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

FORM 10-Q

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

For the quarterly period ended **March 31, 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 May 5, 2022, there were 29,406,172 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;
- the risk that failure to maintain compliance with the continued listing requirements of the Nasdaq Capital Market, or Nasdaq, may result in receipt of a Nasdaq delisting notice; if upon receipt of a delisting notice, we fail to regain compliance within any allowed grace period or other process 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, or with the impact of the geopolitical instability (including the ongoing military conflict between Russia and Ukraine), 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.

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)

	March 31, 2022	December 31, 2021
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,541	$ 22,348
Prepaid expenses and other current assets	906	1,143
Total current assets	16,447	23,491
Property and equipment, net	548	1,011
Restricted cash	154	154
Operating lease right-of-use assets	2,207	2,381
Intangible assets	32,070	32,070
Goodwill	15,682	15,682
Total assets	$ 67,108	$ 74,789
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 724	$ 693
Accrued expenses	3,554	3,408
Operating lease liabilities - current portion	472	528
Loans payable - current portion	-	294
Total current liabilities	4,750	4,923
Operating lease liabilities - non-current portion	1,944	2,071
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	6,885	7,114
Total liabilities	32,379	32,908
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2022 and December 31, 2021	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at March 31, 2022 and December 31, 2021; 28,469,298 and 28,268,950 shares issued at March 31, 2022 and December 31, 2021, respectively; 28,469,274 and 28,268,926 shares outstanding at March 31, 2022 and December 31, 2021, respectively	28	28
Additional paid-in capital	831,206	830,231
Accumulated deficit	(793,451)	(785,324)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	34,729	41,881
Total liabilities & stockholders' equity	$ 67,108	$ 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 March 31,	
	2022	**2021**
Expenses:		
Research and development	$ 5,345	$ 4,410
General and administrative	2,988	4,669
Total operating expenses	8,333	9,079
Operating loss	(8,333)	(9,079)
Other income (expense):		
Interest income	1	50
Interest expense	(13)	(41)
Other income, net	218	109
Total other income, net	206	118
Net loss	$ (8,127)	$ (8,961)
Net loss per common share		
Basic and diluted	$ (0.29)	$ (0.51)
Weighted average number of common shares outstanding		
Basic and diluted	28,295	17,695

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**

	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**

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (8,127)	$ (8,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	466	45
Stock-based compensation	770	2,443
Non-cash lease expense	174	170
Non-cash expense related to equity consideration for a service agreement	-	494
Unrealized gain on foreign exchange rate changes	(236)	(109)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	239	337
Accounts payable	31	(222)
Accrued expenses	151	(69)
Operating lease liabilities	(183)	(176)
Net cash used in operating activities	(6,715)	(6,048)
Cash flows from investing activities:		
Purchase of property and equipment	(3)	-
Net cash used in investing activities	(3)	-
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	-	27,390
Proceeds from ATM Program, net of issuance costs	205	570
Principal payments on loans payable	(294)	(352)
Net cash (used in) provided by financing activities	(89)	27,608
Net (decrease) increase in cash, cash equivalents, and restricted cash	(6,807)	21,560
Cash, cash equivalents, and restricted cash - beginning of period	22,502	17,084
Cash, cash equivalents, and restricted cash - end of period	$ 15,695	$ 38,644
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 heart failure characterized by very low blood pressure and risk for hypoperfusion to critical organs. We recently completed this Phase 2 global clinical study of istaroxime and, 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. Further details of the study results are planned to be presented at the European Society of Cardiology Heart Failure meeting in late May 2022.

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. KL4 surfactant has been in development as a liquid instillate for noninvasive delivery as an aerosol. In September 2020, the FDA accepted our investigational new drug application for an open-label Phase 2 pilot study to assess safety and tolerability in the COVID-19 acute respiratory distress syndrome, or ARDS, population and the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and ARDS resulting from severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the causative agent in novel coronavirus, or COVID-19, infections. In January 2022, we completed enrollment of 20 patients in our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury. 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 aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome in premature infants. We suspended all internal AEROSURF clinical activities in November 2020, because istaroxime, our lead product candidate, has become our primary focus for investment and execution as we believe development of istaroxime represents a greater value opportunity for us and our stockholders than development of KL4 surfactant. Since completing our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury in January 2022, in order to preserve resources for the highest priority programs, we began to reduce costs 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. 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. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing one or more licensing transactions.

