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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, 2020

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	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976-3622
(Address of principal executive offices)

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered

Securities registered pursuant to Section 12(g) 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 OTCQB® 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 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 13, 2020, there were outstanding 13,697,395 shares of the registrant's common stock, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

PART II - OTHER 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 and Section 21E of the Securities Exchange Act of 1934, as amended. The 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;
- delays in our anticipated clinical timelines and milestones associated with COVID-19;
- the results, cost and timing 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 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 ability to successfully execute development activities and commercialize our product candidates;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices and other materials we need;
- the size and growth of the potential markets for our product candidates, 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, including changes to the Patient Protection and Affordable Care Act;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties upon which we depend, including third-party contract research organizations, contract manufacturing organizations, contractor laboratories and independent contractors;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers; and
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyberattacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption.

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 report 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.

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

ITEM 1. FINANCIAL STATEMENTS

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(in thousands, except share data)

	March 31, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 16,799	$ 22,578
Prepaid expenses and other current assets	1,299	1,283
Total current assets	18,098	23,861
Property and equipment, net	756	798
Restricted cash	154	154
Operating lease right-of-use assets	1,213	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 112,993	$ 118,975
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,401	$ 1,708
Collaboration and device development payable, net	1,867	1,972
Accrued expenses	2,971	3,226
Operating lease liabilities - current portion	700	750
Loans payable - current portion	-	161
Total current liabilities	6,939	7,817
Operating lease liabilities - non-current portion	654	794
Loans payable - non-current portion	4,551	4,608
Restructured debt liability - contingent milestone payments	15,000	15,000
Deferred tax liabilities	15,759	15,821
Total liabilities	42,903	44,040
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at March 31, 2020 and December 31, 2019; 13,697,419 shares issued at March 31, 2020 and December 31, 2019; 13,697,395 shares outstanding at March 31, 2020 and December 31, 2019	14	14
Additional paid-in capital	764,786	763,097
Accumulated deficit	(691,656)	(685,122)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	70,090	74,935
Total liabilities & stockholders' equity	$ 112,993	$ 118,975

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,	
	2020	**2019**
Revenues:		
License revenue with affiliate	$ -	$ 40
Total revenues	-	40
Expenses:		
Research and development	3,461	3,342
General and administrative	3,242	3,355
Total operating expenses	6,703	6,697
Operating loss	(6,703)	(6,657)
Other income / (expense):		
Interest income	89	60
Interest expense	(44)	(136)
Other income, net	124	196
Other income / (expense), net	169	120
Net loss	$ (6,534)	$ (6,537)
Net loss per common share		
Basic and diluted	$ (0.48)	$ (0.61)
Weighted average number of common shares outstanding		
Basic and diluted	13,697	10,714

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended March 31,	
	2020	**2019**
Net loss	$ (6,534)	$ (6,537)
Other comprehensive income:		
Unrealized gain on marketable securities	-	40
Comprehensive loss	$ (6,534)	$ (6,497)

See notes to condensed consolidated financial statements

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

(in thousands)

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2018	**-**	**$ -**	**10,711**	**$ 11**	**$ 728,804**	**$ (657,647)**	**$ -**	**-**	**$ (3,054)**	**$ 68,114**
Net Loss						(6,537)				(6,537)
Vesting of restricted stock units			18							-
Withholding tax payments related to net share settlements of restricted stock units					(151)					(151)
Stock-based compensation expense					1,530					1,530
Unrealized gain on marketable securities							40			40
Balance - March 31, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 730,183**	**$ (664,184)**	**$ 40**	**-**	**$ (3,054)**	**$ 62,996**

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2019	**-**	**$ -**	**13,697**	**$ 14**	**$ 763,097**	**$ (685,122)**	**$ -**	**-**	**$ (3,054)**	**$ 74,935**
Net Loss						(6,534)				(6,534)
Stock-based compensation expense					1,689					1,689
Balance - March 31, 2020	**-**	**$ -**	**13,697**	**$ 14**	**$ 764,786**	**$ (691,656)**	**$ -**	**-**	**$ (3,054)**	**$ 70,090**

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (6,534)	$ (6,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	-	(40)
Depreciation	42	50
Amortization of debt discount	3	55
Stock-based compensation	1,689	1,530
Non-cash lease expense	177	192
Realized gain on investments	-	(11)
Changes in:		
Prepaid expenses and other current assets	(16)	5
Accounts payable	(307)	(2,003)
Collaboration and device development payable	(108)	(692)
Accrued expenses	(238)	(1,118)
Operating lease liabilities	(190)	(214)
Other liabilities	-	24
Net cash used in operating activities	(5,482)	(8,759)
Cash flows from investing activities:		
Purchase of property and equipment	-	(74)
Proceeds from sale of marketable securities	-	499
Net cash provided by investing activities	-	425
Cash flows from financing activities:		
Principle payments on loans payable	(199)	(447)
Payment for taxes related to net share settlements of restricted stock units	-	(151)
Net cash used in financing activities	(199)	(598)
Effect of exchange rate changes on cash and cash equivalents	(98)	(202)
Net decrease in cash and cash equivalents	(5,779)	(9,134)
Cash, cash equivalents and restricted cash - beginning of period	22,732	11,358
Cash, cash equivalents and restricted cash - end of period	$ 16,953	$ 2,224

