021. No events or changes in the business environment occurred during the six months ended June 30, 2021 to indicate that the fair value of the IPR&D related to our istaroxime drug candidate was 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. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing our annual goodwill impairment assessment as of December 1, 2021, we estimated the fair value of our reporting unit based upon the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium. Based on the quantitative test performed, we determined that the fair value of our reporting unit exceeded its carrying value and no impairment loss was recognized as of December 31, 2021.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock.

During the second quarter of 2022, 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. As a result, we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including 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. Based on the quantitative test performed, we recorded a loss on impairment of goodwill of $11.6 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2022.

The closing share price of our common stock has continued to decline during July and August 2022. If our share price continues to decline during the remainder of the third quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

The following table represents identifiable intangible assets and goodwill as of June 30, 2022 and December 31, 2021:

(in thousands)	June 30, 2022	December 31, 2021
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	9,730	9,730
Intangible assets	32,070	32,070
Goodwill	$ 4,046	$ 15,682

Foreign Currency Transactions

The functional currency for our foreign subsidiaries 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 (expense), net. Foreign currency transactions resulted in gains of approximately $0.2 million and losses of approximately $0.3 million for the three-month periods ended June 30, 2022 and 2021, respectively. Foreign currency transactions resulted in gains of approximately $0.4 million and losses of approximately $0.2 million for the six-month periods ended June 30, 2022 and 2021, 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, money market funds, and U.S. Treasury notes with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

Severance

In January 2022, in order to focus our resources on the development of our istaroxime pipeline, we began to reduce costs related to KL4 surfactant that were not already transferred to our licensee in Asia, Lee's (HK), under the terms of the Asia 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 active pharmaceutical ingredients 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. In February 2022, management communicated its commitment to provide severance payments to impacted employees, provided that they remain employed with us through their expected termination dates. The total severance cost for impacted employees is approximately $0.4 million, which was ratably accrued over the service periods of the employees, and to be paid through September 30, 2022. We incurred $0.1 million and $0.4 million of expense related to these severance arrangements during the three and six months ended June 30, 2022, respectively, which is included in research and development expense. During the three and six months ended June 30, 2022, $0.2 million was paid. The related liability as of June 30, 2022 is $0.2 million and is included in accrued expenses.

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.

During the first quarter of 2022, we determined that certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform would be abandoned by March 31, 2022. We accelerated depreciation of these assets during the first quarter of 2022, resulting in $0.4 million of additional depreciation expense for the three months ended March 31, 2022. During the second quarter of 2022, the abandoned assets and certain other KL4 surfactant platform assets were disposed.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*see*, Note 7 – Restructured Debt Liability), we have 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 Exchange and Termination Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

Research and Development

We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, 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. Indirect research and development expenses include personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, regulatory, and medical affairs. Research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board, or FASB, 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 since realization is not assured.

For the three and six months ended June 30, 2021, we recorded a deferred income tax benefit of $8.3 million. The deferred tax benefit recorded for these periods relates solely to the reduction of the deferred tax liability as a result of the loss on impairment of intangible assets related to rostafuroxin.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of June 30, 2022 and 2021, 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 21.2 million and 19.9 million shares, respectively. For the three and six months ended June 30, 2022 and 2021, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

COVID-19

The COVID-19 pandemic continues to evolve, and we continue to closely monitor its impact on our business and operations, including its continued impact on our clinical development plans and timelines, and financial condition. There has been intermittent impact of the pandemic in differing geographies, and there may be continued impact, particularly in light of the surge of new COVID-19 cases relating to new variants. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources, and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The extended timelines have required us to expend more of our capital resources than planned to achieve our projected milestones. For example, our Phase 2 study of istaroxime for early cardiogenic shock in heart failure patients experienced delays in trial initiation and enrollment in 2021. Although many countries have re-opened, rises in new cases, including as the result of newly identified COVID-19 variants, have caused certain countries, states, and localities to re-initiate restrictions. The full extent, duration, or impact that the COVID-19 pandemic will have, directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include the severity and transmissibility of new variants of the virus, information about any resurgences in one or more geographic locations where our current or intended clinical trial sites, our principal executive offices, research and development laboratories, or manufacturing facilities are located, and the actions taken to contain it or treat its impact. In addition, regional impact and responses to the COVID-19 pandemic have affected where a clinical trial could be executed and how various elements of the clinical trial are performed. Going forward, the pandemic could also impact how monitoring/auditing of clinical trial sites and data occur. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more geographic locations where our clinical trial sites, principal executive offices, research and development laboratories, or other facilities are located remains possible and if realized, we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts, or modifications to our ongoing and planned trials in 2022 and beyond.

We are not aware of any specific event or circumstance that would require us to further update our estimates, judgments, or revise the carrying value of our assets or liabilities as of the date of issuance of these interim unaudited condensed consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

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 June 30, 2022	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 10,121	$ 10,121	$ -	$ -
Total Assets	$ 10,121	$ 10,121	$ -	$ -

(in thousands)	Fair Value December 31, 2021	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 21,104	$ 21,104	$ -	$ -
Total Assets	$ 21,104	$ 21,104	$ -	$ -

Note 6 – Loans Payable

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% annual interest rate. Payments of approximately $126,000 are due monthly from July 2022 through March 2023. As of June 30, 2022, the outstanding principal of the loan was $1.0 million.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of December 31, 2021, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2022.

Note 7 – Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P., or the Deerfield Loan, in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 8,333 shares of our common stock at an exercise price of $2,360.40 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) 23,703 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain 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 Exchange and Termination Agreement (*see*, Note 4 – Summary of Significant Accounting Policies). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of June 30, 2022 and December 31, 2021, the restructured debt liability balance was $15.0 million.

Note 8 – Stockholders' Equity

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through the ATM Program. When we issue sales 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.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the ATM Program. The rate of compensation will not apply when Ladenburg acts as principal.

For the six months ended June 30, 2022, we sold 1,137,246 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.3 million and net proceeds of approximately $1.2 million. For the six months ended June 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million.

During July and August 2022, we sold 1,221,706 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million.

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. As of August 11, 2022, approximately $3.2 million remains available under the ATM Program. However, we are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited in selling no more than one-third of our public float during any 12-month period. If our public float increases to $75 million or more, we will no longer be subject to such limitations.

March 2021 Public Offering

On March 23, 2021, we entered into an underwriting agreement with Oppenheimer & Co. Inc. as representative for the several underwriters named therein, relating to a public offering, or the March 2021 Offering, of an aggregate of 9,230,500 units with each unit consisting of one share of common stock and a warrant, or the March 2021 Warrants. The March 2021 Warrants are immediately exercisable for shares of common stock at a price of $3.60 per share and expire five years from the date of issuance. The shares of common stock and the March 2021 Warrants were immediately separable and were issued separately in the March 2021 Offering.

The closing of the March 2021 Offering occurred on March 25, 2021. The offering price to the public was $3.25 per unit resulting in gross proceeds to us of $30.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the March 2021 Warrants issued pursuant to the March 2021 Offering, the net proceeds to us were approximately $27.4 million.

We have determined that the appropriate accounting treatment under ASC 480, Distinguishing Liabilities from Equity, or ASC 480, is to classify the common stock and the March 2021 Warrants issued in the March 2021 Offering as equity. We have also determined that the March 2021 Warrants are not in their entirety a derivative under the scope of ASC 815, Derivatives and Hedging, or ASC 815, due to the scope exception under ASC 815-10-15-74, nor are there any material embedded derivatives that require separate accounting. We allocated the net proceeds from the March 2021 Offering based on the relative fair value of the common stock and the March 2021 Warrants.

Note 9 – Stock-Based Compensation

We recognize expense in our 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 typically has been between approximately one to three years.

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2022	3,387	$ 9.74	
Granted	880	0.99	
Forfeited or expired	(220)	9.72	
Outstanding at June 30, 2022	4,047	$ 7.84	7.8
Vested and exercisable at June 30, 2022	2,229	$ 11.35	6.8
Vested and expected to vest at June 30, 2022	3,821	$ 7.85	7.8

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2022	-	$ -
Awarded	582	0.99
Cancelled	(21)	1.02
Outstanding at June 30, 2022	561	$ 0.99
Vested and exercisable at June 30, 2022	-	$ -
Vested and expected to vest at June 30, 2022	561	$ 0.99

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 June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Research and development	$ 147	$ 630	$ 382	$ 1,569
General and administrative	634	914	1,169	2,418
Total	$ 781	$ 1,544	$ 1,551	$ 3,987

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, employee terminations 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.

