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

FORM 10-Q

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

For the quarterly period ended March 31, 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

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

As of May 12, 2021, there were 26,257,065 shares of the registrant's common stock outstanding, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 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 novel coronavirus, or COVID-19, pandemic;
- 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 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. changes to 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 potential impairment of our intangible assets and goodwill on our condensed consolidated balance sheet, which could lead to material impairment charges in the future.

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

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

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

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	March 31, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 38,490	$ 16,930
Prepaid expenses and other current assets	851	1,188
Total current assets	39,341	18,118
Property and equipment, net	879	924
Restricted cash	154	154
Operating lease right-of-use assets	2,747	917
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 135,893	$ 112,885
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 939	$ 1,161
Accrued expenses	3,744	3,813
Operating lease liabilities - current portion	392	805
Loans payable - current portion	2,409	352
Total current liabilities	7,484	6,131
Operating lease liabilities - non-current portion	2,438	201
Loans payable - non-current portion	-	2,423
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	2,800	2,800
Deferred tax liabilities	16,683	16,778
Total liabilities	44,405	43,333
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at March 31, 2021 and December 31, 2020; 26,257,089 and 16,921,506 shares issued at March 31, 2021 and December 31, 2020, respectively; 26,257,065 and 16,921,482 shares outstanding at March 31, 2021 and December 31, 2020, respectively	26	17
Additional paid-in capital	821,165	790,277
Accumulated deficit	(726,649)	(717,688)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	91,488	69,552
Total liabilities & stockholders' equity	$ 135,893	$ 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 March 31,	
	2021	**2020**
Expenses:		
Research and development	$ 4,410	$ 3,461
General and administrative	4,669	3,242
Total operating expenses	9,079	6,703
Operating loss	(9,079)	(6,703)
Other (expense) income:		
Interest income	50	89
Interest expense	(41)	(44)
Other income, net	109	124
Total other (expense) income, net	118	169
Net loss	$ (8,961)	$ (6,534)
Net loss per common share		
Basic and diluted	$ (0.51)	$ (0.48)
Weighted average number of common shares outstanding		
Basic and diluted	17,695	13,697

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**

	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)
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
Issuance of common stock and common stock warrants, net of issuance costs	9,230	9	27,381				27,390
Balance - March 31, 2021	**26,257**	$ **26**	$ **821,165**	$ **(726,649)**	**-**	$ **(3,054)**	$ **91,488**

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (8,961)	$ (6,534)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	45	42
Amortization of debt discount	-	3
Stock-based compensation	2,443	1,689
Non-cash lease expense	170	177
Non-cash expense related to equity consideration for a service agreement	494	-
Unrealized gain on foreign exchange rate changes	(109)	-
Changes in:		
Prepaid expenses and other current assets	337	(16)
Accounts payable	(222)	(307)
Collaboration and device development payable	-	(108)
Accrued expenses	(69)	(238)
Operating lease liabilities	(176)	(190)
Net cash used in operating activities	(6,048)	(5,482)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	27,390	-
Proceeds from the ATM Program, net of expenses	570	-
Principal payments on loans payable	(352)	(199)
Net cash provided by (used in) financing activities	27,608	(199)
Effect of exchange rate changes on cash and cash equivalents	-	(98)
Net increase (decrease) in cash, cash equivalents, and restricted cash	21,560	(5,779)
Cash, cash equivalents, and restricted cash - beginning of period	17,084	22,732
Cash, cash equivalents, and restricted cash - end of period	$ 38,644	$ 16,953
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,000	$ -

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 - The Company and Description of Business

We are a clinical-stage, biopharmaceutical 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 acute cardiovascular 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 small 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 hypo-perfusion to critical organs. We believe that istaroxime may fulfill an unmet need in early cardiogenic shock. In addition, our drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile, for which we are pursuing potential out-licensing transactions or other strategic opportunities and not advancing on our own. Our cardiovascular portfolio also includes early exploratory research programs to evaluate potential preclinical product candidates for development, including oral and intravenous sarco (endo) plasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activator heart failure compounds.

Our lead 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 small phase 2 pilot study to assess the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and acute respiratory distress syndrome, or 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 up to 20 patients with COVID-19 and ARDS who are on mechanical ventilation, with results expected in the third 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 outside of Asia, 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 months ended March 31, 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 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 March 31, 2021, we had cash and cash equivalents of $38.5 million and current liabilities of $7.5 million.

On March 25, 2021, we completed a registered public offering, or the March 2021 Offering, of 9,230,500 shares of our common stock and warrants to purchase 9,230,500 shares of our common stock, at a combined price of $3.25 resulting in net proceeds of $27.4 million (*see*, Note 8 - Stockholders' Equity).

We also 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. As of March 31, 2021, we sold 105,083 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million (*see*, Note 8 - Stockholders' Equity).

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 $9.0 million and $6.5 million, respectively, for the three-month periods ended March 31, 2021 and 2020. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2021, we had an accumulated deficit of $726.6 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 March 31, 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 long-term growth rate, (iii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iv) 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.

Based on our annual quantitative impairment assessment of our indefinite-lived IPR&D intangible assets as of December 1, 2020, we concluded that the assets were not impaired, and no subsequent events or changes in circumstances have occurred indicating the intangible assets are more likely than not impaired. With respect to IPR&D related to our rostafuroxin drug candidate, we are evaluating possible out-licensing arrangements and anticipate securing an agreement in 2021. However, if we are unable to secure an out-licensing agreement during 2021, or if we secure an agreement for an amount less than anticipated, there is a risk for impairment of this intangible asset in the near term.

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 as of December 1, 2020, we elected to 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 amount exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing our annual goodwill impairment assessment as of December 1, 2020, we determined the fair value of our reporting unit based upon the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium. Based on the quantitative test performed, the fair value of our reporting unit exceeded its carrying value and no impairment loss was recognized as of December 31, 2020.

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 amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the

significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in our closing share price following the March 2021 Offering, which was completed on March 25, 2021, 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. However, if our share price does not improve during the remainder of the second quarter, our reporting unit is at risk for future impairment in the near term.

