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

FORM 10-Q

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

For the quarterly period ended June 30, 2021

or

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

For the transition period from _____ to _____

Commission file number 000-26422

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

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

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

As of August 5, 2021, there were 26,704,456 shares of the registrant's common stock outstanding, par value $0.001 per share.

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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. 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 timelines and milestones and additional costs associated with the ongoing novel coronavirus, or COVID-19, pandemic and the overall impact of the COVID-19 pandemic on our business, financial condition and results of operations;
- 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, or U.S., and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- our plans and the plans of our licensee, Lee’s Pharmaceutical (HK) Ltd., or Lee’s (HK), in Asia and our respective abilities to successfully execute clinical and business development activities in a timely manner, if at all, and commercialize our product candidates;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contractor laboratories and independent contractors;
- the size and growth of the potential markets for our product candidates, the regulatory requirements in such markets, the rate and degree of market acceptance of our product candidates and our ability to serve those markets;
- the success of competing therapies and products that are or become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- recently enacted and future legislation regarding the healthcare system in the U.S. and other potential markets, including in the U.S., the repeal, replacement or modification of all or part of the Patient Protection and Affordable Care Act;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to secure electronically stored work product, including clinical data, analyses, research, communications and other materials necessary to gain regulatory approval of our product candidates, including those acquired from third parties, and assure the integrity, proper functionality and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption; and
- the impact of the significant impairment of our intangible assets on our condensed consolidated balance sheet, and any future impairment charges that may be reported.

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.

You should also read carefully the factors described in the “Risk Factors” included in Part II, Item 1A of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on March 29, 2021 and Part II, Item 1A of our Quarterly Report on Form 10-Q for the three months ended March 31, 2021 filed with the SEC on May 13, 2021 to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements.

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

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	June 30, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,965	$ 16,930
Prepaid expenses and other current assets	2,329	1,188
Total current assets	32,294	18,118
Property and equipment, net	834	924
Restricted cash	154	154
Operating lease right-of-use assets	2,581	917
Intangible assets	39,320	77,090
Goodwill	15,682	15,682
Total assets	$ 90,865	$ 112,885
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 288	$ 1,161
Accrued expenses	3,111	3,813
Operating lease liabilities - current portion	336	805
Loans payable - current portion	1,175	352
Total current liabilities	4,910	6,131
Operating lease liabilities - non-current portion	2,318	201
Loans payable - non-current portion	-	2,423
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,200	2,800
Deferred tax liabilities	8,674	16,778
Total liabilities	34,102	43,333
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2021 and December 31, 2020; 26,704,480 and 16,921,506 shares issued at June 30, 2021 and December 31, 2020, respectively; 26,704,456 and 16,921,482 shares outstanding at June 30, 2021 and December 31, 2020, respectively	27	17
Additional paid-in capital	823,828	790,277
Accumulated deficit	(764,038)	(717,688)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	56,763	69,552
Total liabilities & stockholders' equity	$ 90,865	$ 112,885

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Expenses:				
Research and development	$ 4,221	$ 4,495	$ 8,631	$ 7,956
General and administrative	3,371	3,453	8,040	6,695
Loss on impairment of intangible assets	37,770	-	37,770	-
Total operating expenses	45,362	7,948	54,441	14,651
Operating loss	(45,362)	(7,948)	(54,441)	(14,651)
Other income (expense):				
Interest income	39	5	89	94
Interest expense	(46)	(31)	(87)	(75)
Other (expense), net	(352)	(1,584)	(243)	(1,460)
Total other (expense), net	(359)	(1,610)	(241)	(1,441)
Loss before income taxes	(45,721)	(9,558)	(54,682)	(16,092)
Deferred income tax benefit	8,332	-	8,332	-
Net loss	$ (37,389)	$ (9,558)	$ (46,350)	$ (16,092)
Net loss per common share				
Basic and diluted	$ (1.42)	$ (0.63)	$ (2.10)	$ (1.12)
Weighted average number of common shares outstanding				
Basic and diluted	26,350	15,091	22,047	14,394

See notes to condensed consolidated financial statements

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

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance - December 31, 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**
Net loss				(9,558)			(9,558)
Issuance of common stock and common stock warrants, net of issuance costs	3,172	3	20,243				20,246
Stock-based compensation expense			1,566				1,566
Modification of warrants			1,112				1,112
Balance - June 30, 2020	**16,869**	**$ 17**	**$ 787,707**	**$ (701,214)**	**-**	**$ (3,054)**	**$ 83,456**

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

See notes to condensed consolidated financial statements

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

(in thousands)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (46,350)	$ (16,092)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	93	85
Stock-based compensation	3,987	3,255
Non-cash expense related to warrant modifications	-	1,112
Non-cash lease expense	336	356
Non-cash expense related to equity consideration for a service agreement	494	-
Loss on impairment of intangible assets	37,770	-
Deferred income tax benefit	(8,332)	-
Unrealized loss on foreign exchange rate changes	300	-
Changes in assets and liabilities:		
Prepaid expenses and other current assets	179	218
Accounts payable	(873)	(485)
Collaboration and device development payable	-	(1,007)
Accrued expenses	(703)	425
Operating lease liabilities	(352)	(387)
Net cash used in operating activities	(13,451)	(12,520)
Cash flows from investing activities:		
Purchase of property and equipment	(3)	(12)
Net cash used in investing activities	(3)	(12)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	27,390	20,246
Proceeds from ATM Program, net of expenses	1,690	-
Proceeds from research and development funding arrangement	400	1,000
Principal payments on loans payable	(2,991)	(199)
Proceeds from Paycheck Protection Program loan	-	547
Principal payments on Paycheck Protection Program loan	-	(547)
Net cash provided by financing activities	26,489	21,047
Effect of exchange rate changes on cash and cash equivalents	-	422
Net increase in cash, cash equivalents, and restricted cash	13,035	8,937
Cash, cash equivalents, and restricted cash - beginning of period	17,084	22,732
Cash, cash equivalents, and restricted cash - end of period	$ 30,119	$ 31,669
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,000	$ -
Prepayment of insurance through third-party financing	1,321	1,056

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 acute pulmonary diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic aspects of cardiac function and was generally well tolerated in two phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in the phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure in heart failure patients, we initiated a clinical study to evaluate istaroxime for the treatment of early cardiogenic shock, a severe form of heart failure characterized by very low blood pressure and risk for hypo-perfusion to critical organs. We believe that istaroxime may fulfill an unmet need in early cardiogenic shock. Our heart failure cardiovascular portfolio also includes sarco (endo) plasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activator research programs to evaluate our preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potentially oral agents, these candidates would be developed for chronic heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile, for which we are continuing to pursue potential licensing arrangements and/or other strategic partnerships and do not intend to advance without securing such an arrangement or partnership.