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Weighted average expected volatility	106%	105%
Weighted average expected term (in years)	6.9	6.7
Weighted average risk-free interest rate	1.70%	0.48%
Expected dividends	-	-

Note 10 – Licensing and Research Funding Agreements

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 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 are due under the PF Agreement.

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 Asia 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 June 30, 2022, the liability balance related to the payments under the PF Agreement was $3.8 million and is recorded in other liabilities.

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, 2021 that we filed with the Securities and Exchange Commission, or SEC, on March 31, 2022, as supplemented by our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 filed thereafter, and 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, 2021. 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 clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Our development programs are primarily focused on the treatment of acute cardiovascular diseases and secondarily on acute pulmonary diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic 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 in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs. We completed this Phase 2 global clinical study and, in April 2022, announced positive topline results with istaroxime in raising systolic blood pressure. In May 2022, we presented the study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain. We believe that istaroxime has the potential to fulfill an unmet need in early cardiogenic shock. We further believe that the data from our recently completed Phase 2 global clinical study in early cardiogenic shock will not only support that program's continued development but will also support the continued development of our AHF program as well.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activators which activate SERCA2a. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potential oral agents, these candidates would be developed for chronic 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 this product candidate without securing such an arrangement or partnership.

Our pulmonary product candidate portfolio consists of a KL4 surfactant platform to address a range of serious respiratory conditions in children and adults. In January 2022, we completed enrollment of 20 patients in our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe novel coronavirus, or COVID-19, associated acute respiratory distress syndrome, or ARDS. The study demonstrated that intratracheal administration of reconstituted lyophilized lucinactant was generally safe and well tolerated. Oxygenation and other physiological parameters were stable to improved after dosing, supporting the feasibility of this treatment approach to develop a potential treatment for critically ill patients with ARDS due to COVID-19 or other causes.

Previously, we were also developing AEROSURF (lucinactant for inhalation), a novel drug/medical device combination product for noninvasive delivery of aerosolized KL4 surfactant using our aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome in premature infants. 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 transferred to our licensee in Asia, Lee’s Pharmaceutical (HK) Ltd., or Lee’s (HK), under the terms of our License, Development and Commercialization Agreement between us and Lee’s (HK) dated as of June 12, 2017, as amended, or the Asia License Agreement. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing a potential licensing transaction.

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, and 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, which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred operating losses since our incorporation on November 6, 1992. For the three-month periods ended June 30, 2022 and 2021 , we had operating losses of $17.5 million and $45.4 million, respectively. For the six -month periods ended June 30, 2022 and 2021 , we had operating losses of $25.9 million and $54.4 million, respectively. Included in our operating loss for the three and six months ended June 30, 2022 is an $11.6 million loss on impairment of goodwill, and included in our operating loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin (*see*, Note 4 – Summary of Significant Accounting Policies). As of June 30, 2022 , we had an accumulated deficit of $810.8 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred 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.

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, 2021 that we filed with the SEC on March 31, 2022, 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 (Early Cardiogenic Shock)

In September 2020, we initiated a small Phase 2 clinical study of istaroxime for the acute treatment of early cardiogenic shock in heart failure patients with a more severe case of heart failure to evaluate the potential to improve blood pressure. 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 raising systolic blood pressure, the critical clinical objective in treating patients in cardiogenic shock. 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. There is a significant unmet medical need in the area of early cardiogenic shock and severe heart failure. Istaroxime demonstrated a meaningful improvement in blood pressure in clinical trials of this condition, and we believe there may be an opportunity to apply for a Breakthrough Therapy designation that could provide beneficial opportunities for the development program. In order to continue our development of istaroxime for the acute treatment of early cardiogenic shock, subject to adequate resources, we are planning to extend enrollment in this clinical trial by up to 30 patients. We believe that this extension will advance the characterization of the physiology associated with longer dosing as well as evaluate a dose titration. We also believe that this extension will further characterize the effects and potential benefits associated with SERCA2a activation and will support our clinical regulatory strategy for istaroxime. We currently do not have sufficient capital to fully execute the extension of this clinical trial.

Istaroxime (AHF)

To advance istaroxime for the treatment of AHF potentially through the Phase 2 clinical program and be in a Phase 3-ready position, our strategy includes, subject to adequate resources, planning an additional Phase 2 clinical trial that will enroll approximately 300 patients in approximately 60 clinical sites globally. This trial will focus on treating heart failure patients with low blood pressure, who also tend to be diuretic resistant, as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and increase blood pressure while maintaining or improving renal function. This trial will also collect data on measures that may serve as primary endpoints in a Phase 3 clinical trial, and will include an optimized dosing regimen, potentially extending the infusion time beyond 24 hours. We currently do not have sufficient capital to execute this clinical trial.

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 drug product candidate. We currently have not been able to secure a licensing transaction or other strategic opportunity. As a result, we recorded an impairment of the related intangible asset during the year ended December 31, 2021. 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 non-Caucasian and Caucasian patients in treatment resistant hypertension. We are continuing to pursue licensing arrangements, other strategic partnerships, and/or grant funding for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement, partnership, or grant funding.

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. To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements, or other strategic opportunities.

KL4 Surfactant Platform

Our pulmonary product candidate portfolio consists of a KL4 surfactant platform to address a range of serious respiratory conditions in children and adults. In January 2022, we completed enrollment of 20 patients in our study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury. The Phase 2 trial was designed to assess feasibility, safety, and tolerability of administration of reconstituted lyophilized lucinactant in these critically ill patients. The multicenter, single-arm study enrolled 20 critically ill patients in the U.S. and Argentina who were intubated and on mechanical ventilation due to severe COVID-19 associated ARDS. The study demonstrated that intratracheal administration of reconstituted lyophilized lucinactant was generally safe and well tolerated. Lucinactant was safely administered to critically ill, mechanically ventilated patients with severe COVID-19 associated ARDS. Oxygenation and other physiological parameters were stable to improved after dosing, supporting the feasibility of this treatment approach to develop a potential treatment for critically ill patients with ARDS due to COVID-19 or other causes.

Previously, we were also developing AEROSURF (lucinactant for inhalation), a novel drug/medical device combination product for noninvasive delivery of aerosolized KL4 surfactant using our ADS technology for the treatment of respiratory distress syndrome in premature infants. 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 transferred to our licensee in Asia, Lee's (HK), under the terms of the Asia License Agreement. More specifically, since the termination of the Project Financing Agreement in November 2020, we ceased enrollment in our Phase 2b bridging study at the European Union clinical sites, reduced headcount dedicated to KL4 surfactant, and decommissioned both our analytical and technical support laboratory, which previously conducted release testing of active pharmaceutical ingredients 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. While we have no direct insight into such, we are continuing to support Lee's (HK) independent development efforts to advance AEROSURF to a Phase 2 bridging study and Phase 3 clinical trial in Asia. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing a potential licensing transaction.

Impact of COVID-19

The COVID-19 pandemic continues to evolve, and we continue to closely monitor its impact on our business and operations, including its continued impact on our clinical development plans and timelines, and financial condition. There has been intermittent impact of the pandemic in differing geographies, and there may be continued impact, particularly in light of the surge of new COVID-19 cases relating to new variants. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources, and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The extended timelines have required us to expend more of our capital resources than planned to achieve our projected milestones. For example, our Phase 2 study of istaroxime for early cardiogenic shock in heart failure patients experienced delays in trial initiation and enrollment in 2021. Although many countries have re-opened, rises in new cases, including as the result of newly identified COVID-19 variants, have caused certain countries, states, and localities to re-initiate restrictions. The full extent, duration, or impact that the COVID-19 pandemic will have, directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include the severity and transmissibility of new variants of the virus, information about any resurgences in one or more geographic locations where our current or intended clinical trial sites, our principal executive offices, research and development laboratories, or manufacturing facilities are located, and the actions taken to contain it or treat its impact. In addition, regional impact and responses to the COVID-19 pandemic have affected where a clinical trial could be executed and how various elements of the clinical trial are performed. Going forward, the pandemic could also impact how monitoring/auditing of clinical trial sites and data occur. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more geographic locations where our clinical trial sites, principal executive offices, research and development laboratories, or other facilities are located remains possible and if realized, we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts, or modifications to our ongoing and planned trials in 2022 and beyond.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2021. For a discussion of our accounting policies, *see*, 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, 2021, 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.