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

(in thousands)	March 31, 2021	December 31, 2020
Rostafuroxin drug candidate	$ 54,750	$ 54,750
Istaroxime drug candidate	22,340	22,340
Intangible assets	77,090	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) income, net. Foreign currency transactions resulted in gains of approximately $0.1 million and $0.2 million, respectively, for the three-month periods ended March 31, 2021 and 2020.

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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

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 will be paid ratably through August 2021. During the three months ended March 31, 2021, $0.2 million was paid and $0.3 million remains accrued.

Restructured Debt Liability – Contingent Milestone Payment

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

Research and Development

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

Income Taxes

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

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

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of March 31, 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 6.5 million shares, respectively. For the three months ended March 31, 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. 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 other 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 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 and liabilities measured at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value March 31, 2021	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 32,077	$ 32,077	$ -	$ -
U.S. Treasury notes	3,029	3,029	-	-
Total Assets	$ 35,106	$ 35,106	$ -	$ -

(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	$ -	$ -

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 the second quarter of 2020, we were informed by Lee's of their desire to reduce the amount of pledged bank deposits with O-Bank by 50%. To remain in compliance with the terms of the O-Bank Facility, we repaid approximately $2.3 million of the outstanding principal in August 2020. In November 2020, Lee's committed to maintain the required level of pledged bank deposits with O-Bank through the date of full repayment of the O-Bank Facility.

As of March 31, 2021 and December 31, 2020, the outstanding principal of the O-Bank Facility was approximately $2.4 million. As of March 31, 2021, the outstanding principal is classified as loans payable - current portion as it is due within one year of the balance sheet date. As of December 31, 2020, the outstanding principal was classified as loans payable - non-current portion.

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 and there was no outstanding balance on the loan as of March 31, 2021.

Note 7 - Restructured Debt Liability

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

As of March 31, 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 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.

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.

As of March 31, 2021, we sold 105,083 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million.

Note 9 - Stock Options and Stock-Based Employee Compensation

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

A summary of activity under our long-term incentive 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	1,339	5.46	
Forfeited or expired	(2)	11.85	
Outstanding at March 31, 2021	3,240	$ 11.39	8.6
Vested and exercisable at March 31, 2021	1,353	$ 17.19	7.5
Vested and expected to vest at March 31, 2021	3,020	$ 11.50	8.5

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

(in thousands)	Three Months Ended March 31, 2021	2020
Research and development	$ 939	$ 714
General and administrative	1,504	975
Total	$ 2,443	$ 1,689

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

	Three Months Ended March 31, 2021
Weighted average expected volatility	105%
Weighted average expected term (in years)	6.6
Weighted average risk-free interest rate	0.48%
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 have 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.

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

As of March 31, 2021, the liability balance related to the payments under the PF Agreement was $2.8 million and is recorded in other liabilities.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the 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, 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 acute cardiovascular 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 small 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 hypo-perfusion to critical organs. We believe that istaroxime may fulfill an unmet need in early cardiogenic shock. In addition, our drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile, for which we are pursuing potential out-licensing transactions or other strategic opportunities and not advancing on our own. Our cardiovascular portfolio also includes early exploratory research programs to evaluate potential preclinical product candidates for development, including oral and intravenous sarco (endo) plasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activator heart failure compounds.

Our lead 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 small phase 2 pilot study to assess the ability of our KL4 surfactant liquid instillate to impact key respiratory parameters in the treatment of lung injury and acute respiratory distress syndrome, or 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 up to 20 patients with COVID-19 and ARDS who are on mechanical ventilation, with results expected in the third 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 outside of Asia, 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 March 31, 2021 and 2020, we had operating losses of $9.1 million and $6.7 million, respectively. As of March 31, 2021, we had an accumulated deficit of $726.6 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 outside of Asia, 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 September 2020, we initiated a small phase 2 clinical study of istaroxime for the acute treatment of early cardiogenic shock in heart failure patients with a more severe case of heart failure to evaluate the potential to improve blood pressure and organ perfusion. The study also will evaluate the safety and side

effect profile of istaroxime in this patient population. We expect data to be available in the second half of 2021. With the current global COVID-19 pandemic, however, and its disruptive effect on hospital resources, including intensive care units, where this study is being conducted, and availability of services and professional staff, we have experienced delays in our site-set-up activities and 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, planning an additional phase 2 clinical trial that will enroll up to 300 patients in approximately 75 clinical sites globally. The trial will focus on enrolling 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. This trial has been designed to collect data on measures that may serve as primary endpoints in a phase 3 clinical trial, and will include an optimized dosing regimen, potentially extending the infusion time beyond 24 hours. We currently do not have sufficient capital to initiate this clinical trial. We are exploring capital from public and private equity offerings and potential strategic opportunities to fund the initiation of this clinical trial, and plan to initiate the clinical trial after obtaining adequate funding. We plan to closely monitor the impact of the COVID-19 pandemic and its impact on hospital resources and resulting potential changes in regulatory timelines for conducting non-COVID-19-related clinical trials.

Rostafuroxin

Rostafuroxin has been studied in three phase 2 clinical trials assessing reduction in blood pressure in a hypertensive population selected in accordance with the specified genetic profile. After positive phase 2a results, a phase 2b study was initiated. In this most recent phase 2b clinical trial, rostafuroxin demonstrated efficacy in Caucasian patients but not in Chinese patients. We are nearing the end of a process to test the industry's interest in investing in new drugs in this market and are pursuing potential licensing transactions and/or other strategic opportunities.

Preclinical Oral, Chronic and Acute Heart Failure Product Candidates

We are pursuing several early exploratory research programs to assess potential product candidates, including oral and intravenous SERCA2a activator heart failure compounds, and believe that we can add value to our cardiovascular portfolio by advancing these SERCA2a activator candidates through preclinical studies. To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements or other strategic opportunities.

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

In 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 up to 20 patients with COVID-19 and ARDS who are on mechanical ventilation, from four to five U.S. sites, with data expected in the third quarter of 2021.

AEROSURF (lucinactant for inhalation)

We are supporting, and plan to continue to support, 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 preparing to transfer 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.

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. 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 other 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 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.

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 long-term growth rate, (iii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iv) 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.