Our pulmonary product candidate is our proprietary lyophilized KL4 surfactant (lucinactant), which we believe may potentially support a product pipeline, alone or in combination with our proprietary Aerosol Delivery System, or ADS, technology, to address a broad range of serious respiratory conditions in children and adults. We are developing KL4 surfactant to be delivered either as a liquid instillate or noninvasively as an aerosol. In September 2020, the FDA accepted our investigational new drug, or IND, application for a phase 2 pilot study to assess safety and tolerability in the COVID-19 acute respiratory distress syndrome, or ARDS, population and the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and ARDS resulting from severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the causative agent in novel coronavirus, or COVID-19, infections. We dosed the first patient in this clinical trial in January 2021 and plan to enroll approximately 20 patients with COVID-19 and ARDS who are on mechanical ventilation, with results expected in the fourth quarter of 2021. Our aerosolized product candidate, AEROSURF® (lucinactant for inhalation), is a novel drug/medical device combination product for noninvasive delivery of aerosolized KL4 surfactant using our ADS technology for the treatment of respiratory distress syndrome, or RDS, in premature infants. Our licensee in Asia, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), has agreed to fund and conduct a phase 2b clinical bridging study for AEROSURF in Asia, referred to as the phase 2b bridging study, under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Asia License Agreement. Accordingly, we have suspended our AEROSURF clinical activities and ceased enrollment in the phase 2b bridging study being conducted in the European Union. To support the future development of AEROSURF and our lyophilized KL4 surfactant liquid instillate in markets outside of Asia, including the United States, or U.S., we are pursuing one or more licensing transactions, collaboration arrangements or other strategic opportunities.

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

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2020 that we filed with the Securities and Exchange Commission, or the SEC, on March 29, 2021, 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 are 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. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. There have been no changes to our significant accounting policies since December 31, 2020. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with our annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2020 contained in our Annual Report on Form 10-K for the year ended December 31, 2020.

Note 3 - Liquidity Risks and Management's Plans

As of June 30, 2021, we had cash and cash equivalents of $30.0 million and current liabilities of $4.9 million.

We have an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the six months ended June 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million (s*ee*, Note 8 - Stockholders' Equity).

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

We have incurred net losses since inception. Our net loss was $37.4 million and $9.6 million, respectively, for the three-month periods ended June 30, 2021 and 2020. Our net loss was $46.4 million and $16.1 million, respectively, for the six-month periods ended June 30, 2021 and 2020. Included in our net loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 - Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2021, we had an accumulated deficit of $764.0 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.

We believe that our cash and cash equivalents as of the filing date of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 are sufficient to fund operations through at least the next 12 months. In the future, we will need to raise additional capital to continue funding our development activities and 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 thus they are not considered probable.

Our funding requirements 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 and its wholly owned subsidiary, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or IPR&D, assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired.

When performing the quantitative impairment assessment for our indefinite-lived IPR&D intangible assets, we estimate the fair values of the assets using the multi-period excess earnings method, or MPEEM. MPEEM is a variation of the income approach which estimates the fair value of an intangible asset based on the present value of the incremental after-tax cash flows attributable to the intangible asset. Significant factors considered in the calculation of IPR&D intangible assets include the risks inherent in the development process, including the likelihood of achieving commercial success and the cost and related time to complete the remaining development. Future cash flows for each project were estimated based on forecasted revenue and costs, taking into account the expected product life cycles, market penetration, and growth rates. Other significant estimates and assumptions inherent in this approach include (i) the amount and timing of the projected net cash flows associated with the IPR&D assets, (ii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iii) the tax rate, which considers geographic diversity of the projected cash flows. While we use the best available information to prepare our cash flows and discount rate assumptions, actual future cash flows could differ significantly based on the commercial success of the related drug candidates and market conditions which could result in future impairment charges related to our indefinite-lived intangible asset balances.

During the second quarter, we concluded an initial process to test the industry's interest in investing in our rostafuroxin drug candidate and were not able to secure a licensing transaction or other strategic opportunity at that time. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional phase 2 clinical trial to demonstrate efficacy in non-Caucasian patients in treatment resistant hypertension. Due to these developments, and in connection with the preparation of these interim unaudited condensed consolidated financial statements, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not less than its carrying value. As a result, we have performed the required quantitative impairment assessment of the related intangible asset. We estimated the fair value of the asset using MPEEM and determined that the fair value as of June 30, 2021 is approximately $17.0 million. We then compared this fair value to the carrying value of approximately $54.8 million. Since the fair value was less than the carrying value, we calculated the intangible asset impairment as the difference between the fair value and the carrying value of the IPR&D related to our rostafuroxin drug candidate. Accordingly, we recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2021. No events or changes in the business environment occurred during the six months ended June 30, 2021 that would indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. When conducting our annual impairment test of goodwill, we perform a quantitative assessment. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill.

Goodwill is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired. For example, a significant decline in our share price and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying value, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in our closing share price following the registered public offering completed on March 25, 2021, or the March 2021 Offering, due to both market conditions and the dilution of our common stock as a result of the March 2021 Offering. While this trend began prior to the filing of our Annual Report on Form 10-K for the year ended December 31, 2020 that we filed with the SEC on March 29, 2021, we believe that the March 2021 Offering priced at $3.25 per unit corroborated the results of our quantitative analysis of goodwill as of December 1, 2020. While our share price has not improved during the second quarter, our carrying value has decreased significantly as a result of the loss on impairment of intangible assets of $37.8 million recorded. As such, there was no impairment of goodwill as of June 30, 2021.