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or 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 and six months ended June 30, 2022 , no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

During the second quarter of 2021, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not impaired and we performed the required quantitative impairment assessment of the related intangible asset. We recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2021. No events or changes in the business environment occurred during the six months ended June 30, 2021 to indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock.

During the second quarter of 2022, 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. As a result, we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including 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. Based on the quantitative test performed, we recorded a loss on impairment of goodwill of $11.6 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2022.

The closing share price of our common stock has continued to decline during July and August 2022. If our share price continues to decline during the remainder of the third quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

The following table represents identifiable intangible assets and goodwill as of June 30, 2022 and December 31, 2021 :

(in thousands)	**June 30, 2022**	**December 31, 2021**
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	9,730	9,730
Intangible assets	32,070	32,070
Goodwill	$ 4,046	$ 15,682

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended June 30, 2022 and 2021 was $17.5 million and $45.4 million, respectively. The decrease in operating loss from 2021 to 2022 was due to a $37.8 million loss on impairment of intangible assets related to rostafuroxin in 2021 (*see*, Note 4 – Summary of Significant Accounting Policies) and a $1.7 million decrease in operating expenses in 2022, partially offset by an $11.6 million loss on impairment of goodwill in 2022.

The operating loss for the six months ended June 30, 2022 and 2021 was $25.9 million and $54.4 million, respectively. The decrease in operating loss from 2021 to 2022 was due to a $37.8 million loss on impairment of intangible assets related to rostafuroxin in 2021 and a $2.4 million decrease in operating expenses in 2022, partially offset by an $11.6 million loss on impairment of goodwill in 2022.

The net loss for the three months ended June 30, 2022 and 2021 was $17.3 million and $37.4 million, respectively. The decrease in net loss from 2021 to 2022 was due to a $37.8 million loss on impairment of intangible assets related to rostafuroxin in 2021 and a $1.7 million decrease in operating expenses in 2022, partially offset by an $11.6 million loss on impairment of goodwill in 2022, an $8.3 million deferred income tax benefit related to the reduction of the deferred tax liability in 2021, and an increase of $0.5 million in other income.

The net loss for the six months ended June 30, 2022 and 2021 was $25.5 million and $46.4 million, respectively. The decrease in net loss from 2021 to 2022 was due to a $37.8 million loss on impairment of intangible assets related to rostafuroxin in 2021 and a $2.4 million decrease in operating expenses in 2022, partially offset by an $11.6 million loss on impairment of goodwill in 2022, an $8.3 million deferred income tax benefit related to the reduction of the deferred tax liability in 2021, and an increase of $0.6 million in other income.

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, 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) stock-based compensation; (iv) raw materials, aerosol devices and supplies; (v) royalties; (vi) rents and utilities; (vii) depreciation; (viii) travel; and (ix) other. We currently have sufficient capital to execute limited clinical trial work on the extension of our trial of istaroxime for early cardiogenic shock. We expect that our research and development expenses will decrease unless and until we secure additional capital. 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 June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Istaroxime - early cardiogenic shock	$ 974	$ 840	$ 2,174	$ 1,346
Istaroxime - AHF	111	155	656	654
KL4 surfactant	78	263	291	507
Total direct clinical and preclinical programs	1,163	1,258	3,121	2,507
Product development and manufacturing	420	1,085	2,042	2,172
Clinical, medical, and regulatory operations	1,412	1,878	3,177	3,952
Total research and development expenses	$ 2,995	$ 4,221	$ 8,340	$ 8,631

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.7 million, respectively, for the three months ended June 30, 2022 and 2021, and $1.0 million and $1.6 million, respectively, for the six months ended June 30, 2022 and 2021.

Direct Clinical and Preclinical Programs

Direct clinical and preclinical programs include: (i) activities associated with conducting clinical trials, including 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.

Istaroxime - early cardiogenic shock increased $0.1 million and $0.8 million, respectively, for the three and six months ended June 30, 2022 compared to the same periods in 2021 due to our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock and our ongoing extension of this trial following the announcement of positive topline results in April 2022.

Istaroxime - AHF costs relate to limited ongoing clinical and preclinical development activities, including toxicology studies and drug lot production.

KL4 surfactant decreased $0.2 million for both the three and six months ended June 30, 2022 compared to the same periods in 2021 following the completion of enrollment in January 2022 of our Phase 2b study of lucinactant for patients with severe COVID-19 associated ARDS.

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 decreased $0.7 million for the three months ended June 30, 2022 compared to the same period in 2021 due to (i) a decrease of $0.4 million related to our decision in January 2022 to begin to reduce costs related to the development of the KL4 surfactant platform that were not already transferred to Lee's (HK); a decrease of $0.1 million related to reductions in headcount for the KL4 surfactant platform; and (iii) a $0.1 million decrease in non-cash stock-based compensation expense.

Product development and manufacturing expenses decreased$0.1 million for the six months ended June 30, 2022 compared to the same period in 2021 due to (i) a decrease of $0.4 million related to our decision in January 2022 to begin to reduce costs related to the KL4 surfactant platform that were not already transferred to Lee's (HK); and (ii) a $0.1 million decrease in non-cash stock-based compensation expense; partially offset by (iii) $0.4 million in accelerated depreciation during the first quarter of 2022 following the abandonment and decommissioning of certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform.

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 $0.5 million for the three months ended June 30, 2022 compared to the same period in 2021 due to a decrease of $0.4 million in non-cash stock-based compensation expense and a decrease of $0.1 million in personnel costs. Clinical, medical, and regulatory operations expenses decreased$0.8 million for the six months ended June 30, 2022 compared to the same period in 2021 due to a decrease of $0.9 million in non-cash stock-based compensation expense, partially offset by an increase of $0.1 million in personnel costs.

General and Administrative Expenses

(in thousands)	Three Months Ended June 30, 2022	2021	Six Months Ended June 30, 2022	2021
General and administrative expenses	$ 2,907	$ 3,371	$ 5,895	$ 8,040

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

General and administrative expenses decreased $0.5 million for the three months ended June 30, 2022 compared to the same period in 2021 due to (i) a decrease of $0.3 million in non-cash stock-based compensation expense and (ii) a decrease of $0.3 million in professional fees, partially offset by (iii) an increase of $0.1 million in personnel costs.

General and administrative expenses decreased $2.1 million for the six months ended June 30, 2022 compared to the same period in 2021 due to (i) a decrease of $1.2 million in non-cash stock-based compensation expense and (ii) a decrease of $1.2 million in professional fees, partially offset by (iii) an increase of $0.3 million in personnel costs.

Other Income (Expense), Net

(in thousands)	Three Months Ended June 30, 2022	2021	Six Months Ended June 30, 2022	2021
Interest income	17	39	18	89
Interest expense	(13)	(46)	(26)	(87)
Other income (expense), net	201	(352)	419	(243)
Total other income (expense), net	$ 205	$ (359)	$ 411	$ (241)

Interest income relates to interest on our money market account for the three and six months ended June 30, 2022 and 2021, and relates to interest on our U.S. Treasury notes for the three and six months ended June 30, 2021.

For the three and six months ended June 30, 2022 and 2021, interest expense consists of interest expense associated with loans payable.

For the three and six months ended June 30, 2022 and 2021, other income (expense), net primarily consists of gains and losses on foreign currency translation.

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 locations and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $17.3 million and $37.4 million, respectively, for the three-month periods ended June 30, 2022 and 2021. Our net loss was $25.5 million and $46.4 million, respectively, for the six-month periods ended June 30, 2022 and 2021. Included in our net loss for the three and six months ended June 30, 2022 is an $11.6 million loss on impairment of goodwill, and included in our net loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 – Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2022, we had an accumulated deficit of $810.8 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 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.

We are party to an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the six months ended June 30, 2022, we sold 1,137,246 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.3 million and net proceeds of approximately $1.2 million. During July and August 2022, we sold 1,221,706 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million (*see*, Note 8 – Stockholders' Equity).

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited in 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. If our public float increases to $75 million or more, we will no longer be subject to such limitations.

As of June 30, 2022, we had cash and cash equivalents of $11.4 million and current liabilities of $5.3 million. We believe that we have sufficient resources available to support our development activities and fund our business operations into the first quarter of 2023. However, 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 through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, 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. Further, on June 3, 2022, we received a deficiency letter from the Nasdaq Stock Market LLC, or Nasdaq, notifying us that the closing bid price of our common stock had been below the minimum $1.00 per share for 30 consecutive business days, we are out of compliance with the requirements for continued listing on Nasdaq, and are subject to potential delisting. If we are unable to re-achieve compliance with the Nasdaq listing requirements within 180 days, or November 30, 2022, after receipt of a delisting notice, and if we are unable to obtain an extension therefore, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition.