Based on our annual quantitative impairment assessment of our indefinite-lived IPR&D intangible assets as of December 1, 2020, we concluded that the assets were not impaired, and no subsequent events or changes in circumstances have occurred indicating the intangible assets are more likely than not impaired. With respect to IPR&D related to our rostafuroxin drug candidate, we are evaluating possible out-licensing arrangements and anticipate securing an agreement in 2021. However, if we are unable to secure an out-licensing agreement during 2021, or if we secure an agreement for an amount less than anticipated, there is a risk for impairment of this intangible asset in the near term.

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 as of December 1, 2020, we elected to 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 amount exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing our annual goodwill impairment assessment as of December 1, 2020, we determined the fair value of our reporting unit based upon the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium. Based on the quantitative test performed, the fair value of our reporting unit exceeded its carrying value and no impairment loss was recognized as of December 31, 2020.

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 amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in our closing share price following a registered public offering, or the March 2021 Offering, which was completed on March 25, 2021, 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. However, if our share price does not improve during the remainder of the second quarter, our reporting unit is at risk for future impairment in the near term.

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

(in thousands)	**March 31, 2021**	**December 31, 2020**
Rostafuroxin drug candidate	$ 54,750	$ 54,750
Istaroxime drug candidate	22,340	22,340
Intangible assets	77,090	77,090
Goodwill	$ 15,682	$ 15,682

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended March 31, 2021 and 2020 was $9.1 million and $6.7 million, respectively. The increase in operating loss from 2020 to 2021 was due to a $2.4 million increase in operating expenses, which includes a $0.8 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 March 31, 2021 and 2020 was $9.0 million and $6.5 million, respectively.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, consulting and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical and regulatory operations expenses, to specific programs. We also account for research and development and report annually by major expense category as follows: (i) contracted services; (ii) salaries and benefits; (iii) stock-based compensation; (iv) raw materials, aerosol devices and supplies; (v) royalties; (vi) rents and utilities; (vii) depreciation; (viii) travel; and (ix) other. We expect to increase our investment in research and development in order to advance our product candidates through additional clinical trials. As a result, we expect that our research and development expenses will increase throughout the foreseeable future as we pursue clinical development of istaroxime, 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 March 31, 2021	2020
Istaroxime - early cardiogenic shock	$ 506	$ 170
KL4 surfactant	244	331
Istaroxime - AHF	499	174
Preclinical studies	-	4
Total direct clinical and preclinical programs	1,249	679
Product development and manufacturing	1,087	1,064
Clinical, medical and regulatory operations	2,074	1,718
Total research and development expenses	$ 4,410	$ 3,461

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

Direct clinical and preclinical development programs expenses increased $0.6 million for the three months ended March 31, 2021 compared to the same period in 2020 due to ongoing clinical studies of istaroxime for early cardiogenic shock and our continued development of istaroxime for AHF.

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 our AEROSURF clinical development program; and (iii) pharmaceutical and manufacturing development activities of our drug product candidates including development of istaroxime, lyophilized KL4 surfactant, and rostafuroxin. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses were comparable for the three months ended March 31, 2021 and 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 $0.4 million for the three months ended March 31, 2021 compared to the same period in 2020 due to an increase of $0.3 million in personnel costs and an increase of $0.1 million in non-cash, stock compensation expense.

General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2021	2020
General and administrative expenses	$ 4,669	$ 3,242

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 increased $1.4 million for the three months ended March 31, 2021 compared to the same period in 2020 due to (i) an increase of $1.0 million in professional fees and insurance, 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 March 31, 2021	2020
Interest income	$ 50	$ 89
Interest expense	(41)	(44)
Other income, net	109	124
Total other (expense) income, net	$ 118	$ 169

Interest income relates to interest on our money market account and U.S. Treasury notes.

For the three months ended March 31, 2021 and 2020, interest expense consists of interest expense associated with loans payable and for the three months ended March 31, 2020 also includes interest expense related to collaboration and device development payables.

For the three months ended March 31, 2021 and 2020, other income, net primarily consists of $0.1 million and $0.2 million, respectively, in gains on foreign currency translation, partially offset by $38,000 in realized losses on U.S. Treasury notes for the three months ended March 31, 2020.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2021, we had cash and cash equivalents of $38.5 million and current liabilities of $7.5 million.

On March 25, 2021, we completed a registered public offering of 9,230,500 shares of our common stock and warrants to purchase 9,230,500 shares of our common stock, at a combined price of $3.25 resulting in net proceeds of $27.4 million (*see*, Note 8 - Stockholders' Equity).

We also 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. As of March 31, 2021, we sold 105,083 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million (*see*, Note 8 - Stockholders' Equity).

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 $9.0 million and $6.5 million, respectively, for the three-month periods ended March 31, 2021 and 2020. We expect to continue to incur operating losses for at least the next several years. As of March 31, 2021, we had an accumulated deficit of $726.6 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 March 31, 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 three months ended March 31, 2021 consist of $6.0 million of net cash used in operating activities and $27.6 million of net cash provided by financing activities. Cash flows for the three months ended March 31, 2020 consist of $5.5 million of net cash used in operating activities and $0.2 million of net cash used in financing activities.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2021 and 2020 was $6.0 million and $5.5 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The increase in net cash used in operating activities from 2020 to 2021 is primarily due to a $2.4 million increase in operating expenses and $0.1 million in changes in working capital, partially offset by $3.0 million of non-cash items for the three months ended March 31, 2021.

Financing Activities

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

principal payments on loans payable. Net cash used in financing activities for the three months ended March 31, 2020 was $0.2 million and represents principal payments on loans payable.

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

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 the second quarter of 2020, we were informed by Lee's of their desire to reduce the amount of pledged bank deposits with O-Bank by 50%. To remain in compliance with the terms of the O-Bank Facility, we repaid approximately $2.3 million of the outstanding principal in August 2020. In November 2020, Lee's committed to maintain the required level of pledged bank deposits with O-Bank through the date of full repayment of the O-Bank Facility.

As of March 31, 2021 and December 31, 2020, the outstanding principal of the O-Bank Facility was approximately $2.4 million. As of March 31, 2021, the outstanding principal is classified as loans payable - current portion as it is due within one year of the balance sheet date. As of December 31, 2020, the outstanding principal was classified as loans payable - non-current portion.