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 and medical device 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 in the treatment of acute cardiovascular and pulmonary diseases. Our lead cardiovascular product candidate, istaroxime, a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, and cardiogenic shock with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in diastolic and systolic function in phase 2 clinical trials and has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Our lead pulmonary product candidate is AEROSURF (lucinactant for inhalation), a novel drug/medical device combination for non-invasive delivery of our proprietary aerosolized KL4 surfactant, using our proprietary Aerosol Delivery System, or ADS, technology for the treatment of respiratory distress syndrome, or RDS, in premature infants. AEROSURF has been granted Fast Track designation by the FDA for the treatment of RDS. We are also developing plans to study our proprietary KL4 surfactant for treatment of lung injury resulting from severe novel coronavirus, or COVID-19, infections, if we are able to secure the required additional capital resources necessary to initiate and complete the study. Our other drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension, in patients with a specific genetic profile. We also have a number of pipeline preclinical product candidates that we are evaluating for progression into clinical development. We are pursuing a number of early exploratory research programs to identify potential product candidates, including oral and intravenous SERCA 2a heart failure compounds and other product candidates utilizing our KL4 surfactant and ADS technologies.

In December 2018, we acquired CVie Investments Limited, or CVie Investments, an exempted company with limited liability incorporated under the laws of the Cayman Islands, which we refer to herein as the CVie Acquisition. Since the CVie Acquisition, we have operated CVie Investments, and its wholly-owned subsidiary, CVie Therapeutics, a Taiwan corporation organized under the laws of the People's Republic of China, as a subsidiary focused on the development of drug product candidates for cardiovascular diseases.

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, 2019 that we filed with the Securities and Exchange Commission (SEC) on April 3, 2020, 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

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, 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. When necessary, prior year's condensed consolidated financial statements have been reclassified to conform to the current year presentation. Operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. There have been no changes to our significant accounting policies since December 31, 2019. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2019 contained in our Annual Report on Form 10-K for the year ended December 31, 2019.

The interim unaudited condensed consolidated financial statements reflect the 1-for-3 reverse split of our common stock that was approved by our Board of Directors and controlling stockholders and made effective on April 29, 2020. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

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 reliance on third party manufacturers.

We have incurred net losses since inception. Our net loss was $6.5 million for each of the three-month periods ended March 31, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2020, we had an accumulated deficit of $691.7 million. Our future success is dependent on our ability to identify 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.

In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities and, other than the funding recently committed by Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), as discussed below, they are not considered probable. In the absence of such funding, we plan to strategically manage our uncommitted spend to execute our priorities and implement cost saving measures to reduce research and development expenditures which would include limiting or delaying or terminating preclinical and clinical studies or other development activities for our AEROSURF product candidates.

We recently entered into a binding commitment with Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF beginning April 1, 2020 through September 30, 2020. We are in the process of negotiating a definitive agreement with Lee's (HK) to set forth additional funding beyond September 30, 2020 through study completion. If we are unsuccessful at finalizing a definitive agreement with Lee's (HK) or if we are successful but Lee's (HK) subsequently terminates the agreement beyond September 30, 2020, our Board of Directors has approved a plan to suspend or terminate AEROSURF development until such time as we are able to secure the capital required to fund the program.

Management considers the successful implementation of these plans and efforts to manage uncommitted spending, including AEROSURF development, and to carry out necessary cost saving measures to be probable. Therefore, we expect our plans will enable our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the three months ended March 31, 2020 to be sufficient to fund operations through at least the next twelve months.

Our funding requirements, however, are based on estimates that are subject to risks and uncertainties and may change as a result of many factors currently unknown. Although management continues to pursue the plans described above, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, including as a result of market volatility following the COVID-19 pandemic. Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, strategic partnerships and licensing arrangements. The terms of any future financing may adversely affect the holdings or the rights of our existing stockholders.

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, 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. The following table represents identifiable intangible assets as of March 31, 2020 and December 31, 2019:

(in thousands)		Carrying Value
Istaroxime drug candidate	$	22,340
Rostafuroxin drug candidate		54,750
Total	$	77,090

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 its carrying value may be impaired.

Foreign Currency Transactions

The functional currency for our foreign subsidiaries is US Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income (expense). Foreign currency transactions resulted in gains of approximately $0.2 million for each of the three-month periods ended March 31, 2020 and 2019.

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 at the date of the financial statements and the reported amounts of revenues and 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.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (see, - Note 8 - 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 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 account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical development programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities 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*.

Net Loss per Common Share

Basic net loss per 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, 2020 and 2019, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 6.5 million and 5.1 million shares, respectively. For the three months ended March 31, 2020 and 2019, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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.

COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. As of the date of issuance of these interim unaudited condensed consolidated financial statements, our operations, capital and financial resources and overall liquidity position and outlook have not been significantly impacted by COVID-19. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials. We believe there could be an impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials.

We are not aware of any specific event or circumstance that would require us to 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. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

Recently Issued Accounting Standards

Recently Adopted Accounting Standards

In August 2018, the FASB issued Accounting Standards Update, or ASU, 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13, which removes, adds and modifies certain disclosure requirements for fair value measurements in Topic 820. Companies will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy as well as the valuation processes of Level 3 fair value measurements. However, companies will be required to additionally disclose the changes in unrealized gains and losses included in other comprehensive income for recurring Level 3 fair value measurements and the range and weighted average of assumptions used to develop significant unobservable inputs for Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments relating to additional disclosure requirements will be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments will be applied retrospectively to all periods presented upon their effective date. We adopted ASU 2018-13 during the quarter ended March 31, 2020 and the adoption did not have an impact on our financial statement disclosures.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 simplifies the accounting for income taxes by removing exceptions within the general principles of Topic 740 regarding the calculation of deferred tax liabilities, the incremental approach for intra-period tax allocation, and calculating income taxes in an interim period. In addition, the ASU adds clarifications to the accounting for franchise tax (or similar tax). which is partially based on income, evaluating tax basis of goodwill recognized from a business combination, and reflecting the effect of any enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The ASU is effective for fiscal years beginning after December 15, 2020 and will be applied either retrospectively or prospectively based upon the applicable amendments. Early adoption is permitted. We are still evaluating the impact this standard will have on our consolidated financial statements and related disclosures, but do not believe there will be a material impact upon adoption.

Note 5 – Fair Value of Financial Instruments

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 and liabilities measured at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value March 31, 2020	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 15,596	$ 15,596	-	-
Total Assets	$ 15,596	$ 15,596	$ -	$ -

(in thousands)	Fair Value December 31, 2019	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 1,819	$ 1,819	$ -	$ -
U.S. Treasury notes	18,230	18,230	-	-
Total Assets	$ 20,049	$ 20,049	$ -	$ -

Note 6 – Collaboration and Device Development Payable

Restructuring of the Battelle Payables

In March 2020, we entered into the first amendment to the December 2018 payment restructuring agreement, or the Amendment, with Battelle Memorial Institute, or Battelle, in which we agreed to amend the payment terms of two milestone payments previously due no later than January 2020. Under the Amendment, we agreed that (i) the first milestone payment would continue to be due upon enrollment of the first patient in the next AEROSURF clinical study but no later than April 15, 2020; and, (ii) the second milestone payment would continue to be due upon completion of technology transfer of our device manufacturing process for the phase 3 ADS to our new medical device manufacturer but no later than September 1, 2020. The Amendment is treated as a debt modification and, in accordance with debt modification accounting, no gain or loss was recognized.

In April 2020, we made the first milestone payment of $0.8 million to Battelle and announced enrollment of the first patient into the AEROSURF phase 2 bridging study.

Note 7 – Loans Payable

Loans Payable – Current Portion

Loan payable to Bank Direct Capital Finance

In May 2019, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we have financed $0.7 million of certain premiums at a 5.35% annual interest rate. As of December 31, 2019, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the quarter ended March 31, 2020.

Loans Payable – Non-current Portion

Assumption of bank debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $4.5 million in a bank credit facility.

In September 2016, CVie Therapeutics Limited entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd., or O-Bank, to finance operating activities, or the O-Bank Facility. The O-Bank Facility was later renewed and increased to approximately $5.8 million in September 2017. The O-Bank Facility was guaranteed by Lee's Pharmaceutical Holdings Limited, or Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. The guaranty was part of the O-Bank Facility; however, we do not have a written commitment from Lee's to maintain the collateral. Interest, payable in cash on a monthly basis, is determined based on the 90-day Taipei Interbank Offer Rate, or TAIBOR, plus 0.91%. The O-Bank Facility expired on September 11, 2019 and the loans were set to mature six months after the expiration date, on March 11, 2020. In March 2020, the O-Bank Facility was amended, among other things, to extend the maturity date to March 2022, to decrease the total amount of the O-Bank Facility to approximately $5.0 million, to change the applicable interest rate to the TAIBOR plus 1.17% and to adjust the term to 24-month non-revolving. All amounts due under the O-Bank Facility will be payable upon the earlier of (i) six months after the expiration date or (ii) two years after the drawdown date.

As of March 31, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $4.6 million.

Note 8 – Restructured Debt Liability

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P., or 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 5 - Accounting Policies and Recent Accounting Pronouncements). 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, 2020 and December 31, 2019, the restructured debt liability balance was $15.0 million.

Note 9 – Stock Options and Stock-Based Employee Compensation

We recognize in our condensed consolidated financial statements all stock-based awards to employees and non-employee directors based on their fair value on the date of grant, calculated using the Black-Scholes option-pricing model. Compensation expense related to stock-based awards is recognized ratably over the vesting period, which for employees is typically three years. We recognize restricted stock unit awards to employees and non-employee directors based on their fair value on the date of grant. Compensation expense related to restricted stock unit awards is recognized ratably over the vesting period, which typically has been between approximately six to 18 months.