The following table represents identifiable intangible assets as of June 30, 2021 and December 31, 2020:

(in thousands)	**June 30, 2021**	**December 31, 2020**
Rostafuroxin drug candidate	$ 16,980	$ 54,750
Istaroxime drug candidate	22,340	22,340
Intangible assets	39,320	77,090
Goodwill	$ 15,682	$ 15,682

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 (expense), net. Foreign currency transactions resulted in losses of approximately $0.3 million and $0.5 million for the three-month periods ended June 30, 2021 and 2020, respectively. Foreign currency transactions resulted in losses of approximately $0.2 million and $0.3 million for the six-month periods ended June 30, 2021 and 2020, respectively.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents are held at domestic and foreign financial institutions and consist of liquid investments, money market funds, and U.S. Treasury notes with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

Severance

In July 2020, we entered into separation agreements with two executives, which provide that the former employees are entitled to receive: (i) a severance amount equal to the sum of their respective base salaries then in effect and their respective annual target bonus amounts, payable in equal installments through August 2021 and (ii) subject to certain exceptions, a pro rata bonus commensurate with the bonus of other contract executives for the year 2020, prorated for the number of days of their respective employment during 2020, and payable at the time that other contract executives are paid bonuses with respect to 2020. The severance amount related to the departure of these executives is approximately $0.9 million, was accrued at the date of the separations, and is being paid ratably through August 2021. During the three months ended June 30, 2021, $0.2 million was paid and $0.1 million remains accrued. During the six months ended June 30, 2021, $0.4 million was paid.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*see*, Note 7 - Restructured Debt Liability), we have established a $15.0 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017, or the Exchange and Termination Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

Research and Development

We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, consulting and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical and regulatory operations expenses, to specific programs. Indirect research and development expenses include personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, regulatory, and medical affairs. Research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

Income Taxes

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

We use a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Because we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

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

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of June 30, 2021 and 2020, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 19.9 million and 9.7 million shares, respectively. For the three and six months ended June 30, 2021 and 2020, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

COVID-19

The COVID-19 pandemic continues to evolve, and we continue to closely monitor its impact on our business, operations, including its potential impact on our clinical development plans and timelines, and financial condition. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The potentially extended timelines may force us to expend more of our capital resources than planned to achieve our projected milestones. For example, certain of our ongoing clinical trials, including our phase 2 study of istaroxime for early cardiogenic shock in heart failure patients, have experienced delays in trial initiation in 2020. The full extent, duration, or impact that the COVID-19 pandemic will have, directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include new information that may emerge concerning the severity of the COVID-19 outbreak, the severity and transmissibility of new variants of the virus, information about any regional resurgences in one or more markets where our current or intended clinical trial sites, our principal executive offices, research and development laboratories or manufacturing facilities are located, and the actions taken to contain it or treat its impact, which may include, among others, the timing and extent of governments reopening activities and the economic impact on local, regional, national, and international markets. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more markets where our clinical trial sites, principal executive offices, research and development laboratories or other facilities are located remains possible and if realized, we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials in 2021.

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.

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

(in thousands)	Fair Value June 30, 2021	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 28,104	$ 28,104	$ -	$ -
Total Assets	$ 28,104	$ 28,104	$ -	$ -

(in thousands)	Fair Value December 31, 2020	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 6,518	6,518	$ -	$ -
U.S. Treasury notes	9,101	9,101	-	-
Total Assets	$ 15,619	$ 15,619	$ -	$ -

Fair Value on a Non-Recurring Basis

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

(in thousands)	Fair Value June 30, 2021	Fair value measurement using Level 1	Level 2	Level 3
Intangible assets:				
Rostafuroxin drug candidate	$ 16,980	$ -	$ -	$ 16,980

During the second quarter, we concluded an initial process to test the industry's interest in investing in our rostafuroxin drug candidate and were not able to secure a licensing transaction or other strategic opportunity at that time. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional phase 2 clinical trial to demonstrate efficacy in non-Caucasian patients in treatment resistant hypertension. Due to these developments, and in connection with the preparation of these interim unaudited condensed consolidated financial statements, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not less than its carrying value (*see*, Note 4 - Summary of Significant Accounting Policies - Goodwill and Intangible Assets). We have performed the required quantitative impairment assessment of the related intangible asset as of the triggering date and recorded a $37.8 million non-cash impairment charge on our IPR&D related to our rostafuroxin drug candidate for the three and six months ended June 30, 2021.

We estimate the fair value of the IPR&D related to our rostafuroxin drug candidate using MPEEM, a variation of the income approach which estimates the fair value of an intangible asset based on the present value of the incremental after-tax cash flows attributable to the intangible asset. Significant factors considered in the calculation of IPR&D intangible assets include the risks inherent in the development process, including the likelihood of achieving commercial success and the cost and related time to complete the remaining development. Future cash flows for each project were estimated based on forecasted revenue and costs, taking into account the expected product life cycles, market penetration, and growth rates. Other significant estimates and assumptions inherent in this approach include (i) the amount and timing of the projected net cash flows associated with the IPR&D assets, (ii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iii) the tax rate, which considers geographic diversity of the projected cash flows. Quantitative information about the significant unobservable inputs used in the fair value measurement of IPR&D related to our rostafuroxin drug candidate as of June 30, 2021 included a discount rate of 19.5% and a tax rate of 30.0%. While we use the best available information to prepare our cash flows and discount rate assumptions, actual future cash flows could differ significantly based on the commercial success of the related drug candidates and market conditions which could result in future impairment charges related to our indefinite-lived intangible asset balances.

Note 6 - Loans Payable - Current and Non-Current Portions

O-Bank Co., Ltd. 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 is guaranteed by Lee's Pharmaceutical Holdings Limited, or Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. Interest, payable in cash on a monthly basis, was 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.

In August 2020, we repaid approximately $2.3 million of the outstanding principal of the O-Bank Facility. In June 2021, we repaid the remaining outstanding principal of the O-Bank Facility of approximately $2.5 million. As of December 31, 2020, the outstanding principal of the O-Bank Facility was approximately $2.4 million and was classified as loans payable - non-current portion. There was no outstanding principal balance as of June 30, 2021 and the O-Bank Facility is no longer available to us.

Loan Payable to Bank Direct Capital Finance

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 were due monthly from July 2020 through March 2021. As of December 31, 2020, the outstanding principal of the loan was $0.4 million. The balance of the loan was repaid during the first quarter of 2021.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of June 30, 2021, the outstanding principal of the loan was $1.2 million.

Note 7 - Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into the Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P., or the Deerfield Loan, in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 8,333 shares of our common stock at an exercise price of $2,360.40 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) 23,703 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain milestone payments based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15.0 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. We established a $15.0 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement (*see*, Note 4 - Summary of Significant Accounting Policies). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of June 30, 2021 and December 31, 2020, the restructured debt liability balance was $15.0 million.