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 and there was no outstanding balance on the loan as of March 31, 2021.

Common Stock Offerings

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

At-The-Market Program

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

As of March 31, 2021, we sold 105,083 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $0.6 million (*see*, Note 8 - Stockholders' Equity).

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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at March 31, 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 March 31, 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. 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 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 have a significant amount of intangible assets, including goodwill, recorded on our condensed consolidated balance sheets which may lead to potentially significant impairment charges.

We have recorded significant goodwill and intangible assets on our condensed consolidated balance sheets as a result of a previous acquisition, which could become impaired and lead to material charges in the future. The amount of identifiable intangible assets and goodwill in our condensed consolidated balance sheets is significant due to the acquisition of CVie Therapeutics Ltd., or CVie Therapeutics, in December 2018. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin, which as of March 31, 2021 are $22.3 million and $54.8 million, respectively, recorded in aggregate on our condensed consolidated balance sheets as intangible assets of $77.1 million. At March 31, 2021, goodwill recorded on our condensed consolidated balance sheets was $15.7 million.

We review intangible assets and goodwill for impairment at least annually or when events or changes in the business environment indicate that the carrying value may be impaired. If an impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict, including the uncertainties associated with the development of product candidates and the success of business development activities, and are an inherent risk in the pharmaceutical industry.

With respect to IPR&D related to our rostafuroxin drug candidate, we are evaluating possible out-licensing arrangements and anticipate securing an agreement in 2021. However, if we are unable to secure an out-licensing agreement during 2021, or if we secure an agreement for an amount less than anticipated, there is a risk for impairment of this intangible asset in the near term. We have also experienced a declining trend in our closing share price following a registered public offering, or the March 2021 Offering, which was completed on March 25, 2021, due to both market conditions and the dilution of our common stock as a result of the March 2021 Offering. If our share price does not improve during the remainder of the second quarter, our reporting unit is at risk for future impairment in the near term. Should such an impairment of goodwill or intangible assets occur, which would require us to record a potentially significant impairment charge, our financial condition and results of operations in a future period could be negatively impacted.

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

On February 2, 2021, we issued 170,000 warrants to a service provider as compensation for certain financial advisory services. The warrants are immediately exercisable for shares of common stock at a price of $8.25 per share and expire three years from the date of issuance. The issuances of these securities were exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, in that the transactions were by an issuer not involving any public offering.

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
10.1†	Agreement for Scientific Collaboration between Universita degli Studi di Milano-Bicocca and CVie Therapeutics Ltd, a wholly-owned subsidiary of the Registrant, dated March 19, 2021.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101.1	The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of March 31, 2021 (unaudited) and December 31, 2020, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2021 and March 31, 2020, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2021 and March 31, 2020, and (iv) Notes to Condensed Consolidated Financial Statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

Compensation Related Contract.
† Certain confidential portions have been omitted from this exhibit pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: May 13, 2021

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

Date: May 13, 2021

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

Exhibit 10.1

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

AGREEMENT FOR SCIENTIFIC COLLABORATION

BETWEEN

UNIVERSITÀ DEGLI STUDI DI MILANO-BICOCCA with headquarters at Piazza dell'Ateneo Nuovo 1 in Milan, Tax No. [***], in the person of the Vice-Rector for Research Valorisation and Technology Transfer of University of Milano-Bicocca, Prof. Salvatore Torrisi, authority granted by Rector's Decree no. rep. 5291/2019 Prot. 0073728/19 of 1st October 2019, in accordance with Det. Dir. 0030539/21 of 02.03.2021 (hereinafter referred to as "University"),

AND

WINDTREE THERAPEUTICS, INC., by and through its wholly-owned subsidiary CVie Therapeutics Ltd., with offices in Italy at Studio De Giorgi, Via E. Motta N. 10, 20144 Milano, in the person of the Senior Vice President and Chief Medical Officer of Windtree Therapeutics, Inc., Steven G. Simonson, M.D. (hereinafter referred to as "Company").

The following sets forth the general principles, terms and conditions to be contained in this agreement (the "**Agreement**"):

I. DEFINITIONS:

"Background Patents" means the patents and patent applications claiming any of the Istaroxime Products, the SERCA2a Compounds (excluding New SERCA2a Compounds) and the SERCA2a Products (other than New SERCA2a Products) or their manufacture or use owned, licensed to or controlled by Company or any of its affiliates as of the Effective Date, as well as any and all continuations, continuations-in-part or divisions thereof, any patent application claiming priority thereto, any granted patent resulting from such applications and any supplementary protection certificate (SPC) thereof including those set forth on Annex A1.

"Background Know-How" means, without limitation, any and all technical information, test, assay and development, preclinical and clinical data and results, formulations, processes (including manufacturing), ideas, protocols, regulatory files and the like relating to the Istaroxime Products, the SERCA2a Compounds (excluding New SERCA2a Compounds) and the SERCA2a Products (other than New SERCA2a Products), which is secret, non-patented and which is owned, licensed to or controlled by Company or any of its affiliates as of the Effective Date including those set forth on Annex A2.

"Company IP" means collectively Background Patents and Background Know-How.

"Effective Date" means the latest date of signature of this Agreement.

"Foreground Know-How" means, without limitation, all technical information, test, assay and development data and results, formulations, processes (including manufacturing), ideas, protocols, and regulatory documents which may result from the collaboration relating to or leading to:

1) design and/or synthesis of New SERCA2 Compounds and/or New SERCA2a Products; and/or

2) identification of unknown effects and potential therapeutic applications of SERCA2a modulation by SERCA2a Compounds including New SERCA2a Compounds.

"Foreground Patents" means the patents and patent applications claiming any of the New SERCA2a Compounds and/or New SERCA2a Products or their manufacturing or use, as well as any and all continuations, continuations-in-part or divisions thereof, any granted patent resulting from such applications and any supplementary protection certificate (SPC) thereof.

"Foreground Outcome" means collectively Foreground Patents and Foreground Know-How.

"Istaroxime" means the active pharmaceutical ingredient having the chemical name [***].

"Istaroxime Products" means all formulations of pharmaceutical products containing Istaroxime.