The accompanying condensed consolidated 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.

Cash Flows

Cash flows for the six months ended June 30, 2022 primarily consist of $12.0 million of net cash used in operating activities, $0.2 million of net cash provided by investing activities, and $0.8 million of net cash provided by financing activities. Cash flows for the six months ended June 30, 2021 consist of $13.5 million of net cash used in operating activities and $26.5 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $12.0 million for the six months ended June 30, 2022 and consisted primarily of (i) a net loss of $25.5 million; and (ii) an unrealized gain on foreign exchange rate changes of $0.5 million; partially offset by (iii) a non-cash loss on impairment of goodwill of $11.6 million; (iv) non-cash stock-based compensation of $1.6 million; (v) depreciation and amortization of $0.5 million; and (vi) non-cash lease expense of $0.3 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 $13.5 million for the six months ended June 30, 2021 and consisted primarily of (i) a net loss of $46.4 million; (ii) a non-cash deferred income tax benefit of $8.3 million; and (iii) changes in operating assets and liabilities of $1.7 million; partially offset by (iv) a non-cash loss on impairment of intangible assets of $37.8 million; (v) non-cash stock-based compensation of $4.0 million; (vi) non-cash expense related to equity consideration for a financial advisory service agreement of $0.5 million; (vii) non-cash lease expense of $0.3 million; (viii) an unrealized loss on foreign exchange rate changes of $0.3 million; and (ix) depreciation and amortization 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.

Investing Activities

Net cash provided by investing activities was $0.2 million for the six months ended June 30, 2022 and primarily includes proceeds from sale of property and equipment related to the decommissioning and sale of certain manufacturing and laboratory equipment assets previously used for the KL4 surfactant platform.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2022 was $0.8 million and includes (i) $1.2 million in net proceeds from the ATM Program; partially offset by (ii) $0.4 million of principal payments on loans payable.

Net cash provided by financing activities for the six months ended June 30, 2021 was $26.5 million and includes (i) $27.4 million in net proceeds from the March 2021 public offering; (ii) $1.7 million in net proceeds from the ATM Program; and (iii) $0.4 million in proceeds from our research and development funding arrangement with Lee's (HK); partially offset by (iv) $3.0 million of principal payments on loans payable.

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

Loan Payable to Bank Direct Capital Finance

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% annual interest rate. Payments of approximately $126,000 are due monthly from July 2022 through March 2023. As of June 30, 2022, the outstanding principal of the loan was $1.0 million.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of December 31, 2021, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2022.

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 September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal under the ATM Program. When we issue sales 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.

For the six months ended June 30, 2022, we sold 1,137,246 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.3 million and net proceeds of approximately $1.2 million. For the six months ended June 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million (*see*, Note 8 – Stockholders' Equity).

During July and August 2022, we sold 1,221,706 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million.

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. As of August 11, 2022, approximately $3.2 million remains available under the ATM Program. However, we are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited in selling no more than one-third of our public float during any 12-month period. If our public float increases to $75 million or more, we will no longer be subject to such limitations.

March 2021 Public Offering

On March 23, 2021, we entered into an underwriting agreement with Oppenheimer & Co. Inc. as representative for the several underwriters named therein, relating to a public offering, or the March 2021 Offering, of an aggregate of 9,230,500 units with each unit consisting of one share of common stock and a warrant, or the March 2021 Warrants. The March 2021 Warrants are immediately exercisable for shares of common stock at a price of $3.60 per share and expire five years from the date of issuance. The shares of common stock and the March 2021 Warrants were immediately separable and were issued separately in the March 2021 Offering.

The closing of the March 2021 Offering occurred on March 25, 2021. The offering price to the public was $3.25 per unit resulting in gross proceeds to us of $30.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the March 2021 Warrants issued pursuant to the March 2021 Offering, the net proceeds to us were approximately $27.4 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at June 30, 2022 and 2021 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 our Senior Vice President and Chief Financial Officer and Treasurer (principal financial and accounting officer), do 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 and our Senior Vice President and Chief Financial Officer and Treasurer have 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 and our Senior Vice President and Chief Financial Officer and Treasurer 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 and our Senior Vice President and Chief Financial Officer and Treasurer, 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 June 30, 2022 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, 2021, as supplemented by risk factors included in our Quarterly Report on Form 10-Q filed thereafter. 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, 2021 or our Quarterly Report on Form 10-Q filed thereafter. 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, 2021, 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 common stock is listed on the Nasdaq Capital Market. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on the Nasdaq Capital Market.

On June 3, 2022, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of Nasdaq notifying us that, for the last 30 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 Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Capital Market under the symbol "WINT" at this time. We have been given 180 calendar days, or until November 30, 2022, to regain compliance with Rule 5550(a)(2). If at any time before November 30, 2022, the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Staff will provide written confirmation that we have achieved compliance. If we do not regain compliance with Rule 5550(a)(2) by November 30, 2022, we may be afforded a second 180 calendar day period to regain compliance, if we meet certain other conditions. If we fail to maintain compliance, Nasdaq may take steps to de-list our common stock. If such delisting should occur, it would likely have a negative effect on the price of our common stock and would impair an investor's ability to sell or purchase our common stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

We have a significant amount of intangible assets, including goodwill, recorded on our condensed consolidated balance sheets which may lead to potentially significant impairment charges.

We have recorded significant goodwill and intangible assets on our condensed consolidated balance sheets as a result of a previous acquisition, which could become impaired and lead to material charges in the future. The amount of identifiable intangible assets and goodwill in our condensed consolidated balance sheets is significant due to the acquisition of CVie Therapeutics Ltd., or CVie Therapeutics, in December 2018. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin, which, as of June 30, 2022, are $22.3 million and $9.7 million, respectively, recorded in aggregate on our condensed consolidated balance sheets as intangible assets of $32.1 million. At June 30, 2022, goodwill recorded on our condensed consolidated balance sheets was $4.0 million.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that intangible assets or goodwill may be impaired. If an impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict, including the uncertainties associated with the development of product candidates and the success of business development activities, and are an inherent risk in the pharmaceutical industry.

We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock due to, we believe, both market conditions and our need to secure additional capital in the near term to advance our development programs.

During the second quarter of 2022, 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. As a result, we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including 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. Based on the quantitative test performed, we recorded a loss on impairment of goodwill of $11.6 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2022.

The closing share price of our common stock has continued to decline during July and August 2022. If our share price continues to decline during the remainder of the third quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

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

None.

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
3.1	Amended and Restated By-laws of Windtree Therapeutics, Inc., as amended.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief 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 June 30, 2022, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2022 (unaudited) and December 31, 2021, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2022 and June 30, 2021, (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2022 and June 30, 2021, 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.

(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: August 11, 2022

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

Date: August 11, 2022

By: /s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer

AMENDED AND RESTATED BY-LAWS OF WINDTREE THERAPEUTICS, INC. (A Delaware Corporation)

(Effective: April 19, 2016)
(Amended: June 3, 2022)

ARTICLE I

Meetings of Stockholders

Section 1. **Annual Meeting.** The annual meeting of the stockholders of Windtree Therapeutics, Inc. (the "Corporation"), for the election of directors and for the transaction of such other business as may come before the meeting shall be held at such date and time as shall be designated by the Board of Directors (the "Board"), the Chairman of the Board or the President.

Section 2. **Special Meeting.** Special meetings of the stockholders, unless otherwise prescribed by statute, may be called at any time by the Board, the Chairman of the Board or the Chief Executive Officer. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

Section 3. **Notice of Meetings.** Notice of the place, date and time of the holding of each annual and special meeting of the stockholders and, in the case of a special meeting, the purpose or purposes thereof shall be given personally or by mail in a postage prepaid envelope to each stockholder entitled to vote at such meeting, not less than 10 nor more than 60 days before the date of such meeting, and, if mailed, it shall be directed to such stockholder at his or her address as it appears on the records of the Corporation, unless such stockholder shall have filed with the Secretary of the Corporation a written request that notices to such stockholder be mailed to some other address, in which case it shall be directed to the stockholder at such other address. If mailed, such notice shall be deemed to be delivered when deposited in United States mail so addressed with postage thereon prepaid. Notice of any meeting of stockholders shall not be required to be given to any stockholder who shall attend such meeting in person or by proxy and shall not, at the beginning of such meeting, object to the transaction of any business because the meeting is not lawfully called or convened, or who shall, either before or after the meeting, submit a signed waiver of notice, in person or by proxy. Unless the Board shall fix after the adjournment a new record date for an adjourned meeting, notice of such adjourned meeting need not be given if the time and place to which the meeting shall be adjourned were announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which may have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 4. **Place of Meetings.** Meetings of the stockholders my be held at such place, within or without the State of Delaware, as the Board or other officer calling the same shall specify in the notice of such meeting, or in a duly executed waiver of notice thereof.