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; through potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, 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, 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 months ended March 31, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. 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 – Liquidity Risks 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 $8.1 million and $9.0 million, respectively, for the three-month periods ended March 31, 2022 and 2021. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2022, we had an accumulated deficit of $793.5 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 three months ended March 31, 2022, we sold 200,348 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.2 million (see, Note 8 – Stockholders' Equity). During April 2022, we sold 936,898 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.1 million and net proceeds of approximately $1.0 million (see, Note 11 – Subsequent Events).

As of March 31, 2022, we had cash and cash equivalents of $15.5 million and current liabilities of $4.8 million. As of May 5, 2022, we believe that we have sufficient resources available to support our development activities and business operations and satisfy our obligations into the first quarter of 2023. 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 and strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next 12 months following the date that the financial statements are issued. Further, if the market price of our common stock should remain below $1.00 for 30 consecutive business days, we would be out of compliance with the requirements for continued listing on Nasdaq and would be subject to potential delisting. If we were then unable to re-achieve compliance with the Nasdaq listing requirements within 180 days after receipt of a delisting notice, 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. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through 12 months after the issuance of the accompanying financial statements.

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 months ended March 31, 2022 and 2021, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired. 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 our share price 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 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock. While this trend began prior to the filing of this Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, we believe that the sale during April 2022 of 936,898 shares of our common stock under the ATM Program at a weighted average price per share of $1.13 corroborated our conclusions that there were no impairment indicators for goodwill as of March 31, 2022. However, if our share price does not improve during the remainder of the second quarter of 2022, our reporting unit may be at risk for future impairment in the near term.

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

(in thousands)	March 31, 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	$ 15,682	$ 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, net. Foreign currency transactions resulted in gains of approximately $0.2 million and $0.1 million for the three-month periods ended March 31, 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 APIs and supportive research for our lyophilized and aerosolized KL4 surfactant, and our medical device development laboratory, which was previously used to conduct development activities and testing for our ADS technologies. 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 is being ratably accrued over the expected service periods of the employees, and is expected to be paid ratably through September 30, 2022. We incurred $0.3 million of expense related to these severance arrangements during the three months ended March 31, 2022, which is included in research and development expense. The related liability as of March 31, 2022 is also $0.3 million and is included as part of 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 2021, 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, resulting in $0.4 million of additional depreciation expense for the three months ended March 31, 2022. The assets are recorded at their estimated salvage value as of March 31, 2022.

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.

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 March 31, 2022 and 2021, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 21.4 million and 19.9 million shares, respectively. For the three months ended March 31, 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. 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 new information that may emerge concerning the severity of the COVID-19 outbreak, 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, which may include, among others, the timing and extent of government reopening activities and the economic impact on local, regional, national, and international markets. 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 March 31, 2022	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 14,104	$ 14,104	$ -	$ -
Total Assets	$ 14,104	$ 14,104	$ -	$ -

(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 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.

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 were due monthly from July 2020 through March 2021. The balance of the loan was repaid during the first quarter of 2021.

Note 7 – Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into the 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 March 31, 2022 and December 31, 2021, the restructured debt liability balance was $15.0 million.

Note 8 – Stockholders' Equity

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.

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 three months ended March 31, 2022, we sold 200,348 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.2 million. For the three months ended March 31, 2021, we sold 105,083 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million. During April 2022, we sold 936,898 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.1 million and net proceeds of approximately $1.0 million (*see*, Note 11 – Subsequent Events).

As of May 5, 2022, approximately $3.7 million remained available under the ATM Program.

Note 9 – Stock-Based Employee 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	835	1.02	
Forfeited or expired	(49)	6.06	
Outstanding at March 31, 2022	4,173	$ 8.04	8.2
Vested and exercisable at March 31, 2022	2,142	$ 12.38	7.1
Vested and expected to vest at March 31, 2022	3,925	$ 8.06	8.2

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2022	-	$ -
Awarded	554	1.02
Outstanding at March 31, 2022	554	$ 1.02
Vested and exercisable at March 31, 2022	-	$ -
Vested and expected to vest at March 31, 2022	554	$ 1.02

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

(in thousands)	Three Months Ended March 31, 2022	2021
Research and development	$ 235	$ 939
General and administrative	535	1,504
Total	$ 770	$ 2,443

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.