"New SERCA2a Compound" means a SERCA2a Compound first designed under this Agreement.

"New SERCA2a Product" means a formulation of a pharmaceutical product containing one or more New SERCA2a Compounds.

"PLN" means Phospholamban, a low molecular weight phosphoprotein, expressed by cardiac cells, that, by reversibly inhibiting SERCA2a function, mediates physiological regulation of cardiac calcium handling and contractility.

"SERCA2a" means the cardiac sarcoplasmic reticulum Ca(2+) ATPase.

"SERCA2a Compound(s)" means molecules that are endowed with SERCA2a stimulating effect, including those acting through regulation of PLN interaction with SERCA2a.

II. WHEREAS:

a) On April 14, 2015, University and Company entered into an agreement of scientific collaboration in the sector of basic and pharmacological research**;**

b) Company is the owner of the Company IP;

c) Company has among its objectives to discover and develop new molecules endowed of stimulatory activity on SERCA2a for the treatment of conditions resulting from SERCA2a dysfunction, including acute and/or chronic heart failure in humans, by using scientific and commercially reasonable efforts;

d) Company has unique expertise in the evaluation of modulation of SERCA2a-/Na^+/K^+ pump enzymatic activities in cardiac microsomes and the associated pharmacological/toxicological tools aimed at selecting a candidate compound to move to clinical development.

e) The "University research groups" participating in the Study and Research Program (see Annex B) have 1) significant expertise in the field of pathophysiology of cardiac excitation-contraction coupling with particular reference to the role of SERCA2a activity and its pharmacological modulation; and 2) unique expertise in the design, synthesis and biological validation of SERCA2a Compounds.

f) Company and University desire to continue the collaboration started through (1) the Collaboration Agreement signed by University and CVie Therapeutics, Ltd. on April 14, 2015 and extended on August 14, 2018, and (2) the Research Agreement signed by University and CVie Therapeutics, Ltd. on April 19, 2018 having Professor Francesco Peri as Principal Investigator for University; in particular, University and Company desire to continue a scientific collaboration concerning the study of the role of SERCA2a and PLN in modulating cell function and the discovery of new molecules endowed of modulatory activity on SERCA2a and PLN in order to develop a drug(s) useful for the chronic and acute treatment of heart failure.

g) Company and University agreed to review and amend the aforementioned agreements as listed in section f) above, and any related agreements not listed, through a new agreement stipulated on 13 June 2019, expiring on 12 June 2020.

h) On January 24, 2019 University and CVie Therapeutics Ltd. signed an "Assignment" concerning the European patent application no. [***]. This agreement shall remain fully executed between University and Company.

i) On 12 June 2020 University and Company agreed on an extension of the duration of the Agreement signed on 13 June 2019 until 31 December 2020;

j) University and Company have agreed that University will assign ownership in the jointly filed European patent application no [***] and counterpart application [***] and [***] to Company;

k) University and Company intend to continue their cooperation under the following conditions

IT IS AGREED AS FOLLOWS

Article 1 – Subject Matter

By way of this Agreement, University and Company (hereinafter each a "**Party**" and collectively the "**Parties**") agree to continue their relationship of scientific collaboration in the sector of synthetic chemistry, basic and pharmacological research aimed at developing New SERCA2a Compounds for use in New SERCA2a Products indicated for the treatment of chronic and acute human heart failure.

The Study and Research Program, as described in the Technical Annex to this Agreement (Annex B), sets out the objectives and purposes of the Study and Research Program (sometimes referred to herein as the "**Project**"), which shall be pursued through the scientific collaboration of researchers from University (the "**University research units**") and Company (the "**Company research unit**"), hosted by University in the Department of Biotechnology and Bioscience.

The Study and Research Program will conclude with the preparation by the Parties of a full report on the Study and Research Program results.

Any further research activities, not included in the Study and Research Program (Annex B), will be regulated in separate agreements between the Parties.

Article 2 – Scientific Heads of the Study and Research Program

University designates as its Scientific Heads of the Study and Research Program, all of them operating in University's Department of Biotechnology and Biosciences: Prof. Antonio Zaza (tenured Professor of Physiology); Prof. Francesco Peri (tenured Professor of Organic Chemistry), Prof. Marcella Rocchetti (tenured Associate Professor of Physiology) and Prof. Cristina Airoldi (tenured Associate Professor of Organic Chemistry).

Company designates Dr. Steven G. Simonson (Chief Medical Officer of Company) and one other delegate, which at the outset shall be Professor Giuseppe Bianchi, as its Scientific Heads of the Study and Research Program.

The Scientific Heads of the Study and Research Program undertake to collaborate for the success of the Project and for the solution of any problem connected with the realization of the Project.

Any replacement of the Scientific Heads of the Study and Research Program must be notified to and approved in advance in writing by the other Party.

Article 3 – Facilities, Equipment or Resources Made Available for the Study and Research Program

The resources necessary to carry out the activity covered by this Agreement will be provided by Company and University respectively, as detailed in Annex C. In general, these will include:

- The knowledge and confidential information necessary for the implementation and development of the Study and Research Program;
- Staff with specific skills for the activities of the Project;
- Laboratory space;
- Equipment and instrumentation in support of the Project activities to be carried out in the laboratories of Organic Chemistry, Cardiac Biochemistry and Cardiac Cell Physiology;
- Consumable materials required to carry out the activities of the Project.

Article 3.1 – **Facilities made available by University**

University, for the purposes of the activities covered by this Agreement, to be carried out in cooperation between the Parties, will provide some resources and facilities available at the Biotechnology and Biosciences Department, as specified below:

1) two laboratories of "Cardiac Cell Physiology" directed by Prof. Antonio Zaza and Prof. Marcella Rocchetti respectively, housed in Building U3 rooms # [***] and [***] will be made available to research activities related to the present Agreement on a non-exclusive basis and for the duration of this Agreement.

2) two laboratories of "Organic Chemistry" directed by Prof. Francesco Peri and Prof. Cristina Airoldi, housed in Building U3 room # [***] and [***] will be made available to research activities related to the present Agreement on a non-exclusive basis and for the duration of this Agreement.