Note 8 - Stockholders' Equity

March 2021 Public Offering

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

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

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

May 2020 Public Offering

On May 20, 2020, we entered into an underwriting agreement, or the Underwriting Agreement, with Ladenburg as representative for the several underwriters named therein, or collectively, the Underwriters, relating to the May 2020 Offering for an aggregate of 2,758,620 units with each unit consisting of one share of our common stock and the May 2020 Warrants. The May 2020 Warrants were immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance. The shares of common stock and the May 2020 Warrants were immediately separable and were issued separately in the May 2020 Offering.

In addition, we granted the Underwriters a 45-day option, or the Overallotment Option, to purchase up to 413,793 additional shares of common stock and/or May 2020 Warrants to purchase up to 413,793 additional shares of common stock, which such Overallotment Option was exercised in full.

The closing of the May 2020 Offering occurred on May 22, 2020, inclusive of the Overallotment Option. The offering price to the public was $7.25 per unit. After deducting underwriting discounts and commissions and offering expenses of $2.8 million payable by us, and excluding the proceeds, if any, from the exercise of the May 2020 Warrants issued pursuant to this May 2020 Offering, the net proceeds to us were approximately $20.2 million.

We have determined that the appropriate accounting treatment under ASC 480 is to classify the common stock and the May 2020 Warrants issued in the May 2020 Offering as equity. We have also determined that the May 2020 Warrants are not in their entirety a derivative under the scope of ASC 815, *Derivatives and Hedging*, or ASC 815, due to the scope exception under ASC 815-10-15-74, nor are there any material embedded derivatives that require separate accounting. We allocated the net proceeds from the May 2020 Offering based on the relative fair value of the common stock and the May 2020 Warrants.

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. When we issue sales notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

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

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

As of June 30, 2021, approximately $8.3 million remained available under the ATM Program.

Warrant Amendments

On April 24, 2020, we and each of the holders of our Series F Warrants dated as of December 24, 2018, or the Series F Warrants, entered into Amendment No. 1 to the Series F Warrant to Purchase Common Stock 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 our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by the 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. The lock-up provision commenced upon closing of the May 2020 Offering discussed above and has expired. The Series F Warrants expired on December 24, 2020.

On May 6, 2020, we and certain holders of our Series I Warrants dated as of December 6, 2019, or the Series I Warrants, entered into Amendment No. 1 to the Series I Warrant to Purchase Common Stock 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 our 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. The lock-up provision commenced upon closing of the May 2020 Offering discussed above and has expired.

While there is no specific guidance that addresses the modification of an equity-classified contract, such as the amendments to the Series F Warrants and the Series I Warrants, it is the practice to determine the accounting for such modifications based on analogy to the share-based compensation guidance. The model for a modified share-based payment award that is classified as equity and remains classified in equity after the modification is addressed in ASC 718-20, *Compensation – Stock Compensation*, or ASC 718-20. Pursuant to that guidance, the incremental fair value from the modification (the change in the fair value of the instrument before and after the modification) is recognized as an expense in the income statement to the extent the modified instrument has a higher fair value.

For the Series F Warrants, the amendment to the terms related to a six-month extension of the expiration date and the incremental fair value from the modification was determined by comparing the Black-Scholes value before and after the modification. The amendment to the Series I Warrants related to a reduced exercise price for an 18-month period and the reversion after that period to the initial exercise price. As a result, the incremental fair value was determined by comparing the Black-Scholes value before the modification to a Monte Carlo valuation after the modification.

We have determined, based on the guidance in ASC 718-20 and our valuation of the Series F Warrants and the Series I Warrants, that the incremental fair value resulting from the modifications is $1.1 million, which was recorded as an increase to equity, with a corresponding expense recognized in the interim unaudited condensed consolidated statement of operations as other expense.

Note 9 - Stock Options and Stock-Based Employee Compensation

We recognize in our condensed consolidated financial statements stock options 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 options is recognized ratably over the vesting period, which 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 one to two years.

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2021	1,903	$ 15.57	
Granted	1,368	5.39	
Forfeited or expired	(5)	17.71	
Outstanding at June 30, 2021	3,266	$ 11.30	8.3
Vested and exercisable at June 30, 2021	1,368	$ 17.06	7.3
Vested and expected to vest at June 30, 2021	3,045	$ 11.40	8.3

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

(in thousands)	Three Months Ended June 30, 2021	2020	Six Months Ended June 30, 2021	2020
Research and development	$ 630	$ 596	$ 1,569	$ 1,310
General and administrative	914	970	2,418	1,945
Total	$ 1,544	$ 1,566	$ 3,987	$ 3,255

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

	Six Months Ended June 30, 2021	2020
Weighted average expected volatility	105%	98%
Weighted average expected term (in years)	6.7	6.0
Weighted average risk-free interest rate	0.48%	2.60%
Expected dividends	-	-

Note 10 - Collaboration, Licensing and Research Funding Agreements

In March 2020, we entered into the Term Sheet with Lee's (HK), pursuant to which Lee's (HK) provided financing for the development of AEROSURF. In August 2020, we entered into a Project Financing Agreement with Lee's (HK), the PF Agreement, formalizing the terms of the Term Sheet, and under which we received payments totaling $2.8 million through October 2020. In November 2020, Lee's (HK) provided notice of termination of additional funding under the PF Agreement. Thereafter, we and Lee's (HK) revised our plans for the continued development of AEROSURF. Lee's (HK) agreed to continue the development of AEROSURF in Asia at its cost. Lee's (HK) has agreed to fund an additional $1.0 million to us in 2021 for certain transition and analytical services to be provided by us with respect to the development of AEROSURF, which will be considered "Project Expenses" under the terms of the PF Agreement. In June 2021, we received payments totaling $0.4 million. In August 2021, we received payments totaling $0.4 million.

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

As of June 30, 2021, the liability balance related to the payments under the PF Agreement was $3.2 million and is recorded in other liabilities.