	Three Months Ended March 31,	
	2022	2021
Weighted average expected volatility	106%	105%
Weighted average expected term (in years)	6.9	6.6
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 March 31, 2022, the liability balance related to the payments under the PF Agreement was $3.8 million and is recorded in other liabilities.

Note 11 – Subsequent Events

During April 2022, we sold 936,898 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.1 million and net proceeds of approximately $1.0 million

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, 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 shall 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 heart failure characterized by very low blood pressure and risk for hypoperfusion to critical organs. We recently completed this Phase 2 global clinical study of istaroxime and, 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. Further details of the study results are planned to be presented at the European Society of Cardiology Heart Failure meeting in late May 2022. 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. KL4 surfactant has been in development as a liquid instillate for noninvasive delivery as an aerosol. In September 2020, the FDA accepted our investigational new drug application for an open-label Phase 2 pilot study to assess safety and tolerability in the COVID-19 acute respiratory distress syndrome, or ARDS, population and the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and ARDS resulting from severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the causative agent in novel coronavirus, or COVID-19, infections. In January 2022, we completed enrollment of 20 patients in our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury. 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 aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome in premature infants. We suspended all internal AEROSURF clinical activities in November 2020, because istaroxime, our lead product candidate, has become our primary focus for investment and execution as we believe development of istaroxime represents a greater value opportunity for us and our stockholders than development of KL4 surfactant. Since completing our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury in January 2022, in order to preserve resources for the highest priority programs, we began to reduce costs 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. 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. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing one or more licensing transactions.

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; through potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, 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, 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 March 31, 2022 and 2021, we had operating losses of $8.3 million and $9.1 million, respectively. As of March 31, 2022, we had an accumulated deficit of $793.5 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. Further details of the study results are planned to be presented at the European Society of Cardiology Heart Failure meeting in late May 2022. There is a significant unmet medical need in the area of early cardiogenic shock and severe heart failure. If istaroxime is able to demonstrate a meaningful improvement in blood pressure in clinical trials of this condition, 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 approximately 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.

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. We are exploring capital from public and private equity offerings and potential strategic opportunities to fund the initiation of this clinical trial, and plan to initiate the clinical trial after obtaining adequate funding. We plan to closely monitor the impact of the COVID-19 pandemic and its impact on hospital resources and resulting potential changes in regulatory timelines for conducting non-COVID-19-related clinical trials.

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 and/or other strategic partnerships for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement or partnership.

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.

Lyophilized KL4 Surfactant (COVID-19 related Lung Injury)

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 who were intubated and on mechanical ventilation due to severe COVID-19 associated ARDS. Study sites were in the U.S. and Argentina. 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.

AEROSURF (lucinactant for inhalation)

We are supporting Lee's (HK) efforts to plan, fund, and initiate in Asia the Phase 2b bridging study needed to advance AEROSURF to Phase 3 clinical trials. With 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 and are transferring AEROSURF development activities to Lee's (HK) to be implemented under the terms of the Asia License Agreement. Since the 2018 acquisition of CVie Investments Limited and its wholly owned subsidiary CVie Therapeutics Limited, istaroxime has become our primary focus for investment and execution due to what we believe represents a greater potential value opportunity for us and our stockholders. Since completing our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury in January 2022, in order to preserve resources for the highest priority programs, we began to reduce costs 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 APIs and supportive research for our lyophilized and aerosolized KL4 surfactant, and our medical device development laboratory, which was previously used to conduct development activities and testing for our ADS technologies. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing one or more licensing transactions.

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. 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 new information that may emerge concerning the severity of the COVID-19 outbreak, 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, which may include, among others, the timing and extent of government reopening activities and the economic impact on local, regional, national, and international markets. 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 months ended March 31, 2022 and 2021 , no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not 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 our share price 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 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock. While this trend began prior to the filing of this Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, we believe that the sale during April 2022 of 936,898 shares of our common stock under the ATM Program at a weighted average price per share of $1.13 corroborated our conclusions that there were no impairment indicators for goodwill as of March 31, 2022. However, if our share price does not improve during the remainder of the second quarter of 2022, our reporting unit may be at risk for future impairment in the near term.