A summary of activity under our long-term incentive plan 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, 2020	1,772	$	17.61	
Forfeited or expired	(7)		65.17	
Outstanding at March 31, 2020	1,765	$	17.40	8.7
Vested and exercisable at March 31, 2020	599	$	26.66	8.7
Vested and expected to vest at March 31, 2020	1,696	$	17.37	8.8

There was no activity during the quarter with respect to restricted stock units.

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, 2020	2019
Research and development	$ 714	$ 489
General and administrative	975	1,041
Total	$ 1,689	$ 1,530

Note 10 – Collaboration, Licensing and Research Funding Agreements

On March 18, 2020, we entered into a binding term sheet, or the Term Sheet, with Lee's (HK), pursuant to which the parties agreed that Lee's (HK) would provide financing for the continued development of our product candidate, AEROSURF. The Term Sheet provides that in connection with the development of AEROSURF, Lee's (HK) will make non-refundable payments to us in the amount of (i) $1.0 million no later than April 1, 2020; (ii) $1.4 million no later than July 1, 2020; and (iii) $1.5 million no later than September 1, 2020; provided, however, that the amount of the last payment will be reduced to $0.4 million if on or prior to August 31, 2020, (i) we receive net proceeds from the sale of our equity securities of at least $4.5 million and (ii) our common stock becomes listed on the Nasdaq Capital Market. The parties have agreed that they will negotiate in good faith to determine the terms of a definitive agreement prior to September 30, 2020. The definitive agreement will set forth additional semi-annual, non-refundable payments to fund the continued development of AEROSURF after September 30, 2020. In April 2020, we received the first $1.0 million non-refundable payment.

The Term Sheet provides that, 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 License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the License Agreement, and subject to reduction for any payments made by us with respect to third-party intellectual property not previously funded by Lee's (HK).

The Term Sheet also provides that we and Lee's (HK) will amend existing provisions of the License Agreement to reduce future royalty payments payable to us from Lee's (HK) on net sales of certain licensed products, reducing the range of such royalty payment percentage from a range of high single to low mid-double digits to a range of mid-single to low-double digits.

We have determined that the Term Sheet is within the scope of ASC 730-20, *Research and Development Arrangements*, or ASC 730-20. We concluded that there has not been a substantive and genuine transfer of risk related to the Term Sheet as there is a presumption that we are obligated to repay Lee's (HK) based on the significant related party relationship that exists at the time the parties entered into the Term Sheet, including Lee's (HK)'s approximate 35% ownership of the outstanding shares of our common stock.

We have determined that the appropriate accounting treatment under ASC 730-20 is to record the proceeds received from Lee's (HK) as cash and cash equivalents, as we have the ability to direct the usage of funds, and a long-term liability on our condensed consolidated balance sheet when received. The liability will remain on the balance sheet until we repay such amounts as a result of any revenues and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, as defined in the Term Sheet, or through the reduction of future milestone payments or royalties payable by Lee's (HK) to us under the existing License Agreement, as amended by the Term Sheet.

We have also determined that the Term Sheet is not in its entirety a derivative under the scope of ASC 815, *Derivatives and Hedging*, or ASC 815, due to the scope exception under ASC 815-10-15-59, nor are there any embedded derivatives that require separate accounting.

Note 11 – Subsequent Events

Series F Warrant Amendment

On April 24, 2020, we and each of the holders of our Series F Warrants, or the Series F Warrants, entered into Amendment No. 1 to the Series F Warrants whereby the expiration date of the Series F Warrants was extended from June 24, 2020 to December 24, 2020 in consideration for the holders agreeing to be bound by a lock-up provision with respect to any shares of common stock or securities convertible, exchangeable or exercisable into shares of common stock that are beneficially owned, held or acquired by the holders. The lock-up provision provides that the holders will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of our securities for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020.

Series I Warrant Amendment

On May 6, 2020, we and certain holders of our Series I Warrants, or the Series I Warrants, entered into Amendment No. 1 to the Series I Warrants pursuant to which the exercise price of the Series I Warrants was amended from $12.09 to $9.67 if the Series I Warrants are exercised, in whole or in part, prior to December 5, 2021. In addition, the certain holders of the Series I Warrants agreed to be bound by a lockup provision with respect to any shares of our common stock or securities convertible, exchangeable or exercisable into shares of common stock that are beneficially owned, held or acquired by such holders for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020. During the lock-up period, the certain holders of the Series I Warrants will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock.