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

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the Forward-Looking Statements section, any risk factors discussed elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2020 that we filed with the Securities and Exchange Commission, or SEC, on March 29, 2021, our Quarterly Report on Form 10-Q filed thereafter, and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

This Management's Discussion and Analysis, or MD&A, is provided as a supplement to the accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) to help provide an understanding of our financial condition and changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) and our Annual Report on Form 10-K for the year ended December 31, 2020. 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 acute pulmonary diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic aspects of cardiac function and was generally well tolerated in two phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in the phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure in heart failure patients, we initiated a clinical study to evaluate istaroxime for the treatment of early cardiogenic shock, a severe form of heart failure characterized by very low blood pressure and risk for hypo-perfusion to critical organs. We believe that istaroxime may fulfill an unmet need in early cardiogenic shock. Our heart failure cardiovascular portfolio also includes sarco (endo) plasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activator research programs to evaluate our preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potentially oral agents, these candidates would be developed for chronic heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile, for which we are continuing to pursue potential licensing arrangements and/or other strategic partnerships and do not intend to advance without securing such an arrangement or partnership.

Our pulmonary product candidate is our proprietary lyophilized KL4 surfactant (lucinactant), which we believe may potentially support a product pipeline, alone or in combination with our proprietary Aerosol Delivery System, or ADS, technology, to address a broad range of serious respiratory conditions in children and adults. We are developing KL4 surfactant to be delivered either as a liquid instillate or noninvasively as an aerosol. In September 2020, the FDA accepted our investigational new drug, or IND, application for a phase 2 pilot study to assess safety and tolerability in the COVID-19 acute respiratory distress syndrome, or ARDS, population and the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and ARDS resulting from severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the causative agent in novel coronavirus, or COVID-19, infections. We dosed the first patient in this clinical trial in January 2021 and plan to enroll approximately 20 patients with COVID-19 and ARDS who are on mechanical ventilation, with results expected in the fourth quarter of 2021. Our aerosolized product candidate, AEROSURF® (lucinactant for inhalation), is a novel drug/medical device combination product for noninvasive delivery of aerosolized KL4 surfactant using our ADS technology for the treatment of respiratory distress syndrome, or RDS, in premature infants. Our licensee in Asia, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), has agreed to fund and conduct a phase 2b clinical bridging study for AEROSURF in Asia, referred to as the phase 2b bridging study, under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Asia License Agreement. Accordingly, we have suspended our AEROSURF clinical activities and ceased enrollment in the phase 2b bridging study being conducted in the European Union. To support the future development of AEROSURF and our lyophilized KL4 surfactant liquid instillate in markets outside of Asia, including the United States, or U.S., we are pursuing one or more licensing transactions, collaboration arrangements or other strategic opportunities.

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

We have incurred operating losses since our incorporation on November 6, 1992. For the three-month periods ended June 30, 2021 and 2020, we had operating losses of $45.4 million and $7.9 million, respectively. For the six-month periods ended June 30, 2021 and 2020, we had operating losses of $54.4 million and $14.7 million, respectively. Included in our operating loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin (*see*, Note 4 - Summary of Significant Accounting Policies - Goodwill and Intangible Assets). As of June 30, 2021, we had an accumulated deficit of $764.0 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock and borrowings from investors and financial institutions.

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

As a result, we will need additional financing to support our continuing operations. Until such time that we can generate substantial product revenues, if ever, we expect to finance our operations through public or private equity offerings; through potential strategic opportunities, including licensing agreements, drug product development and marketing collaboration arrangements, pharmaceutical research cooperation arrangements or other similar transactions in geographic markets, including the U.S.; and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs, or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business, financial condition and results of operations.

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, 2020 that we filed with the SEC on March 29, 2021, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Istaroxime (Early Cardiogenic Shock)

In the second half of 2020, we initiated a phase 2 clinical study of istaroxime for the acute treatment of early cardiogenic shock due to heart failure to evaluate the potential of istaroxime to improve blood pressure in these severely ill patients. The study also will evaluate the safety and tolerability profile of istaroxime in this population. We expect data to be available in the fourth quarter of 2021. The current global COVID-19 pandemic continues to have disruptive effects on hospital resources, including intensive care units, where this study is being conducted. The availability of services and professional staff have contributed to delays in our trial execution activities and we anticipate that we may have continuing delays that could affect our clinical timelines and milestones.

Istaroxime (AHF)

To advance istaroxime for the treatment of AHF potentially through the phase 2 clinical program and be in a phase 3-ready position, our strategy includes, subject to adequate resources, executing an additional phase 2b clinical trial that will enroll up to 300 patients in approximately 60 clinical sites globally. The trial will focus on collecting additional data on measures that may serve as primary endpoints in a phase 3 clinical trial, and will focus on further dose optimizing regimen, potentially extending the infusion time beyond 24 hours. In order to enrich the patient population, we plan to also enroll patients with low blood pressure and those who are diuretic resistant, two of the specific patient populations that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function, increase blood pressure and improve renal function. We currently do not have sufficient capital to fund this clinical trial. We are exploring capital from public and private equity offerings and potential strategic opportunities to fund the initiation of this clinical trial, and plan to initiate the clinical trial after obtaining adequate funding.

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

We are pursuing several early exploratory research programs to assess our SERCA2a activator product candidates, including oral and intravenous SERCA2a activator heart failure compounds, and believe that we can add value to our cardiovascular portfolio by advancing these SERCA2a activator candidates through preclinical studies. As oral therapies, these candidates would be developed for chronic heart failure. To aid in the advancement of these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements or other strategic opportunities.

Rostafuroxin

Rostafuroxin has demonstrated efficacy in Caucasian patients in treatment naïve hypertension in a phase 2b trial. During the second quarter, we concluded an initial process to test the industry's interest in investing in our product. We were not able to secure a licensing transaction or other strategic opportunity at that time. As a result, we recorded an impairment of the related intangible asset (*see*, Note 4 - Summary of Significant Accounting Policies - Goodwill and Intangible Assets). Based on feedback received from potential licensing partners, we have determined that there is a need for an additional phase 2 clinical trial to demonstrate efficacy in non-Caucasian patients in treatment resistant hypertension. We are continuing to pursue licensing arrangements and/or other strategic partnerships for rostafuroxin. We do not intend to conduct the additional phase 2 clinical trial without securing such an arrangement or partnership.

Lyophilized KL4 Surfactant (*COVID-19 related Lung Injury)*

In September 2020, the FDA accepted our IND application for a phase 2 clinical trial to assess the impact of our lyophilized KL4 surfactant on key respiratory parameters in ventilated COVID-19 patients. This small pilot study is designed to evaluate changes in physiological parameters in patients who are intubated and mechanically ventilated for COVID-19 associated lung injury and ARDS. The study will evaluate the dosing regimen, tolerability, and functional changes in gas exchange and lung compliance after KL4 surfactant administration. We dosed the first patient in this clinical trial in January 2021 and plan to enroll approximately 20 patients with COVID-19 and ARDS who are on mechanical ventilation, from four to five U.S. sites and three to four Latin American sites, with data expected in the fourth quarter of 2021.