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

(in thousands)	March 31, 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	$ 15,682	$ 15,682

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended March 31, 2022 and 2021 was $8.3 million and $9.1 million, respectively. The decrease in operating loss from 2021 to 2022 was due to a $0.7 million decrease in operating expenses, which includes a $1.7 million decrease in non-cash stock compensation expense and a $0.5 million decrease in non-cash expense related to equity consideration for a financial advisory service agreement, partially offset by an increase of $0.7 million in expenses related to the clinical trial of istaroxime for early cardiogenic shock and $0.4 million in depreciation expense related to the abandonment of certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform.

The net loss for the three months ended March 31, 2022 and 2021 was $8.1 million and $9.0 million, respectively.

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 expect to increase our investment in research and development in order to advance our product candidates through additional clinical trials. As a result, we expect that our research and development expenses will increase throughout the foreseeable future as we pursue clinical development of istaroxime, and our other current and future product candidates. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates.

Research and development expenses are as follows:

(in thousands)	Three Months Ended March 31, 2022	2021
Istaroxime - early cardiogenic shock	$ 1,200	$ 506
Istaroxime - AHF	545	499
KL4 surfactant	213	244
Total direct clinical and preclinical programs	1,958	1,249
Product development and manufacturing	1,622	1,087
Clinical, medical, and regulatory operations	1,765	2,074
Total research and development expenses	$ 5,345	$ 4,410

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.7 million and $1.0 million, respectively, for the three months ended March 31, 2022 and 2021, respectively.

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 device and drug supply, and related external costs, such as consultant fees and expenses; and (ii) development activities, toxicology studies, and other preclinical studies.

Total direct clinical and preclinical programs expenses increased$0.7 million for the three months ended March 31, 2022 compared to the same period in 2021 due to an increase of $0.7 million for ongoing clinical studies of istaroxime for early cardiogenic shock.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, with our contract manufacturing organization, quality assurance and analytical chemistry capabilities that support the manufacture of our drug products used in research and development activities, and our medical devices, including our ADS, (ii) design and development activities related to our ADS; and (iii) 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 control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses increased $0.5 million for the three months ended March 31, 2022 compared to the same period in 2021 due to $0.4 million in depreciation expense related to the abandonment of certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform. We accelerated depreciation of these assets during the first quarter of 2022, and the assets are recorded at their estimated salvage value as of March 31, 2022.

Clinical, Medical, and Regulatory Operations

Clinical, medical, and regulatory operations include (i) medical, scientific, preclinical and clinical, regulatory, data management, and biostatistics activities in support of our research and development programs; and (ii) medical affairs activities to provide scientific and medical education support for our KL4 surfactant. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Clinical, medical, and regulatory operations expenses decreased $0.3 million for the three months ended March 31, 2022 compared to the same period in 2021 due to a decrease of $0.5 million in non-cash, stock compensation expense, partially offset by an increase of $0.2 million in employee-related incentive bonus expense.

General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2022	2021
General and administrative expenses	$ 2,988	$ 4,669

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 $1.7 million for the three months ended March 31, 2022 compared to the same period in 2021 due to (i) a decrease of $1.0 million in non-cash, stock compensation expense and (ii) a decrease of $0.9 million in professional fees, partially offset by (iii) an increase of $0.2 million in personnel costs.

Other Income, Net

(in thousands)	Three Months Ended March 31, 2022	2021
Interest income	1	50
Interest expense	(13)	(41)
Other income, net	218	109
Total other income, net	$ 206	$ 118

Interest income relates to interest on our money market account for the three months ended March 31, 2022 and 2021, and relates to interest on our U.S. Treasury notes for the three months ended March 31, 2021.

For the three months ended March 31, 2022 and 2021, interest expense consists of interest expense associated with loans payable.

For the three months ended March 31, 2022, other income, net primarily consists of $0.2 million and $0.1 million, respectively, in gains 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 $8.1 million and $9.0 million, respectively, for the three-month periods ended March 31, 2022 and 2021. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2022, we had an accumulated deficit of $793.5 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 three months ended March 31, 2022, we sold 200,348 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.2 million (see, Note 8 – Stockholders' Equity). During April 2022, we sold 936,898 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.1 million and net proceeds of approximately $1.0 million (see, Note 11 – Subsequent Events).