3) rooms # [***] and [***] (the layout of which is shown in Annex D) in which the laboratory "Cardiac Biochemistry" was set up by virtue of the agreement stipulated on April 14, 2015 and assigned to Prof. Antonio Zaza as extra laboratory space for the establishment of the Laboratory "Cardiac Biochemistry", that is intended exclusively for the conduct of research activities related to the present Agreement. The rooms, Room # [***] and [***], will be made available by University for the whole duration of the collaboration, as ruled by the present Agreement. Access to the facilities of the Department of Biotechnology and Biosciences and to the spaces that will form the Laboratories of Cardiac Biochemistry, Cardiac Cell Physiology and Organic Chemistry will be permitted to staff and researchers employed by Company whose names must be notified in advance to the those responsible for this Agreement and authorized by the competent bodies of University, in accordance with current Italian legislation on insurance and occupational safety. The University will have to bear the radiation and health surveillance of researcher employed by the Company working in the Department of Biotechnology and Biosciences.

University Scientific Heads must always be informed by Company Scientific Head regarding the staff assigned by Company to participate in the Study and Research Program, including any replacement or additional staff in the course of work as may be necessary for technical and organizational reasons.

It is understood that the equipment made available or purchased by University for the purposes of the Project will remain the property of University.

Article 3.2 – **Resources made available from Company**

Company, for the purposes of the activities covered by this Agreement, to be carried out in cooperation between the Parties, will make available the following:

1) equipment necessary for conducting Project activities, already placed at Cardiac Biochemistry Laboratory (to be hosted in Room # [***]), by virtue of the Agreement stipulated on April 14, 2015, described in the Annex C. The expenses related to ordinary and extraordinary maintenance and transport of the equipment will be paid by Company;

2) consumable materials necessary for conducting Project activities in the Cardiac Biochemistry Laboratory (room #[***]);

3) staff qualified to carry out research activities in the Cardiac Biochemistry Laboratory as specified in Annex C;

4) a grant equal to € [***] (not including VAT pursuant to art. 7-ter dpr 633/1972 – Italian law), to fund research activities by the Organic Chemistry and Cell Physiology laboratories for 12 months, to be used by University Research Units accordingly to costs justification in Annex B. This amount will be paid as follows:

   - € [***] will be invoiced by University to Company as soon as practicable upon the signing of the present Agreement.
   - € [***] will invoiced by University to Company after six months from the signing of the present Agreement.
   - € [***] will be invoiced by University to Company upon expiry of the present Agreement, after the release of the final, exhaustive and detailed Scientific Report related to the activities carried out in the collaboration (see Article 5, point 2).

5) € [***], to cover laboratory space and operation costs (as example: waste disposal – including radioactive material, technical gases, use of core facilities and equipment) of rooms #[***] and [***], hosting the research activities of the Cardiac Biochemistry Laboratory, to be invoiced by University to Company upon signing of this Agreement. It is understood that this amount of € [***] shall not include costs for other research facilities as indicated in the research budget under Annex C.

University will issue invoices for all payments to be made by Company; the invoices will be sent to:

[***].

Invoices will be payable within 30 days of receipt by Company.

Article 4 – **Secrecy**

For the purposes of this Agreement the Parties consider as classified and confidential any information that a Party deems necessary to supply the other with for the implementation of the Study and Research Program and supplied through a document, other tangible media, verbally or following a visit to the business or laboratory, during meetings or talks and the like (hereinafter "**Confidential Information**").

To be considered as confidential the Confidential Information must be revealed in writing and marked as confidential. If information is revealed verbally it will be reduced to writing within 30 days and clearly marked as confidential. Notwithstanding the foregoing, if the information revealed is of a nature that a person of skill in the relevant area would understand it to be confidential, then such information will be considered confidential for purpose of this Agreement, even if it is not so designated in the above mentioned 30 days' term.

The Parties undertake to:

- maintain the Confidential Information secret and classified and not disclose it to third parties;

- limit the use of the Confidential Information to activities connected to the Study and Research Program and not extend the use and/or application thereof to anything else;

- assure that the Confidential Information is circulated and disseminated within one's organization solely to persons directly involved in activities in connection with the development of the Study and Research Program;

- assure that all of the persons to whom the Confidential Information is made available are aware of its confidential nature and adhere to the terms and conditions of this agreement regarding the protection, use and publication of the Confidential Information and the results of Study and Research Program.

The Parties shall be liable for the observance of the obligations laid down in this article by their Scientific Heads and collaborators.

The Parties also consider as confidential all of the results of the Study and Research Program and their use shall be governed by the provisions of articles 5 and 6 below.

Article 5 – Results of the Scientific Collaboration

1. The technical, scientific, applicational and inventive assessment of the results of the Study and Research Program will be carried out by the researchers referred to in Art. 2, in accordance with the terms and conditions agreed upon by them.

2. Scientific Report on the results achieved through the Study and Research Program will be filed by the Research Units of both Parties under the supervision of their respective Scientific Heads at the end of the Agreement period, as reported at Article 3.2, point #4. The Scientific Report must be based on data developed under this Agreement, all of which must be recorded and stored in the laboratory note books available for any consultations related to patent filing and review and/or due diligence by regulatory agencies or possible partners.

3. Property on the outcome of the Study and Research Program will be ruled as follows:

i. Company will remain the exclusive owner of Background Patents and Background Know-How (Company IP);

ii. Foreground Patents and Foreground Know-How and of the related investigation results (Foreground Outcome), achieved through the collaboration in accordance with this Agreement between Company and University, shall remain the joint property of the two Parties.

iii. In the event that the Parties, in full and effective collaboration, will achieve Foreground Outcome worthy of patent or similar forms of protection, or which can be protected by copyright, the regime for these results will be that of equal co-ownership.

iv. If Company confirms its interest in patenting or registration of such inventive Foreground Outcome – by sending appropriate communication to University concerning such interest within 30 (thirty) days after University or Company provides a formal disclosure to the other Party of the achievement of the inventive Foreground Outcome – the Parties shall immediately initiate joint procedures for its legal protection, provided that Company will bear the full expenses for the professional fees of the patent attorney in charge of any such patent application, and related patent office fees.