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 Forward-Looking Statements section, any risk factors discussed in the "Risk Factors" Section and 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, 2019 that we filed with the Securities and Exchange Commission, or SEC, on April 3, 2020, 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, 2019. 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 and medical device 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 in the treatment of acute cardiovascular and pulmonary diseases. Our lead cardiovascular product candidate istaroxime, a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, and cardiogenic shock with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in diastolic and systolic function in phase 2 clinical trials and has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Our lead pulmonary product candidate is AEROSURF (lucinactant for inhalation), a novel drug/medical device combination for non-invasive delivery of our proprietary aerosolized KL4 surfactant, using our proprietary aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome, or RDS, in premature infants. AEROSURF has been granted Fast Track designation by the FDA for the treatment of RDS. We are also developing plans to study our proprietary KL4 surfactant for the treatment of lung injury resulting from severe novel coronavirus, or COVID-19, infection if we are able to secure the required additional capital resources necessary to initiate and complete the study. Our other drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile. We also have a number of pipeline preclinical product candidates that we are evaluating for progression into clinical development. We are pursuing a number of early exploratory research programs to identify potential product candidates, including oral and intravenous SERCA 2a heart failure compounds and other product candidates utilizing our KL4 surfactant and ADS technologies.

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, 2019 that we filed with the SEC on April 3, 2020, 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 (AHF)

In April 2020, we announced the presentation at the American College of Cardiology 2020 virtual meeting of a new subset analysis from a phase 2b study of istaroxime in patients hospitalized with AHF. We previously presented the overall results of the study where the primary endpoint demonstrated a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses. This post-hoc analysis characterized the responses between Caucasian and Asian patients. The istaroxime dose of 0.5 µg/kg/min produced a similar response on E/e', the primary study endpoint, and stroke volume index, an important measure of cardiac performance, in Asian and Caucasian patients.

AEROSURF (lucinactant for inhalation)

In April 2020, as part of the phase 2 clinical program, we enrolled the first patient and commenced our small, approximately 90-patient, phase 2b bridging study in premature infants with RDS and prepare to transition to our phase 3 clinical program by demonstrating the performance of our new ADS, in the neonatal intensive care unit, or NICU, as well as a more intensive dosing regimen. This trial will not be powered to establish statistical significance but will generate clinical experience with the ADS as well as additional higher dose treatment data to augment data previously obtained in the phase 2b clinical trial. The AEROSURF phase 2b bridging study is a multicenter, randomized, controlled study with masked treatment assignment in up to 90 premature infants 26 to 32 weeks gestational age, or GA, receiving nasal continuous airway pressure, or nCPAP, for RDS. The trial will leverage the favorable safety profile from the previous phase 2 studies to evaluate higher and more frequent dosing of aerosolized KL4 surfactant compared to premature infants receiving standard care of nCPAP alone. The trial will utilize the new ADS technology and bridge to data generated in the phase 2 program utilizing a prototype device on the following endpoints: time to nCPAP failure (the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. Due to the recent global outbreak of COVID-19, our phase 2b bridging study may be impacted and we may experience delays in anticipated timelines and milestones. See "*Part II – Other Information — Item 1A. Risk Factors — Risks Related to our Business and Operations — The recent outbreak of COVID-19 may negatively impact our ability to develop our product candidates*."

Lyophilized KL4 Surfactant – Lung Injury and Other Studies

We are developing plans to study our proprietary KL4 surfactant for the treatment of lung injury resulting from severe COVID-19 infection, if we are able to secure the required additional capital resources necessary to initiate and complete the study as existing cash resources will not be used to conduct this work. We plan to file an investigational new drug, or IND, application with the FDA in May 2020 for an initial pilot clinical trial to assess the ability of our proprietary KL4 surfactant to impact key respiratory parameters in ventilated COVID-19 patients with a targeted start date by mid-year 2020. We recently applied to Biomedical Advanced Research and Development Authority, or BARDA, requesting funding for our development plans of KL4 surfactant in COVID-19 patients and we were granted a meeting to review our proposal with BARDA representatives. In addition, we continue to pursue multiple COVID-19 study funding opportunities with other government and private foundations as well as potential collaboration arrangements with leading academic institutions. Due to the recent global outbreak of COVID-19 our plans for an initial pilot clinical trial may be impacted and we may experience delays in anticipated timelines and milestones. See "*Part II – Other Information — Item 1A. Risk Factors — Risks Related to our Business and Operations — The recent outbreak of COVID-19 may negatively impact our ability to develop our product candidates*."

Reverse Stock Split

On April 28, 2020, we filed an amendment to our Amended and Restated Certificate of Incorporation, to implement a 1-for-3 reverse split stock of our issued and outstanding common stock. The reverse stock split of our outstanding common stock was effected at a ratio of one-for-three as of 12:01 a.m. Eastern Time on April 29, 2020. The reverse stock split correspondingly adjusted, the per share exercise price and the number of shares issuable upon the exercise of all outstanding options and the per share exercise price of all outstanding options and all shares underlying any of our outstanding warrants by reducing the conversion ratio for each outstanding warrant and increasing the applicable exercise price or conversion price in accordance with the terms of each outstanding warrant and based on the reverse stock split ratio. After giving effect to the reverse split, if any stockholder beneficially owned a fractional share of common stock, such stockholder received in lieu of the fractional share a prorated cash payment. The number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation is unchanged at 120 million shares. The accompanying interim unaudited condensed consolidated financial statements reflect the 1-for-3 reverse split of our common stock. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Impact of COVID-19

The COVID-19 pandemic continues to evolve and we are closely monitoring the situation, including its potential impact on our clinical development plans and timelines. As of the date of the filing of this Quarterly Report on Form 10-Q, our operations, capital and financial resources and overall liquidity position and outlook have not been significantly impacted by COVID-19. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials. We believe there could be an impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials.