As of March 31, 2022, we had cash and cash equivalents of $15.5 million and current liabilities of $4.8 million. As of May 5, 2022, we believe that we have sufficient resources available to support our development activities and business operations and satisfy our obligations into the first quarter of 2023. 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 and strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next 12 months following the date that the financial statements are issued. Further, if the market price of our common stock should remain below $1.00 for 30 consecutive business days, we would be out of compliance with the requirements for continued listing on the Nasdaq Capital Market, or Nasdaq, and would be subject to potential delisting. If we were then unable to re-achieve compliance with the Nasdaq listing requirements within 180 days after receipt of a delisting notice, 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. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through 12 months after the issuance of the accompanying financial statements.

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 three months ended March 31, 2022 primarily consist of $6.7 million of net cash used in operating activities and $0.1 million of net cash used in financing activities. Cash flows for the three months ended March 31, 2021 consist of $6.0 million of net cash used in operating activities and $27.6 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $6.7 million for the three months ended March 31, 2022 and consisted primarily of (i) a net loss of $8.1 million, and (ii) an unrealized gain on foreign exchange rate changes of $0.2 million, partially offset by (iii) non-cash stock-based compensation of $0.8 million, (iv) depreciation and amortization of $0.5 million, (v) changes in operating assets and liabilities of $0.2 million, and (vi) non-cash lease expense of $0.2 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 $6.0 million for the three months ended March 31, 2021 and consisted primarily of (i) a net loss of $9.0 million and (ii) changes in operating assets and liabilities of $0.1 million, and (iii) an unrealized gain on foreign exchange rate changes of $0.1 million, partially offset by (iv) non-cash stock-based compensation of $2.4 million, (v) non-cash expense related to equity consideration for a financial advisory service agreement of $0.5 million, and (vi) non-cash lease expense of $0.2 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2022 was $0.1 million and includes the following: $0.3 million of principal payments on loans payable, partially offset by $0.2 million in net proceeds from the ATM Program.

Net cash provided by financing activities for the three months ended March 31, 2021 was $27.6 million and includes the following: (i) $27.4 million in net proceeds from the March 2021 public offering, (ii) $0.6 million in net proceeds from the ATM Program, partially offset by (iii) $0.4 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 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.

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 were due monthly from July 2020 through March 2021. The balance of the loan was repaid during the first quarter of 2021.

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 three months ended March 31, 2022, we sold 200,348 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.2 million. For the three months ended March 31, 2021, we sold 105,083 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). During April 2022, we sold 936,898 shares of our common stock under the ATM Program resulting in aggregate gross proceeds to us of approximately $1.1 million and net proceeds of approximately $1.0 million (*see*, Note 11 – Subsequent Events).

As of May 5, 2022, approximately $3.7 million remained available under the ATM Program.

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 March 31, 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 March 31, 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. 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. 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, or Nasdaq. 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 Nasdaq.

In May 2020, we successfully listed our common stock on Nasdaq. However, we can give no assurance that we will be able to satisfy the continued listing requirements of Nasdaq in the future, including maintaining a minimum closing bid price of $1.00 per share. Since April 21, 2022, the closing price of our common stock has been below $1.00. If the closing bid price of our common stock is below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from Nasdaq advising us that we have a certain period of time, typically 180 days, to regain compliance by maintaining a minimum closing bid price of at least $1.00 for at least ten consecutive business days, although Nasdaq could require a longer period. If we fail to maintain compliance with the minimum closing bid price requirement, or any other of the continued listing requirements of Nasdaq, the exchange 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 March 31, 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 March 31, 2022, goodwill recorded on our condensed consolidated balance sheets was $15.7 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 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. If our share price does not improve during the remainder of the second quarter of 2022, our reporting unit may be at risk for future impairment in the near term. Should such an impairment of goodwill occur, which would require us to record a potentially significant impairment charge, our financial condition and results of operations in a future period could be negatively impacted.

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
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 March 31, 2022, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of March 31, 2022 (unaudited) and December 31, 2021, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2022 and March 31, 2021, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2022 and March 31, 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: May 5, 2022

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

Date: May 5, 2022

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

Exhibit 31.1

CERTIFICATION

I, Craig E. Fraser, certify that:

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial 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: May 5, 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: May 5, 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 March 31, 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: May 5, 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.