Within 30 (thirty days) from the joint filing, University shall sign an agreement to assign to Company its entire share of joint patent application that is filed, such that Company will become the sole owner of any such patent application and all patents issuing therefrom, and Company will prosecute to bear the full expenses for the professional fees of the patent attorney in charge of any such patent application, and patent office fees, provided that the assignment will be recorded only after publication of the patent applications, for example, publication of a PCT patent application.

v. In the case of point iv, Company will pay to University:

i. € (Euro) 25.000 (twenty-five thousand) at the signature of the above-mentioned agreement for assignment to Company of University's share in the Foreground Patents;

ii. a non-reimbursable, non-creditable amount which shall correspond to the stage of development of the Foreground Outcome toward commercial exploitation, as follows:

a) € (Euro) 75.000 (seventy-five thousand) in reference to the Foreground Outcome for which the proof of biological efficacy of new compounds on modulating the SERCA2a activity in cell-free systems, or its functional counterpart in isolated cells will be available. This proof means that subsequent preclinical testing in animals, that may be completed outside of Bicocca University, are consistent with the data generated from cellular systems, and the compound has characteristics indicating its potential utility as a drug product.

b) € (Euro) 1.500.000 (one million-five hundred thousand) in reference to the Foreground Outcome that will be developed upon the obtainment of the marketing authorization of any New SERCA2a Products for use in humans in any of the following countries: USA, EU, China of new compounds with, if any, the corresponding companion diagnostic assay**.**

vi. Royalties for the Foreground Outcome: Company shall pay to University the following a progressive downgrade of the royalty proportionally to the rise of the sales of the Foreground Outcomes sold by Company, its affiliates or third-party sublicenses in the world:

a)

ROYALTY	SALES (Euros)
[***]% royalty in countries where there is any Foreground Patent covering the New SERCA2a Compound, until expiry of the last to expire of such Foreground Patents.	Up to [***]
[***]% royalty in countries where there is any Foreground Patent covering the New SERCA2a Compound, until expiry of the last to expire of such Foreground Patents.	From [***] to [***]
[***]% royalty in countries where there is any Foreground Patent covering the New SERCA2a Compound, until expiry of the last to expire of such Foreground Patents.	From [***] to [***]
[***]% royalty in countries where there is any Foreground Patent covering the New SERCA2a Compound, until expiry of the last to expire of such Foreground Patents.	Above [***]

b)

ROYALTY	SALES (Euros)
[***]% royalty in countries where there are no Foreground Patents, for [***] years from the first commercial sale of the Foreground Outcome.	Up to [***]
[***]% royalty in countries where there are no Foreground Patents, for [***] years from the first commercial sale of the Foreground Outcome.	From [***] to [***]
[***]% royalty in countries where there are no Foreground Patents, for [***] years from the first commercial sale of the Foreground Outcome.	From [***] to [***]
[***]% royalty in countries where there are no Foreground Patents, for [***] years from the first commercial sale of the Foreground Outcome.	Above [***]

vii. Revenues from sales of products manufactured using the Foreground Outcome will be accounted for separately and an annual report of sales and revenues earned will be sent to University.

viii. Company shall assign free of charge to University its entire titles, interests and rights on its share of such inventive Foreground Outcome:

a. if within 30 (thirty) days after University or Company provides a formal disclosure to the other Party of the achievement of any inventive Foreground Outcome, Company will not confirm its interest in patenting or registration of such inventive Foreground Outcome; or

b. if Company will not be interested in carrying on/prosecuting pre-clinical and/or clinical studies related to any Foreground Outcome. In such case, Company shall inform University 30 (thirty) days in advance; or

c. if Company will not be interested in carrying on/prosecuting patent protection. In such case, Company shall inform University 30 days in advance of the expiry date of the patent action.

d. if Company will not be interested in carrying on/prosecuting any actions for commercial exploitation of Foreground Outcome. In such case, Company shall inform University 30 (thirty) days in advance.

4. It is understood that the payments/royalties of the precedent clause 3 of the present article shall be due to University also in any case of assignment to third parties of Company rights on Foreground Outcome and/or Foreground Patents and Company agrees and warrants that it shall procure that the interest third party shall agree with all terms and conditions of the present Agreement and shall pay to University any and all amounts due/payable at the date of assignment.

5. University warrants that: (a) to the extent required by University rules, it has entered into separate internal agreements with any inventors on patent applications and patents directed to Foreground Outcomes who are employees of University as to such inventors' shares of any proceeds paid to University by Company in connection with this Agreement, and that Company has no financial obligation whatsoever with respect to such inventors; and (b) since the inception of this collaboration and the signing of the first collaboration agreement on April 14, 2015, Company has no financial obligations whatsoever to any person, other than the obligations recited specifically in this Agreement.

6. No prejudice exists, in any case, with regard to the exclusive ownership of knowledge obtained independently outside the scope of this Agreement by the Parties, and with their own means.

7. Except as provided for in this Agreement, it is understood that the results which do not give rise to intellectual property rights may be publicly disseminated, but any such use or disclosure thereof may be made only according to the unanimous agreement of the parties.

8. The Researchers of University and Company that will be involved in the activities covered by this Agreement, before participation in such activities, must sign a statement and contextual act of transfer of their results according to the model of Annex E and F.

9. It is understood that, in the case Company will remain the sole owner of Foreground Outcome, University shall be entitled to request Company authorization to use any Foreground Outcome (knowledge and compounds) for institutional study and research purposes, including research projects, wherein such request will be in writing and will fully detail the proposed research, and express written agreement by Company must be received by University before commencement of such research. The authorization shall not be unreasonably refused.

10. University shall have the right to record the patent application in University's public database of patents, where will be indicated just number and date of filing.

Article 6 – Publication of the Results

Any publication of the results of the Study and Research Program must be agreed in advance by the Scientific Heads referred to in article 2 and shall be governed by the following rules.

In the case of results that are jointly achieved in full and effective collaboration stemming from homogeneous contributions by the Parties that cannot objectively be distinguished from each other, the Parties undertake to jointly publish even though it may be information made known by one Party to another confidentially. In that case the publications must state the names of the authors in conformity with applicable guidelines.