Section 5. **Quorum.** At all meetings of the stockholders, the holders of one third of the votes of the shares of stock of the Corporation issued and outstanding and entitled to vote shall be present in person or by proxy to constitute a quorum for the transaction of any business, except when stockholders are required to vote by class, in which event a majority of the issued and outstanding shares of the appropriate class shall be present in person or by proxy, or except as otherwise provided by statute or in the Corporation's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"). In the absence of a quorum, the holders of a majority of the votes of the shares of stock present in person or by proxy and entitled to vote, or if no stockholder entitled to vote is present, then the chairman of the meeting, as set forth in Section 6 below, may adjourn the meeting from time to time. At any such adjourned meeting at which a quorum may be present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 6. **Organization.** At each meeting of the stockholders, the Chairman of the Board, or in his absence or inability to act, the President, or in the absence or inability to act of the Chairman of the Board and the President or an Executive Vice President, or in the absence of all the foregoing, any person chosen by a majority of those stockholders present shall act as chairman of the meeting. The Secretary, or, in his absence or inability to act, the Assistant Secretary or any person appointed by the chairman of the meeting shall act as secretary of the meeting and keep the minutes thereof.

Section 7. **Order of Business.** The order of business at all meetings of the stockholders shall be as determined by the chairman of the meeting.

Section 8. **Voting.** Except as otherwise provided by statute, the Certificate of Incorporation or any certificate duly filed in the office of the Secretary of State of the State of Delaware, each holder of record of shares of stock of the Corporation having voting power shall be entitled at each meeting of the stockholders to one vote for every share of such stock standing in his name on the record of stockholders of the Corporation on the date fixed by the Board as the record date for the determination of the stockholders who shall be entitled to notice of and to vote at such meeting; or if such record date shall not have been so fixed, then at the close of business on the day next preceding the day on which the meeting is held; or each stockholder entitled to vote at any meeting of stockholders may authorize another person or persons to act for him by a proxy signed by such stockholder or his attorney-in-fact. Any such proxy shall be delivered to the secretary of such meeting at or prior to the time designated in the order of business for so delivering such proxies. No proxy shall be valid after the expiration of three years from the date thereof, unless otherwise provided in the proxy. Every proxy shall be revocable at the pleasure of the stockholder executing it, except in those cases where an irrevocable proxy is permitted by law. Except as otherwise provided by statute, these Amended and Restated By-Laws (the "By-Laws"), or the Certificate of Incorporation, any corporate action to be taken by vote of the stockholders shall be authorized by a majority of the total votes, or when stockholders are required to vote by class by a majority of the votes of the appropriate class, cast at a meeting of stockholders by the holders of shares present in person or represented by proxy and entitled to vote on such action. Unless required by statute, or determined by the chairman of the meeting to be advisable, the vote on any question need not be by written ballot. On a vote by written ballot, each ballot shall be signed by the stockholder voting, or by his proxy, if there be such proxy, and shall state the number of shares voted.

Section 9. **Nominations.** The procedures governing stockholder nominees of candidates to elections of the Board of Directors or to fill vacancies, as applicable, shall be administered by the Corporation's Nomination Committee. This Section 9 shall be the exclusive means by which a stockholder may make such nominations before any meeting of stockholders (other than matters properly brought under Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and included in the Corporation's notice of meeting). For nominations for election to the Board or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Corporation. In addition to other applicable requirements, to be timely, a notice of nominations or other business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Corporation to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Corporation did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the preceding year's annual meeting; provided, that if the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Corporation. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Corporation. Any stockholder delivering notice to the Secretary under this Section 9, Article I must be a stockholder of record on the date such notice is delivered. The Secretary shall deliver the notice to the Nomination Committee. No stockholder nominee may be a candidate for election at any meeting of stockholders or otherwise elected to fill a vacancy in the Board unless such person has been approved by the Nomination Committee and was nominated in accordance with the procedures set forth in this Section 9, Article I. If the facts warrant, the Board, or the chairman of a stockholders meeting at which Directors are to be elected may determine and declare that a nomination was not made in accordance with the foregoing procedure and, if it is so determined, no election may be made with respect to such nominee. The right of stockholders to make nominations pursuant to the foregoing procedure is subject to the superior rights, if any, of the holders of any class or series of stock having a preference over the common stock. The procedures set forth in this Section 9 of Article I for nomination for the election of Directors by stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof.

If a stockholder attempts to nominate a candidate to the Board and complies with the procedure set forth in this Section 9, Article I but the Nomination Committee rejects such stockholder's nomination, such stockholder may nominate such candidate notwithstanding the decision of the Nomination Committee at the next election of Directors after such candidate was rejected by the Nomination Committee if such stockholder delivers to the Secretary written requests that such person be nominated to the Board from stockholders holding at least 50% of the eligible votes as of the record date of such election.

To be in proper written form, each such notice to the Secretary delivered in connection with a stockholder nomination must set forth as to each person whom the stockholder proposes to nominate for election as a director:

(i) the name, age, business address and residence address of the person;

(ii) the principal occupation or employment of the person;

(iii) the class or series and number of shares of capital stock of the Corporation that are owned beneficially or of record by the person;

(iv) a representation that the person does not have, nor will not have, any undisclosed voting commitments or other arrangements with respect to such person's actions as a director; and

(v) any other information relating to the person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder;

Each such notice to the Secretary must also set forth as to the stockholder giving the notice:

(i) the name and record address of such stockholder;

(ii) the class or series and number of shares of capital stock of the Corporation that are owned beneficially or of record by such stockholder;

(iii) a description of all arrangements, material relationships, or understandings between such stockholder and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are to be made by such stockholder;

(iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice;

(v) any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the Corporation or otherwise (a "Derivative Instrument") directly or indirectly owned beneficially by such stockholder and any other director indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the Corporation;

(vi) any proxy, contract, arrangement, understanding, or relationship pursuant to which such stockholder has a right to vote any shares of any security of the Corporation;

(vii) any short interest in any security of the Corporation (for purposes of this By-Law a person shall be deemed to have a short interest in a security if such person directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has the opportunity to profit or share in any profit derived from any decrease in the value of the subject security);

(viii) any rights to dividends on the shares of the Corporation owned beneficially by such stockholder that are separated or separable from the underlying shares of the Corporation;

(ix) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder is a general partner or, directly or indirectly, beneficially owns an interest in a general partner;

(x) any performance-related fees (other than an asset-based fee) that such stockholder is entitled to based on any increase or decrease in the value of shares of the Corporation or Derivative Instruments, if any, as of the date of such notice, including without limitation any such interests held by members of such stockholder's immediate family sharing the same household (which information shall be supplemented by such stockholder and beneficial owner, if any, not later than 10 days after the record date for the meeting to disclose such ownership as of the record date; and

(xi) any other information relating to such stockholder that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder.

All notices delivered to the Secretary in connections must be accompanied by a written consent of each proposed nominee to being named as a nominee and to serve as a Director if elected.

Section 10. **Stockholder Proposals.** The procedures governing stockholder proposals, other than the nomination of a director or directors by a stockholder, ("Other Business") of business to be conducted at meetings of stockholders shall be administered by the Corporation's Nomination Committee. This Section 10 shall be the exclusive means by which a stockholder may submit any Other Business that the stockholder proposes to bring before an any meeting of stockholders (other than matters properly brought under Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and included in the Company's notice of meeting). At any meeting of the stockholders, only such Other Business shall be conducted as shall have been properly brought before such meeting. To be properly brought before a meeting, Other Business must be: (a) as specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board; (b) otherwise properly brought before the meeting by or at the direction of the Board; or (c) otherwise properly brought before the meeting by a stockholder. For Other Business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Corporation. In addition to other applicable requirements set forth in the Exchange Act, to be timely, a notice of other Other Business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Corporation to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Corporation did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the date of the Corporation's proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, that if (A) the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, or (B) no proxy statement was delivered to stockholders by the Corporation in connection with the preceding year's annual meeting, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Corporation. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Corporation. Any stockholder delivering notice to the Secretary under this Section 10 of Article I must be a stockholder of record on the date such notice is delivered. The Nomination Committee must approve each stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise. No stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise unless such proposal was approved in accordance with the procedures set forth in this Section 10 of Article I. The procedures set forth in this Section 10 of Article I for submission of any Other Business that the stockholder proposes to bring before any meeting of stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof. If the chairman of a meeting of stockholders determines that Other Business was not properly brought before the meeting in accordance with the foregoing procedures, the chairman shall declare to the meeting that the Other Business was not properly brought before the meeting and such Other Business shall not be transacted.