Payroll Protection Program Loan

On April 9, 2020, we applied to Newtek Small Business Finance, LLC, or the Lender, under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020, or the CARES Act, for a loan of $0.5 million, or the PPP Loan. On April 20, 2020, we entered into a promissory note in favor of the Lender. We planned to use the loan proceeds for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. On April 30, 2020, we announced that we are repaying the PPP Loan.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2019. For a discussion of our accounting policies, *see*, Note 4 – Summary of Significant Accounting Policies and, in the Notes to Consolidated Financial Statements (Notes) in our Annual Report on Form 10-K for the year ended December 31, 2019, Note 5 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss was $6.7 million for each of the three months ended March 31, 2020 and 2019. The net loss was $6.5 million for each of the three months ended March 31, 2020 and 2019.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we account for such costs by category rather than by project. As many of our research and development activities likely form the foundation for the potential development of multiple product candidates, including istaroxime, our KL4 surfactant and drug delivery technologies, and rostafuroxin, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) product development and manufacturing, (b) clinical, medical and regulatory operations, and (c) direct preclinical and clinical development programs. We also account for research and development and report annually by major expense category as follows: (i) salaries and benefits, (ii) contracted services, (iii) raw materials, aerosol devices and supplies, (iv) rents and utilities, (v) depreciation, (vi) contract manufacturing, (vii) travel, (viii) stock-based compensation and (ix) other.

Research and development expenses by category are as follows:

(in thousands)	Three Months Ended March 31, 2020	2019
Product development and manufacturing	$ 1,064	$ 993
Clinical, medical and regulatory operations	1,718	1,688
Direct preclinical and clinical programs	679	661
Total research and development expenses	$ 3,461	$ 3,342

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.7 million and $0.5 million for the three months ended March 31, 2020 and 2019, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with contract manufacturing organizations, or CMOs, validation activities, 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 for use in our AEROSURF clinical development program; and (iii) pharmaceutical and manufacturing development activities of our drug product candidates including development of istaroxime, lyophilized KL4 surfactant, and rostafuroxin. 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 were comparable for the three months ended March 31, 2020 and 2019.

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 and aerosol delivery systems under development. 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 were comparable for the three months ended March 31, 2020 and 2019.

Direct Preclinical and Clinical Development Programs

Direct preclinical and clinical development programs include: (i) development activities, toxicology studies and other preclinical studies; and (ii) 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.

Direct preclinical and clinical development programs expenses were comparable for the three months ended March 31, 2020 and 2019 and relate to costs associated with continued clinical development of istaroxime and AEROSURF and preclinical activities related to potential follow-on product candidates in acute heart failure.

General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2020	2019
General and administrative expenses	$ 3,242	$ 3,355

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

General and administrative expenses decreased $0.1 million for the three months ended March 31, 2020 compared to the same period in 2019 due to a $0.5 million increase in professional fees partially offset by (i) a $0.2 million decrease in employee-related incentive bonus accruals; (ii) a $0.1 million decrease in franchise taxes; and (iii) a $0.1 million decrease in personnel costs.

Other Income and (Expense)

(in thousands)	Three Months Ended March 31, 2020	2019
Interest income	89	60
Interest expense	(44)	(136)
Other income, net	124	196
Other income, net	$ 169	$ 120

Interest income relates to interest on our U.S. Treasury notes.

For the three months ended March 31, 2020 and 2019, interest expense consists of interest expense associated with the collaboration and device development payables and with the loans payable. The $0.1 million decrease in interest expense is related to the repayment of $2.1 million in loans payable during the year ended December 31, 2019.

For the three months ended March 31, 2020 and 2019, other income primarily consists of $0.2 million in gains on foreign currency translation, partially offset by $38,000 in realized losses on U.S. Treasury notes for the three months ended March 31, 2020.

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 reliance on third party manufacturers.

We have incurred net losses since inception. Our net loss was $6.5 million for each of the three-month periods ended March 31, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2020, we had an accumulated deficit of $691.7 million. Our future success is dependent on our ability to identify 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.

In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities and, other than the funding recently committed by Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), as discussed below, they are not considered probable. In the absence of such funding, we plan to strategically manage our uncommitted spend to execute our priorities and implement cost saving measures to reduce research and development expenditures which would include limiting or delaying or terminating preclinical and clinical studies or other development activities for our AEROSURF product candidates.