AEROSURF for preterm infants with Respiratory Distress Syndrome (lucinactant for inhalation)

We are supporting Lee's (HK) efforts to plan, fund and initiate in Asia the phase 2b bridging study needed to advance AEROSURF to phase 3 clinical trials. With termination of the Project Financing Agreement, we ceased enrollment in our phase 2b bridging study at the EU clinical sites and are transferring AEROSURF development activities to Lee's (HK) to be implemented under the terms of our Asia License Agreement. Our decision to cease enrollment and transfer the AEROSURF development activities to Lee's (HK) in Asia was not related to any communications between ourselves and the FDA or the EU regulatory authorities and was not based on any underlying safety or efficacy concern, but rather compelled by our desire to preserve our limited capital to focus on acute cardiovascular and other KL4 surfactant programs, primarily treatment of lung injury in patients with COVID-19. In the event that Lee's (HK) does not develop a firm plan and commit to funding certain support activities for their continued development of AEROSURF, our board of directors has approved a plan to suspend or terminate our support of the development of AEROSURF.

Lyophilized KL4 Surfactant (Lung Injury and Other Studies)

We believe our lyophilized KL4 surfactant and ADS technologies may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have from time to time worked with independent investigators and pharmaceutical companies to conduct or assist with preclinical studies, some of which were funded under grants from National Institutes of Health, or NIH, and other government agencies, to assess the utility of using our KL4 surfactant, alone or in combination with other pharmaceutical compounds, to address various respiratory conditions.

Impact of COVID-19

The COVID-19 pandemic continues to evolve, and we continue to closely monitor its impact on our business, operations, including its potential impact on our clinical development plans and timelines, and financial condition. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The potentially extended timelines may force us to expend more of our capital resources than planned to achieve our projected milestones. For example, certain of our ongoing clinical trials, including our phase 2 study of istaroxime for early cardiogenic shock in heart failure patients, have experienced delays in trial initiation in 2020. The full extent, duration, or impact that the COVID-19 pandemic will have, directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include new information that may emerge concerning the severity of the COVID-19 outbreak, the severity and transmissibility of new variants of the virus, information about any regional resurgences in one or more markets where our current or intended clinical trial sites, our principal executive offices, research and development laboratories or manufacturing facilities are located, and the actions taken to contain it or treat its impact, which may include, among others, the timing and extent of governments reopening activities and the economic impact on local, regional, national, and international markets. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more markets where our clinical trial sites, principal executive offices, research and development laboratories or other facilities are located remains possible and if realized, we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials in 2021.

Paycheck 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 had 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 would repay the PPP Loan and on May 12, 2020 the loan was repaid in full.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2020. For a discussion of our accounting policies, *see*, Note 4 - Summary of Significant Accounting Policies and, in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2020, Note 4 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or IPR&D, assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired.

When performing the quantitative impairment assessment for our indefinite-lived IPR&D intangible assets, we estimate the fair values of the assets using the multi-period excess earnings method, or MPEEM. MPEEM is a variation of the income approach which estimates the fair value of an intangible asset based on the present value of the incremental after-tax cash flows attributable to the intangible asset. Significant factors considered in the calculation of IPR&D intangible assets include the risks inherent in the development process, including the likelihood of achieving commercial success and the cost and related time to complete the remaining development. Future cash flows for each project were estimated based on forecasted revenue and costs, taking into account the expected product life cycles, market penetration, and growth rates. Other significant estimates and assumptions inherent in this approach include (i) the amount and timing of the projected net cash flows associated with the IPR&D assets, (ii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iii) the tax rate, which considers geographic diversity of the projected cash flows. While we use the best available information to prepare our cash flows and discount rate assumptions, actual future cash flows could differ significantly based on the commercial success of the related drug candidates and market conditions which could result in future impairment charges related to our indefinite-lived intangible asset balances.

During the second quarter, we concluded an initial process to test the industry’s interest in investing in our rostafuroxin drug candidate and were not able to secure a licensing transaction or other strategic opportunity at that time. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional phase 2 clinical trial to demonstrate efficacy in non-Caucasian patients in treatment resistant hypertension. Due to these developments, and in connection with the preparation of these interim unaudited condensed consolidated financial statements, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not less than its carrying value. As a result, we have performed the required quantitative impairment assessment of the related intangible asset. We estimated the fair value of the asset using MPEEM and determined that the fair value as of June 30, 2021 is approximately $17.0 million. We then compared this fair value to the carrying value of approximately $54.8 million. Since the fair value was less than the carrying value, we calculated the intangible asset impairment as the difference between the fair value and the carrying value of the IPR&D related to our rostafuroxin drug candidate. Accordingly, we recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2021. No events or changes in the business environment occurred during the six months ended June 30, 2021 that would indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. When conducting our annual impairment test of goodwill, we perform a quantitative assessment. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill.

Goodwill is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired. For example, a significant decline in our share price and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying value, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in our closing share price following the registered public offering completed on March 25, 2021, or the March 2021 Offering, due to both market conditions and the dilution of our common stock as a result of the March 2021 Offering. While this trend began prior to the filing of our Annual Report on Form 10-K for the year ended December 31, 2020 that we filed with the SEC on March 29, 2021, we believe that the March 2021 Offering priced at $3.25 per unit corroborated the results of our quantitative analysis of goodwill as of December 1, 2020. While our share price has not improved during the second quarter, our carrying value has decreased significantly as a result of the loss on impairment of intangible assets of $37.8 million recorded. As such, there was no impairment of goodwill as of June 30, 2021.

The following table represents identifiable intangible assets as of June 30, 2021 and December 31, 2020:

(in thousands)	**June 30, 2021**	**December 31, 2020**
Rostafuroxin drug candidate	$ 16,980	$ 54,750
Istaroxime drug candidate	22,340	22,340
Intangible assets	39,320	77,090
Goodwill	$ 15,682	$ 15,682

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended June 30, 2021 and 2020 was $45.4 million and $7.9 million, respectively. The increase in operating loss from 2020 to 2021 was due to a $37.8 million loss on impairment of intangible assets related to rostafuroxin (*see*, Note 4 - Summary of Significant Accounting Policies - Goodwill and Intangible Assets), partially offset by a $0.4 million decrease in operating expenses.