To be in proper written form, a stockholder's notice to the Secretary must set forth as to each matter such stockholder proposes to bring before the meeting:

(i) a brief description of the Other Business desired to be brought before the meeting and the reasons for conducting such Other Business at the meeting;

(ii) the name and record address of such stockholder;

(iii) the class or series and number of shares of capital stock of the Corporation that are owned beneficially or of record by such stockholder;

(iv) a description of all arrangements or understandings between such stockholder and any other person or persons (including their names) in connection with the proposal of such Other Business by such stockholder and any material interest of such stockholder in such business;

(v) a representation that such stockholder intends to appear in person or by proxy at the meeting to bring such business before the meeting;

(vi) any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the Corporation or otherwise (a “Derivative Instrument”) directly or indirectly owned beneficially by such stockholder and any other director indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the Corporation;

(vii) any proxy, contract, arrangement, understanding, or relationship pursuant to which such stockholder has a right to vote any shares of any security of the Corporation;

(viii) any short interest in any security of the Corporation (for purposes of this By-Law a person shall be deemed to have a short interest in a security if such person directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has the opportunity to profit or share in any profit derived from any decrease in the value of the subject security);

(ix) any rights to dividends on the shares of the Corporation owned beneficially by such stockholder that are separated or separable from the underlying shares of the Corporation;

(x) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder is a general partner or, directly or indirectly, beneficially owns an interest in a general partner;

(xi) any performance-related fees (other than an asset-based fee) that such stockholder is entitled to based on any increase or decrease in the value of shares of the Corporation or Derivative Instruments, if any, as of the date of such notice, including without limitation any such interests held by members of such stockholder’s immediate family sharing the same household (which information shall be supplemented by such stockholder and beneficial owner, if any, not later than 10 days after the record date for the meeting to disclose such ownership as of the record date); and

(xii) any other information that is required by law to be provided by the stockholder in his capacity as proponent of a stockholder proposal.

Section 11. **List of Stockholders.** The officer who has charge of the stock ledger of the Corporation, or the transfer agent of the Corporation's stock, if there be one then acting, shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting, either at a place within the city where the meeting is to be held, at the place where the meeting is to be held or at the office of the transfer agent. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

Section 12. **Inspectors.** The Board may, in advance of any meeting of stockholders, appoint one or more inspectors to act at such meeting or any adjournment thereof. If the inspectors shall not be so appointed or if any of them shall fail to appear or act, the chairman of the meeting may, and on the request of any stockholder entitled to vote thereat shall, appoint inspectors. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector at such meeting with strict impartiality and according to the best of his ability. The inspectors shall determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, the validity and effect of proxies, and shall receive votes, ballots or consents, hear and determine all challenges and questions arising in connection with the right to vote, count and tabulate all votes, ballots or consents, determine the result, and do such acts as are proper to conduct the election or vote with fairness to all stockholders. Upon the request of the chairman of the meeting or any stockholder entitled to vote thereat, the inspectors shall make a report in writing of any challenge, request or matter determined by them and shall execute a certificate of any fact found by them. No director or candidate for the office of director shall act as inspector of an election of directors. Inspectors need not be stockholders.

Section 13. **Consent of Stockholders in Lieu of Meeting.** Unless otherwise provided in the Certificate of Incorporation, any action required by Subchapter VII of the General Corporation Law of the State of Delaware, to be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the corporation by delivery to its registered office in this State, its principal place of business, or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be by hand or by certified or registered mail, return receipt requested.

ARTICLE II

Board Of Directors

Section 1. **General Powers.** The business and affairs of the Corporation shall be managed by the Board. The Board may exercise all such authority and powers of the Corporation and do all such lawful acts and things as are not by statute or the Certificate of Incorporation or by these By-Laws directed or required to be exercised or done by the stockholders.

Section 2. **Number, Qualifications, Elections and Term of Office.** The number of directors of the Corporation ("Directors") shall be fixed from time to time by the vote of a majority of the entire Board then in office and the number thereof may thereafter by like vote be increased or decreased to such greater or lesser number (not less than three) as may be so provided, subject to the provisions of Section 11 of this Article II. All of the Directors shall be of full age and need not be stockholders. Except as otherwise provided by statute or these By-Laws, the Directors shall be elected at the annual meeting of the Stockholders for the election of Directors at which a quorum is present, and the persons receiving a plurality of the votes cast at such meeting shall be elected. Each Director shall hold office until the next annual meeting of the stockholders and until his successors shall have been duly elected and qualified, or until such Director's death, or until such Director shall have resigned, or have been removed, as hereinafter provided in these By-Laws, or as otherwise provided by statute or the Certificate of Incorporation.

Section 3. **Place of Meetings.** Meetings of the Board may be held at such place, within or without the State of Delaware, as the Board may from time to time determine or as shall be specified in the notice or waiver of notice of such meeting.

Section 4. **Annual Meeting.** The Board shall meet for the purpose of organization, the election or appointment of officers and the transaction of other business, as soon as practicable after each annual meeting of the stockholders, on the same day and at the same place where such annual meeting shall be held. Notice of such meeting need not be given. Such meeting may be held at any other time or place (within or without the State of Delaware) which shall be specified in a notice thereof given as hereinafter provided in Section 7 of this Article II.

Section 5. **Regular Meetings.** Regular meetings of the Board shall be held at such time and place as the Board may from time to time determine. If any day fixed for a regular meeting shall be a legal holiday at the place where the meeting is to be held, then the meeting which would otherwise be held on that day shall be held at the same hour on the next succeeding business day. Notice of regular meetings of the Board need not be given except as otherwise required by statute or these By-Laws.

Section 6. **Special Meetings.** Special meetings of the Board may be called by the Chairman of the Board, two or more directors or the President of the Corporation.

Section 7. **Notice of Meetings.** Notice of each special meeting of the Board (and of each regular meeting for which notice shall be required) shall be given by the Secretary as hereinafter provided in this Section 7 of Article II, in which notice shall be stated the time and place (within or without the State of Delaware) of the meeting. Notice of each such meeting shall be delivered to each Director either personally or by telephone, telegraph, cable or wireless, at least 24 hours before the time at which such meeting is to be held or by first-class mail, postage prepaid, addressed to him at his residence, or usual place of business, at least three days before the day on which such meeting is to be held. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail. Notice of any such meeting need not be given to any director who shall, either before or after the meeting, submit a signed waiver of notice or who shall attend such meeting without protesting, prior to or at its commencement, the lack of notice to him. Except as otherwise specifically required by these By-Laws, a notice or waiver of notice of any regular or special meeting need not state the purposes of such meeting.

Section 8. **Quorum and Manner of Acting.** A majority of the entire Board shall be present in person at any meeting of the Board in order to constitute a quorum for the transaction of business at such meeting, and, except as otherwise expressly required by statute or the Certificate of Incorporation, the act of a majority of the Directors present at any meeting at which a quorum is present shall be the act of the Board. Any one or more members of the Board or any committee thereof may participate in a meeting of the Board or such committee by means of a conference telephone or similar communications equipment allowing all participants in the meeting to hear each other at the same time and participation by such means shall constitute presence in person at a meeting. In the absence of a quorum at any meeting of the Board, a majority of the directors present thereat, or if no director be present, the Secretary, may adjourn such meeting to another time and place, or such meeting, unless it be the annual meeting of the Board, need not be held. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called. Except as provided in Article III of these By-Laws, the directors shall act only as a Board and the individual directors shall have no power as such.

Section 9. **Organization.** At each meeting of the Board, the Chairman of the Board (or, in his or her absence or inability to act, the President, or, in his or her absence or inability to act, another Director chosen by a majority of the Directors present) shall act as chairman of the meeting and preside thereat. The Secretary (or, in his or her absence or inability to act, any person appointed by the chairman of the meeting) shall act as secretary of the meeting and keep the minutes thereof.