We recently entered into a binding commitment with Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF beginning April 1, 2020 through September 30, 2020. We are in the process of negotiating a definitive agreement with Lee's (HK) to set forth additional funding beyond September 30, 2020 through study completion. If we are unsuccessful at finalizing a definitive agreement with Lee's (HK) or if we are successful but Lee's (HK) subsequently terminates the agreement beyond September 30, 2020, our board of directors has approved a plan to suspend or terminate AEROSURF development until such time as we are able to secure the capital required to fund the program.

Management considers the successful implementation of these plans and efforts to manage uncommitted spending, including AEROSURF development, and to carry out necessary cost saving measures to be probable. Therefore, we expect our plans will enable our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the three months ended March 31, 2020 to be sufficient to fund operations through at least the next twelve months.

Our funding requirements, however, are based on estimates that are subject to risks and uncertainties and may change as a result of many factors currently unknown. Although management continues to pursue the plans described above, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, including as a result of market volatility following the COVID-19 pandemic. Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, strategic partnerships and licensing arrangements. The terms of any future financing may adversely affect the holdings or the rights of our existing stockholders.

Cash Flows

Cash outflows for the three months ended March 31, 2020, consist of $5.5 million used for ongoing operating activities and $0.2 million used for financing activities.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2020 and 2019 was $5.5 million and $8.8 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The decrease in net cash used in operating activities from 2019 to 2020 is due to costs related to the acquisition of CVie Investments Limited, or the CVie Acquisition, costs from the December 2018 private placement financing and the payment of pre-existing obligations with the proceeds of the December 2018 private placement financing during the three months ended March 31, 2019.

Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2019 represents $0.5 million related to the sale of marketable securities, partially offset by $0.1 million in purchase of property and equipment.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2020 was $0.2 million and represents principal payments on loans payable – current portion. Net cash used in financing activities for the three months ended March 31, 2019 was $0.6 million and represents $0.4 million in principal payments on our loans payable – current portion and $0.1 million related to withholding tax payments for net share settlements of restricted stock units.

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

Loans Payable – Current Portion

Loan payable to Bank Direct Capital Finance

In May 2019, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we have financed $0.7 million of certain premiums at a 5.35% annual interest rate. As of December 31, 2019, the outstanding principal of the loan was $0.2 million. The remaining payments were made during the first quarter of 2020.

Loans Payable – Non-current Portion

Assumption of bank debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $4.5 million in a bank credit facility.

In September 2016, CVie Therapeutics Limited entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd., or O-Bank, to finance operating activities, or the O-Bank Facility. The O-Bank Facility was later renewed and increased to approximately $5.8 million in September 2017. The O-Bank Facility was guaranteed by Lee's Pharmaceutical Holdings Limited, or Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. The guaranty was part of the O-Bank Facility; however, we do not have a written commitment from Lee's to maintain the collateral. Interest, payable in cash on a monthly basis, is determined based on the 90-day Taipei Interbank Offer Rate, or TAIBOR, plus 0.91%. The O-Bank Facility expired on September 11, 2019 and the loans were set to mature six months after the expiration date, on March 11, 2020. In March 2020, the O-Bank Facility was amended, among other things, to extend the maturity date to March 2022, to decrease the total amount of the O-Bank Facility to approximately $5.0 million, to change the applicable interest rate to the TAIBOR plus 1.17% and to adjust the term to 24-month non-revolving. All amounts due under the O-Bank Facility will be payable upon the earlier of (i) six months after the expiration date or (ii) two years after the drawdown date.

As of March 31, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $4.6 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at March 31, 2020 or 2019 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 (principal financial officer), does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer 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 Securities Exchange Act of 1934, as amended, or 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 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, 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, 2020 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 risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2019. These risks are not the only risks that could materialize. 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, 2019 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 a stockholder could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.

Risks Related to our Business and Operations

The recent outbreak of COVID-19 may negatively impact our ability to develop our product candidates.

In December 2019, a novel strain of coronavirus, or COVID-19, was reported to have surfaced in Wuhan, China. As of March 2020, COVID-19 had spread to other countries, including Europe and the U.S., and been declared to be a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and the U.S., Europe and Asia have implemented severe travel restrictions, social distancing and delays or cancellations of elective surgeries. The outbreak of COVID-19 poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting normal business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities.

The continued spread of COVID-19 globally could materially and adversely impact our operations. We plan to initiate clinical trials for our product candidates in Poland, Italy, the United States and other worldwide locations impacted by the COVID-19 outbreak. These clinical trials could be materially delayed by governmental restrictions and enrollment difficulties as hospitals reduce and divert staffing, divert resources to patients suffering from the infectious disease and limit hospital access for nonpatients.

There is a risk that clinical supplies of our products may be significantly delayed or may become unavailable as a result of COVID-19 and the resulting impact on our suppliers' labor forces and operations, including as a result of governmental restrictions on business operations and the movement of people and goods in an effort to curtail the spread of the virus. There can be no assurance that we would be able to timely implement any mitigation plans. Disruptions in our supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact clinical supplies of our products, which could materially adversely impact our clinical trial and development timelines

The continued spread of COVID-19 has also led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. It is likely that the continued spread of COVID-19 has resulted in an economic slowdown or recession and could cause other unpredictable events, each of which could adversely affect our business, results of operations or financial condition.