The operating loss for the six months ended June 30, 2021 and 2020 was $54.4 million and $14.7 million, respectively. The increase in operating loss from 2020 to 2021 was due to a $37.8 million loss on impairment of intangible assets and a $2.0 million increase in operating expenses, which includes a $0.7 million increase in non-cash stock compensation expense and $0.5 million of non-cash expense related to equity consideration for a financial advisory service agreement.

The net loss for the three months ended June 30, 2021 and 2020 was $37.4 million and $9.6 million, respectively. The net loss for the six months ended June 30, 2021 and 2020 was $46.4 million and $16.1 million, respectively. The increase in net loss from 2020 to 2021 was due to a $37.8 million loss on impairment of intangible assets, partially offset by a deferred income tax benefit of $8.3 million related to the reduction of the deferred tax liability. Included in the net loss for the three and six months ended June 30, 2020 is $1.1 million in non-cash expenses related to the modification of certain warrants.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, consulting and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical and regulatory operations expenses, to specific programs. We also account for research and development and report annually by major expense category as follows: (i) contracted services; (ii) salaries and benefits; (iii) stock-based compensation; (iv) raw materials, aerosol devices and supplies; (v) royalties; (vi) rents and utilities; (vii) depreciation; (viii) travel; and (ix) other. We expect to increase our investment in research and development in order to advance our product candidates through additional clinical trials. As a result, we expect that our research and development expenses will increase throughout the foreseeable future as we pursue clinical development of istaroxime, KL4 surfactant and our other current and future product candidates. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates.

Research and development expenses are as follows:

(in thousands)	Three Months Ended June 30, 2021	2020	Six Months Ended June 30, 2021	2020
Istaroxime - early cardiogenic shock	$ 840	580	$ 1,346	750
KL4 surfactant	263	403	507	734
Istaroxime - AHF	155	254	654	428
Preclinical studies	-	14	-	18
Total direct clinical and preclinical programs	1,258	1,251	2,507	1,930
Product development and manufacturing	1,085	1,544	2,172	2,608
Clinical, medical and regulatory operations	1,878	1,700	3,952	3,418
Total research and development expenses	$ 4,221	$ 4,495	$ 8,631	$ 7,956

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.7 million and $0.6 million, respectively, for the three months ended June 30, 2021 and 2020, and $1.6 million and $1.4 million, respectively, for the six months ended June 30, 2021 and 2020.

Direct Clinical and Preclinical Development Programs

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

Total direct clinical and preclinical development programs expenses were comparable for the three months ended June 30, 2021 and 2020. The changes in the direct clinical and preclinical development programs expenses for the three months ended June 30, 2021 compared to the same period in 2020 is due to (i) an increase of $0.2 million for ongoing clinical studies of istaroxime for early cardiogenic shock; offset by (ii) a decrease of $0.1 million in the phase 2b studies of KL4 surfactant; and (iii) a decrease of $0.1 million for our continued development of istaroxime for AHF. Direct clinical and preclinical development programs expenses increased $0.6 million for the six months ended June 30, 2021 compared to the same periods in 2020 due to (i) an increase of $0.6 million for ongoing clinical studies of istaroxime for early cardiogenic shock; (ii) an increase of $0.2 million for our continued development of istaroxime for AHF; partially offset by (iii) a decrease of $0.2 million in the phase 2b studies of KL4 surfactant.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with contract manufacturing organizations, 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 the AEROSURF clinical development program; and (iii) pharmaceutical and manufacturing development activities of our drug product candidates including development of istaroxime and lyophilized KL4 surfactant. 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 decreased $0.5 million and $0.4 million, respectively, for the three and six months ended June 30, 2021 compared to the same periods in 2020 due to the purchase of raw materials during the second quarter of 2020.

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 increased $0.2 million for the three months ended June 30, 2021 compared to the same period in 2020 due to an increase of $0.2 million in personnel costs and employee-related incentive bonus expense. Clinical, medical and regulatory operations expenses increased $0.5 million for the six months ended June 30, 2021 compared to the same period in 2020 due to an increase of $0.5 million in personnel costs and employee-related incentive bonus expense.

General and Administrative Expenses

(in thousands)	Three Months Ended June 30, 2021	2020	Six Months Ended June 30, 2021	2020
General and administrative expenses	$ 3,371	$ 3,453	$ 8,040	$ 6,695

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 June 30, 2021 compared to the same period in 2020 due to a decrease of $0.1 million in professional fees. General and administrative expenses increased $1.3 million for the six months ended June 30, 2021 compared to the same period in 2020 due to (i) an increase of $0.9 million in professional fees, including $0.5 million of non-cash expense related to equity consideration for a financial advisory service agreement; (ii) an increase of $0.5 million in non-cash, stock compensation expense; partially offset by (iii) a decrease of $0.1 million in personnel costs.

Other (Expense) Income, Net

(in thousands)	Three Months Ended June 30, 2021	2020	Six Months Ended June 30, 2021	2020
Interest income	39	5	89	94
Interest expense	(46)	(31)	(87)	(75)
Other (expense), net	(352)	(1,584)	(243)	(1,460)
Total other (expense), net	$ (359)	$ (1,610)	$ (241)	$ (1,441)

Interest income relates to interest on our money market account for the three months ended June 30, 2021. Interest income relates to interest on our money market account and U.S. Treasury notes for the six months ended June 30, 2021 and the three and six months ended June 30, 2020.

For the three and six months ended June 30, 2021 and 2020, interest expense consists of interest expense associated with loans payable and for the three and six months ended June 30, 2020 also includes interest expense related to collaboration and device development payables. Interest expense was comparable for the three and six months ended June 30, 2021 compared to the same periods in 2020.

For the three and six months ended June 30, 2021, other (expense), net primarily consists of $0.3 million and $0.2 million, respectively in losses on foreign currency translation.

For the three and six months ended June 30, 2020, other (expense), net primarily consists of $1.1 million in non-cash expenses related to the modification of certain warrants and losses on foreign currency translation of $0.5 million and $0.3 million, respectively, for the three and six months ended June 30, 2020.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2021, we had cash and cash equivalents of $30.0 million and current liabilities of $4.9 million.

We have an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the six months ended June 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million (*see*, Note 8 - Stockholders' Equity).