Section 10. **Resignations.** Any Director may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 11. **Vacancies.** Vacancies, including newly created directorships, may be filled by the decision of majority of the Directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section for the filling of other vacancies.

Section 12. **Removal of Directors.** Except as otherwise provided in the Certificate of Incorporation or in these By-Laws, any Director may be removed, either with or without cause, at any time, by the affirmative vote of a majority of the votes of the issued and outstanding shares of stock entitled to vote for the election of the stockholders called and held for that purpose, or by a majority vote of the Board at a meeting called for such purpose, and the vacancy in the Board caused by any such removal may be filled by such stockholders or Directors, as the case may be, at such meeting, and if the stockholders shall fail to fill such vacancy, such vacancy shall be filled in the manner as provided by these By-Laws.

Section 13. **Compensation.** The Board shall have authority to fix the compensation, including fees and reimbursement of expenses, of Directors for services to the Corporation in any capacity, provided no such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

Section 14. **Action by the Board.** To the extent permitted under the laws of the State of Delaware, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of the proceedings of the Board or committee.

ARTICLE III

Executive and Other Committees

Section 1. **Executive and Other Committees.** The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of two or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the Committee. Any such committee, to the extent provided in the resolution, shall have and may exercise the powers of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it, provided, however, that in the absence or disqualification of any member of such committee or committees, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Each committee shall keep minutes of its proceedings and shall, report such minutes to the Board when required. All such proceedings shall be subject to revision or alteration by the Board; provided, however, that third parties shall not be prejudiced by such revision or alteration.

Section 2. **General.** A majority of any committee may determine its action and fix the time and place of its meetings, unless the Board shall otherwise provide. Notice of such meetings shall be given to each member of the committee in the manner provided for in Article II, Section 7. The Board shall have the power at any time to fill vacancies in, to change the membership of, or to dissolve any such committee. Nothing herein shall be deemed to prevent the Board from appointing one or more committees consisting in whole or in part of persons who are directors of the Corporation; provided, however, that no such committee shall have or may exercise any authority of the Board.

ARTICLE IV

Officers

Section 1. **Number and Qualifications.** The officers of the Corporation shall include the Chairman of the Board, the President, one or more Vice Presidents (one or more of whom may be designated an Executive Vice President or a Senior Vice President), the Treasurer and the Secretary. Any two or more offices may be held by the same person. Such officers shall be elected or appointed from time to time by the Board, each to hold office until the meeting of the Board following the next annual meeting of the stockholders, or until his or her successor shall have been duly elected or appointed and shall have qualified, or until such Officer's death, or until such Officer shall have resigned, or have been removed, as hereinafter provided in these By-Laws. The Board may from time to time elect a Vice Chairman of the Board, and the Board may from time to time elect, or the Chairman of the Board, or the President may appoint, such other officers (including one or more Assistant Vice Presidents, Assistant Secretaries and Assistant Treasurers), as may be necessary or desirable for the business of the Corporation. Such other officers and agents shall have such duties and shall hold their offices for such terms as may be prescribed by the Board or by the appointing.

Section 2. **Resignation.** Any officer of the Corporation may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 3. **Removal.** Any officer or agent of the Corporation may be removed, either with or without cause, at any time, by the vote of the majority of the entire Board at any meeting of the Board or, except in the case of an officer or agent elected or appointed by the Board, by the Chairman of the Board or the President. Such removal shall be without prejudice to the contractual rights, if any, of the person so removed.

Section 4. **Vacancies.** A vacancy in any office, whether arising from death, disability, resignation, removal or any other cause, may be filled for the unexpired portion of the term of the office which shall be vacant, in the manner prescribed in these By-Laws for the regular election or appointment to such office.

Section 5. **a.** **The Chairman of the Board.** The Chairman of the Board, if one be elected, shall, if present, preside at each meeting of the stockholders and of the Board and shall be an ex officio member of all committees of the Board. He shall perform all duties incident to the office of Chairman of the Board and such other duties as may from time to time be assigned to him by the Board.

b. **The Vice Chairman of the Board.** The Vice Chairman of the Board, if one be elected, shall have such powers and perform all such duties as from time to time may be assigned to him by the Board or the Chairman of the Board and, unless otherwise provided by the Board, shall in the case of the absence or inability to act of the Chairman of the Board, perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board.

Section 6. **The President.** The President shall be the chief executive officer of the Corporation and shall have general and active supervision and direction over the business and affairs of the Corporation and over its several officers, subject, however, to the direction of the Chairman of the Board and the control of the Board. If no Chairman of the Board is elected or at the request of the Chairman of the Board, or in the case of his absence or inability to act, unless there be a Vice Chairman of the Board so designated to act, the President shall perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board. He shall perform all duties incident to the office of President and such other duties as from time to time may be assigned to him by the Board or the Chairman of the Board.

Section 7. **Vice Presidents.** Each Executive Vice President, each Senior Vice President and each Vice President shall have such powers and perform all such duties as from time to time may be assigned to such person by the Board, the Chairman of the Board or the President. They shall in the order of their seniority, have the power and may perform the duties of the Chairman of the Board and the President.

Section 8. **The Treasurer.** The Treasurer shall exercise general supervision over the receipt, custody and disbursement of corporate funds. He or she shall have such further powers and duties as may be conferred upon him from time to time by the President or the Board of Directors. He or she shall perform the duties of controller if no one is elected to that office.

Section 9. **The Secretary.** The Secretary shall:

(a) keep or cause to be kept in one or more books provided for the purpose, the minutes of all meetings of the Board, the committees of the Board and the stockholders;

(b) see that all notices are duly given in accordance with the provisions of these By-Laws and as required by law;

(c) be custodian of the records and the seal of the Corporation and affix and attest the seal to all stock certificates of the Corporation (unless the seal be a facsimile, as hereinafter provided) and affix and attest the seal to all other documents to be executed on behalf of the Corporation under its seal;

(d) see that the books, reports, statements, certificates and other documents and records required by law to be kept and filed are properly kept and filed; and

(e) in general, perform all the duties incident to the office of Secretary and such other duties as from time to time may be assigned to him by the Board, the Chairman of the Board, or the President.

Section 10. **Officer's Bonds or Other Security.** If required by the Board, any officer of the Corporation may be required to give a bond or other security for the faithful performance of his duties, in such amount and with such surety or sureties as the Board may require.

Section 11. **Compensation.** The compensation of the officers of the Corporation for their services as such officers shall be fixed from time to time by the Board; provided, however, that the Board may delegate to the Chairman of the Board or the President the power to fix the compensation of officers and agents appointed by the Chairman of the Board or the President, as the case may be. An officer of the Corporation shall not be prevented from receiving compensation by reason of the fact that he is also a director of the Corporation, but any such officer who shall also be a Director shall not have any vote in the determination of the amount of compensation paid to him.

ARTICLE V

Indemnification

The Corporation shall, to the fullest extent permitted by the laws of the state of Delaware, indemnify any and all persons whom it shall have power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by them by reason of having been officers or Directors of the Corporation, any subsidiary of the Corporation or of any other corporation for which such person acted as officer or director at the request of the Corporation.

ARTICLE VI

Contracts, Checks, Drafts, Bank Account, Etc.

Section 1. **Execution of Contracts.** Except as otherwise required by statute, the Certificate of Incorporation or these By-Laws, any contracts or other instruments may be executed and delivered in the name and on behalf of the Corporation by such officer or officers (including any assistant officer) of the Corporation as the Board may, from time to time, direct. Such authority may be general or confined to specific instances as the Board may determine. Unless authorized by the Board or expressly permitted by these By-Laws, an officer or agent or employee shall not have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it pecuniarily liable for any purpose or to any amount.

Section 2. **Loans.** Unless the Board shall otherwise determine, either (a) the Chairman of the Board, the Vice Chairman of the Board or the President, singly, or (b) a Vice President, together with the Treasurer, may effect loans and advances at any time for the Corporation or guarantee any loans and advances to any subsidiary of the Corporation, from any bank, trust company or other institution, or from any firm, corporation or individual, and for such loans and advances way make, execute and deliver promissory notes, bonds or other certificates or evidences of indebtedness of the Corporation, or guarantee of indebtedness of subsidiaries of the Corporation, but no officer or officers shall mortgage, pledge, hypothecate or transfer any securities or other property of the Corporation, except when authorized by the Board.