The extent to which COVID-19 impacts our financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 outbreak and the actions to contain the outbreak or treat its impact, among others. Moreover, the COVID-19 outbreak has begun to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID-19 or any other pandemic harms the global economy generally.

Risks Related to the Ownership of our Securities

We effected a reverse stock split on April 29, 2020 which may adversely impact the market price of our common stock.

We effected a reverse stock split of our outstanding common stock at a ratio in of one-for-three shares, which was effected at 12:01 a.m. Eastern Time on April 29, 2020. The effect of the reverse stock split upon the market price of our common stock cannot be predicted with certainty and there is no assurance that our common stock will trade at a price consistent with such reverse stock split. Accordingly, it is possible that the market price of our common stock following the reverse stock split will decline, possibly more than would occur in the absence of a reverse stock split.

The effective increase in the number of shares of our common stock available for issuance as a result of our reverse stock split could result in further dilution to our existing stockholders and have antitakeover implications.

The reverse stock split alone had no effect on our authorized capital stock, and the total number of authorized shares remains the same as before the reverse stock split. The reverse stock split of our issued and outstanding shares increased the number of shares of our common stock (or securities convertible or exchangeable for our common stock) available for issuance by decreasing the number of shares of our common stock issued and outstanding. The additional available shares are available for issuance from time to time at the discretion of our Board of Directors when opportunities arise, without further stockholder action or the related delays and expenses, except as may be required for a particular transaction by law, the rules of any exchange on which our securities may then be listed, or other agreements or restrictions. Any issuance of additional shares of our common stock would increase the number of outstanding shares of our common stock and (unless such issuance was pro-rata among existing stockholders) the percentage ownership of existing stockholders would be diluted accordingly. In addition, any such issuance of additional shares of our common stock could have the effect of diluting the earnings per share and book value per share of outstanding shares of our common stock.

Additionally, the effective increase in the number of shares available for issuance could, under certain circumstances, have anti-takeover implications. For example, the additional shares of common stock that have become available for issuance could be used by us to oppose a hostile takeover attempt or to delay or prevent changes in control or our management. Although our reverse stock split is prompted by other considerations and not by the threat of any hostile takeover attempt, stockholders should be aware that our reverse stock split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation	Incorporated by reference to Exhibit 3.1 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 17, 2018.
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Windtree's Form 8-K filed on April 29, 2020.
4.1	Form of Series F Warrant Amendment dated April 24, 2020.	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 29, 2020.
4.2	Form of Series I Warrant Amendment dated May 6, 2020, to the Series I Warrant dated December 6, 2019.	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 7, 2020.
10.1	Amendment No. 1 dated March 30, 2020 to Payment Restructuring Agreement effective December 7, 2018, between Windtree and Battelle Memorial Institute.	Incorporated by reference to Exhibit 10.48 to Windtree's Registration Statement on Form S-1/A (File No. 333-236085), as filed with the SEC on May 6, 2020.
10.2†	Binding Term Sheet dated March 18, 2020, between Windtree and Lee's Pharmaceutical (HK) LTD.	Incorporated by reference to Exhibit 10.49 to Windtree's Registration Statement on Form S-1/A (File No. 333-236085), as filed with the SEC on May 6, 2020.
10.3	Loan Agreement dated March 17, 2020, between CVie Therapeutics, Lee's Pharmaceutical Holdings Limited, and O-Bank Co., Ltd.	Incorporated by reference to Exhibit 10.50 to Windtree's Registration Statement on Form S-1/A (File No. 333-236085), as filed with the SEC on May 6, 2020.
10.4	Note dated April 20, 2020, between Windtree and Newtek Small Business Finance, LLC.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 24, 2020.
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, 2020, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of March 31, 2020 (unaudited) and December 31, 2019, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2020 and March 31, 2019, (iii) Statements of Comprehensive Loss (unaudited) for the three months ended March 31, 2020 and March 31, 2019, (iv) Statements of Cash Flows (unaudited) for the three months ended March 31, 2020 and March 31, 2019, and (v) Notes to Condensed Consolidated Financial Statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

† Confidential treatment received for certain portions of this exhibit.

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 13, 2020

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

Date: May 13, 2020

By: /s/ John Tattory
John Tattory
Senior Vice President and Chief Financial Officer

Exhibit 31.1

CERTIFICATION

I, Craig 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 officer(s) 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, 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 officer(s) 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 functions):

   (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 13, 2020

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

Exhibit 31.2

CERTIFICATION

I, John A. Tattory, 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 officer(s) 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, 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 officer(s) 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 functions):

   (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 13, 2020

/s/ John A. Tattory
John A. Tattory
Senior Vice President and Chief Financial Officer
(Principal Finance 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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

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

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

Date: May 13, 2020

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

/s/ John A. Tattory
John A. Tattory
Senior Vice President and Chief Financial Officer
(Principal Finance 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.