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

We have incurred net losses since inception. Our net loss was $37.4 million and $9.6 million, respectively, for the three-month periods ended June 30, 2021 and 2020. Our net loss was $46.4 million and $16.1 million, respectively, for the six-month periods ended June 30, 2021 and 2020. Included in our net loss for the three and six months ended June 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 - Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2021, we had an accumulated deficit of $764.0 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.

We believe that our cash and cash equivalents as of the filing date of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 are sufficient to fund operations through at least the next 12 months. In the future, we will need to raise additional capital to continue funding our development activities and 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 thus they are not considered probable.

Our funding requirements 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 flows for the six months ended June 30, 2021 consist of $13.5 million of net cash used in operating activities and $26.5 million of net cash provided by financing activities. Cash flows for the six months ended June 30, 2020 consist of $12.5 million of net cash used in operating activities and $21.0 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $13.5 million for the six months ended June 30, 2021 and consisted primarily of (i) a net loss of $46.4 million, (ii) a non-cash deferred income tax benefit of $8.3 million, and (iii) changes in operating assets and liabilities of $1.7 million, partially offset by (iv) a non-cash loss on impairment of intangible assets of $37.8 million, (v) non-cash stock-based compensation of $4.0 million, (vi) non-cash expense related to equity consideration for a financial advisory service agreement of $0.5 million, (vii) non-cash lease expense of $0.3 million, (viii) an unrealized loss on foreign exchange rate changes of $0.3 million, and (ix) depreciation and amortization of $0.1 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in operating activities was $12.5 million for the six months ended June 30, 2020 and consisted primarily of (i) a net loss of $16.1 million and (ii) changes in operating assets and liabilities of $1.2 million, partially offset by (iii) non-cash stock-based compensation of $3.3 million, (iv) non-cash expenses related to the modification of certain warrants of $1.1 million, (v) non-cash lease expense of $0.4 million, and (vi) depreciation and amortization of $0.1 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Financing Activities

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

Net cash provided by financing activities for the six months ended June 30, 2020 was $21.0 million and includes the following: (i) $20.2 million in net proceeds from the May 2020 public offering; (ii) $1.0 million in proceeds from our research and development funding arrangement with Lee's (HK); partially offset by (iii) $0.2 million of principal payments on loans payable.

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

Loan Payable to Bank Direct Capital Finance

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 were due monthly from July 2020 through March 2021. As of December 31, 2020, the outstanding principal of the loan was $0.4 million. The balance of the loan was repaid during the first quarter of 2021.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of June 30, 2021, the outstanding principal of the loan was $1.2 million.

Common Stock Offerings

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

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal under the ATM Program. When we issue sales notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

For the six months ended June 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million (s*ee*, Note 8 - Stockholders' Equity).

As of June 30, 2021, approximately $8.3 million remained available under the ATM Program.

March 2021 Public Offering

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

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

May 2020 Public Offering

On May 20, 2020, we entered into an underwriting agreement, or the Underwriting Agreement, with Ladenburg as representative for the several underwriters named therein, or collectively, the Underwriters, relating to the May 2020 Offering for an aggregate of 2,758,620 units with each unit consisting of one share of our common stock and the May 2020 Warrants. The May 2020 Warrants were immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance. The shares of common stock and the May 2020 Warrants were immediately separable and were issued separately in the May 2020 Offering.

In addition, we granted the Underwriters a 45-day option, or the Overallotment Option, to purchase up to 413,793 additional shares of common stock and/or May 2020 Warrants to purchase up to 413,793 additional shares of common stock, which such Overallotment Option was exercised in full.

The closing of the May 2020 Offering occurred on May 22, 2020, inclusive of the Overallotment Option. The offering price to the public was $7.25 per unit. After deducting underwriting discounts and commissions and offering expenses of $2.8 million payable by us, and excluding the proceeds, if any, from the exercise of the May 2020 Warrants issued pursuant to this May 2020 Offering, the net proceeds to us were approximately $20.2 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at June 30, 2021 and 2020 or during the periods then ended.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended June 30, 2021 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 Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020 and Part II, Item 1A Risk Factors in our Quarterly Report on Form 10-Q filed thereafter. 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, 2020 or our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 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 *Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources*.

We may never realize the full value of our intangible assets.

We have recorded significant goodwill and intangible assets on our condensed consolidated balance sheets as a result of the acquisition of CVie Therapeutics Limited, or CVie Therapeutics, in December 2018. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin. In accordance with applicable accounting standards, we are required to review intangible assets and goodwill for impairment on an annual basis, or more frequently where there is an indication of impairment. As discussed in Note 4 of the Notes to our Condensed Consolidated Financial Statements contained in this Quarterly Report on Form 10-Q, during the second quarter, we concluded an initial process to test the industry's interest in investing in our rostafuroxin drug candidate and were not able to secure a licensing transaction or other strategic opportunity at that time. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional phase 2 clinical trial to demonstrate efficacy in non-Caucasian patients in treatment resistant hypertension. Due to these developments, and in connection with the preparation of these interim unaudited condensed consolidated financial statements, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not less than its carrying value. As a result, we have performed the required quantitative impairment assessment of the related intangible asset and determined that the fair value as of June 30, 2021 is approximately $17.0 million, which resulted in us recording a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the three and six months ended June 30, 2021. No events or changes in the business environment occurred during the six months ended June 30, 2021 that would indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired. We are continuing to pursue licensing arrangements and/or other strategic partnerships for rostafuroxin. However, if we are unable to secure such an arrangement or partnership, or if we secure an arrangement for an amount less than anticipated, we may have to record additional impairments related to rostafuroxin in the future, which may materially adversely affect our results of operations and financial condition.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101.1	The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2021 (unaudited) and December 31, 2020, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2021 and June 30, 2020, (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2021 and June 30, 2020, and (iv) Notes to Condensed Consolidated Financial Statements.	
101.INS	Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) (1).	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1).	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1).	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1).	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1).	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1).	Filed herewith.
104	Cover Page Interactive Data File (formatted as Inline XBRL and combined in Exhibit 101.1)	Filed herewith.

(1) These Interactive Data Files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Act of 1934, as amended, or otherwise subject to liability under those sections.

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: August 5, 2021

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

Date: August 5, 2021

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

Exhibit 31.1

CERTIFICATION

I, Craig E. Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 5, 2021

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

Exhibit 31.2

CERTIFICATION

I, John P. Hamill, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 5, 2021

/s/ John P. Hamill
John P. Hamill
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 June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 5, 2021

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

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

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