Section 3. **Checks, Drafts, Etc.** All checks, drafts, bills of exchange or other orders for the payment of money out of the funds of the Corporation, and all notes or other evidences of indebtedness of the Corporation, shall be signed in the name and on behalf of the Corporation by such persons and in such manner as shall from time to time be authorized by the Board.

Section 4. **Deposits.** All funds of the Corporation not otherwise employed shall be deposited from time to time to the credit of the Corporation in such banks, trust companies or other depositories as the Board may from time to time designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. For the purpose of deposit and for the purpose of collection for the account of the Corporation, checks, drafts and other orders for the payment of money which are payable to the order of the Corporation my be endorsed, assigned and delivered by any officer or agent of the Corporation, or in such manner as the Board may determine by resolution.

Section 5. **General and Special Bank Accounts.** The Board may, from time to time, authorize the opening and keeping of general and special bank accounts with such banks, trust companies or other depositories as the Board may designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. The Board may make such special rules and regulations with respect to such bank accounts, not inconsistent with the provisions of these By-Laws, as it may deem expedient.

Section 6. **Proxies in Respect of Securities of Other Corporations.** Unless otherwise provided by resolution adopted by the Board, the Chairman of the Board, the President or a Vice President may from time to time appoint an attorney or attorneys or agent or agents of the Corporation, in the name and on behalf of the Corporation, to cast the votes which the Corporation may be entitled to cast as the holder of stock or other securities in any other corporation, any of whose stock or other securities may be held by the Corporation, at meetings of the holders of the stock or other securities of such other corporation, or to consent in writing, in the name of the Corporation as such holder, to any action by such other corporation, and may instruct the person or persons so appointed as to the manner of casting such votes or giving such consent, and may execute or cause to be executed, in the name and on behalf of the Corporation, and under its corporate seal, or otherwise, all such written proxies or other instruments as he or she may deem necessary or proper in the premises.

ARTICLE VII

Shares, Etc.

Section 1. **Stock Certificates.** Shares of stock of the Corporation shall be represented by certificates, or shall be uncertificated shares that may be evidenced by a book-entry system maintained by the registrar of such stock, or a combination of both. To the extent that shares are represented by certificates, such certificates shall be in a form approved by the Board. Each certificate shall be signed in the name of the Corporation by (A) the Chairman or Vice Chairman of the Board or the President or a Vice President, and (B) the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer, and sealed with the seal of the Corporation (which seal may be a facsimile, engraved or printed); provided, however, that where any such certificate is countersigned by a transfer agent other than the Corporation or one of its employees, or is registered by a registrar other than the Corporation or one of its employees, the signature of the officers of the Corporation upon such certificates may be facsimiles, engraved or printed. In case any officer who shall have signed or whose facsimile signature has been placed upon such certificates shall have ceased to be such officer before such certificates shall be issued, they may nevertheless be issued by the Corporation with the same effect as if such officer were still in office at the date of their issue.

Section 2. **Books of Account and Record of Shareholders.** The books and records of the Corporation may be kept at such places within or without the state of incorporation as the Board of Directors may from time to time determine. The stock record books and the blank stock certificate books shall be kept by the Secretary or by any other officer or agent designated by the Board of Directors.

Section 3. **Transfer of Shares.** Subject to any restrictions on transfer and unless otherwise provided by the Board, shares of stock may be transferred only on the books of the Corporation by the surrender to the Corporation or its transfer agent of the shares in certificated form, properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, or upon proper instructions from the holder of uncertificated shares, in each case with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require. Except as otherwise provided by applicable law, the Corporation shall be entitled to recognize the exclusive right of a person in whose name any share or shares stand on the record of stockholders as the owner of such share or shares for all purposes, including, without limitation, the rights to receive dividends or other distributions and to vote as such owner, and the Corporation may hold any such stockholder of record liable for calls and assessments and the Corporation shall not be bound to recognize any equitable or legal claim to or interest in any such share or shares on the part of any other person whether or not it shall have express or other notice thereof. Whenever any transfers of shares shall be made for collateral security and not absolutely, and both the transferor and transferee request the Corporation to do so, such fact shall be stated in the entry of the transfer.

Section 4. **Regulations.** The Board may make such additional rules and regulations, not inconsistent with these By-Laws, as it may deem expedient concerning the issue, transfer and registration of certificates for shares of stock of the Corporation. It may appoint, or authorize any officer or officers to appoint, one or more transfer agents or one or more transfer clerks and one or more registrars and may require all certificates for shares of stock to bear the signature or signatures of any of them.

Section 5. **Lost, Destroyed or Mutilated Certificates.** The holder of any certificate representing shares of stock of the Corporation shall immediately notify the Corporation of any loss, destruction or mutilation of such certificate, and the Corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it which the owner thereof shall allege to have been lost, stolen or destroyed or which shall have been mutilated, and the Board may, in its discretion, require such owner or his legal representative to give the Corporation a bond in such sum, limited or unlimited, and in such form and with such surety or sureties as the Board in its absolute discretion shall determine, to indemnify the Corporation against any claim that way be made against it on account of the alleged loss, theft or destruction of any such certificate, or the issuance of a new certificate. Anything herein to the contrary notwithstanding, the Board, in its absolute discretion, may refuse to issue any such new certificate, except pursuant to legal proceedings under the laws of the State of Delaware.

Section 6. **Fixing of Record Date.** In order that the Corporation may determine the stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix in advance a record date, which shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action. A determination of stockholders of record entitled to notice of, or to vote at, a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

ARTICLE VIII

Offices

Section 1. **Principal or Registered Office.** The principal registered office of the Corporation shall be at such place as may be specified in the Certificate of Incorporation or other certificate filed pursuant to law, or if none be so specified, at such place as may from time to time be fixed by the Board.

Section 2. **Other Offices.** The Corporation also may have an office or offices other than said principal or registered office, at such place or places either within or without the State of Delaware.

ARTICLE IX

Fiscal Year

The fiscal year of the Corporation shall be determined by the Board.

ARTICLE X

Seal

The Board shall provide a corporate seal which shall contain the name of the Corporation, the words "Corporate Seal" and the year and State of Delaware.

ARTICLE XI

Amendments

Section 1. **Stockholders.** These By-Laws may be amended or repealed, or new By-Laws may be adopted, at any annual or special meeting of the stockholders, by a majority of the total votes of the stockholders or when stockholders are required to vote by class by a majority of the appropriate class, in person or represented by proxy and entitled to vote on such action; provided, however, that the notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of these By-Laws, or the adoption of new By-Laws, is one of the purposes of such meeting.

Section 2. **Board of Directors.** These By-Laws may also be amended or repealed or new By-Laws may be adopted by the Board at any meeting of the Board; provided, however, that notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of the By-Laws, or the adoption of new By-Laws, is one of the purposes of such meetings. By-Laws adopted by the Board may be amended or repealed by the stockholders as provided in Section 1 of this Article XI.

ARTICLE XII

Miscellaneous

Section 1. **Interested Directors.** No contract or other transaction between the Corporation and any other corporation shall be affected and invalidated solely by the fact that any one or more of the Directors of the Corporation is or are interested in or is a director or officer or are directors or officers of such other corporation, and any Director or Directors, individually or jointly, may be a party or parties to or may be interested in any contract or transaction of the Corporation or in which the Corporation is interested; and no contract, act or transaction of the Corporation with any person or persons, firm or corporation shall be affected or invalidated by the fact that any Director of the Corporation is a party or are parties to or interested in such contract, act or transaction, or in any way connected with such person or persons, firms or associations, and each and every person who may become a Director of the Corporation is hereby relieved from any liability that might otherwise exist from contracting with the Corporation for the benefit of himself or herself, any firm, association or corporation in which such Director may be in any way interested.

Section 2. **Ratification.** Any transaction questioned in any stockholders derivative suit on the grounds of lack of authority, defective or irregular execution, adverse interest of director, officer or stockholder, nondisclosure, miscomputation, or the application of improper principles or practices of accounting, may be ratified before or after judgment, by the Board or, by the stockholders in case less than a quorum of Directors are qualified, and, if so ratified, shall have the same force and effect as if the questioned transaction had been originally duly authorized, and said ratification shall be binding upon the Corporation and its stockholders, and shall constitute a bar to any claim or execution of any judgment, in respect of such questioned transaction.

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 reports (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: August 11, 2022

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

Exhibit 31.2

CERTIFICATION

I, John P. Hamill, 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: August 11, 2022

/s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer
(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 June 30, 2022, 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 Section13(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: August 11, 2022

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

/s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer
(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.