In the case of results achieved stemming from independent and separable contributions by the Parties even though organized in a unitary manner, each Party may independently publish and/or disclose the results of its own studies, research and experimental results, recognizing the contribution of the other Party for the conclusion and implementation of this contract. However, if those publications contain data and information made known by one Party to the other Party confidentially, the Parties must seek the prior authorization of the Party who disclosed such data and information and must cite the names of the authors in the publications, if any, in conformity with applicable guidelines.

The publication of the results must be temporarily postponed for the time necessary for the legal protection of the inventive results, if any. Each Party agrees to postpone any publication for 90 days after notifying the other Party of its intention to publish.

Article 7 – Use of the Parties' Names and/or Logos

Each Party undertakes not to use the name and/or logo of the other Party for advertising purposes, unless otherwise specifically agreed between the Parties.

Article 8 – Insurance Coverage

University personnel are insured against accidents, according to the applicable law, and civil liability. University may use duly and specifically authorised external personnel (for example, doctoral students, research grantees and collaborators). If the said external personnel turn out not to be covered by suitable insurance, participation in the research program is conditional on the taking out of such appropriate insurance coverage.

Company assures that it either has or will take out insurance coverage against accidents and civil liability for its employees, scholarship holders or collaborators involved in the carrying out of activities pursuant to this Agreement.

Article 9 – Occupational Health and Safety

Further to the laws and regulations in force regarding occupational health and safety and especially articles 2 and 26 of Legislative Decree No. 81/08 as amended and associated implementing regulations, it is agreed that:

- before the commencement of any activities covered by this agreement the Scientific Heads for this agreement shall notify their respective Safety and Prevention Officers of the names, job descriptions and contact details of the individuals involved and the effective start date of the activities, specifying – if necessary and not otherwise specified in this Agreement – the areas that those same activities concern;

- the Safety and Prevention Officers shall liaise with each other pursuant to article 26 to establish whether it is necessary to exchange Risk Assessment Documents under article 28 of Legislative Decree No. 81/08 as amended so as to enable the relevant steps to be taken;

- if envisaged and necessary the said individuals, whose names are to be communicated, must undergo additional medical checkups by the body that they belong to.

- The host body must in any case arrange to:

- provide training on emergencies and the emergency procedures in force in the places that the abovementioned individuals visit;

- provide information to guests on the specific risks of the areas that they are visiting;

- provide the specific protection devices, if any, for the areas and activities involved;

- guarantee appropriate supervision for the health and safety of the workers and students through its own managers and executives during activities and for specific areas of activities.

Article 10 – **Term of this Agreement**

This Agreement takes effect from the date of its signature and its term will be 12 months after the signing, with a possibility for renewal on the basis of an agreement in writing approved by the Parties.

The termination or expiry of this Agreement shall not affect the operation of Article 4, Article 5 and Article 6 of this Agreement which shall remain in full force and effect.

In the event of renewal of this contract, the report on the results of the Study and Research Program must be accompanied by a report on future objectives.

Article 11 – **Withdrawal from and Termination of the Contract**

The Parties may withdraw from this Agreement or terminate it by mutual consent. Withdrawal must be communicated by giving at least 3 months' notice in writing by registered letter with return receipt.

In the event a Party fails to meet its obligations under this Agreement and fails to remedy such failures within thirty (60) days after written notification thereof, the other Party will have the option of terminating this Agreement upon thirty (30) days written notice.

In the event of withdrawal or early termination, each Party will furnish to the other Party copies of all results achieved as of the withdrawal date, including but not limited to copies of laboratory notebooks and other notes, reports, summaries and documents produced in accordance with the Project as of the date of withdrawal.

Withdrawal or early termination of this Agreement has future effects only and does not affect the parts of this Agreement already performed.

Article 12 – **Processing of Personal Data**

Each Party shall arrange for the processing of the personal data regarding this Agreement to pursue the aims of it in compliance with Legislative Decree No. 196 of 30 June 2003 (Italian Law), of "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)" and its own University Regulations.

Article 13 – **Disputes**

This Agreement will be governed by Italian law. The Courts of Milan have jurisdiction over any dispute that may arise in relation to the performance of this contract.

Article 14 – **Registration and Expenses**

This Agreement shall be registered in case of use at a flat fee pursuant to articles 5 and 39 of Presidential Decree No. 131/1986. The expenses, if any, shall be borne by the party seeking registration.

[Signature page to follow]

Read, approved and signed.

University of Milano-Bicocca

Vice-Rector for Research Valorisation and Technology Transfer

Prof. Salvatore Torrisi

/s/ Salvatore Torrisi Date: *5 March 2021*

Windtree Therapeutics, Inc.

Senior Vice President and Chief Medical Officer

Steven G. Simonson, M.D.

/s/ Steven G. Simonson Date: *19 March 2021*

According to Articles 1341 and 1342 of the Italian Civil Code, the following clauses are specifically approved: Article 3 – Facilities, Equipment or Resources Made Available for the Study and Research Program; Article 4 – Secrecy; Article 5 – Results of the Scientific Collaboration; Article 6 – Publication of the Results; Article 10 – Term of the Agreement; and Article 13 – Disputes.

By:

University of Milano-Bicocca

Prof. Salvatore Torrisi

/s/ Salvatore Torrisi Date: *5 March 2021*

Windtree Therapeutics, Inc.

Steven G. Simonson, M.D.

/s/ Steven G. Simonson Date: *19 March 2021*

ANNEX A1

(100% IP Windtree)

DEFINITION OF THE "COMPANY IP", "BACKGROUND PATENTS", “BACKGROUND PAPERS” AND "BACKGROUND KNOW-HOW" THAT HAVE BEEN ACCUMULATED OVER [***] YEARS ACTIVITY LEADING TO THE SYNTHESIS OF [***] NEW COMPOUNDS AND THAT ARE AND REMAIN EXCLUSIVE PROPERTY OF THE COMPANY AND WILL BE NOT CONSIDERED AS JOINT PROPERTY OF THE SCIENTIFIC COLLABORATION, THEREFORE, NOT INCLUDED IN THE "FORGROUND PATENTS" AND/NOR IN THE "FOREGROUND KNOW-HOW" AND, IN GENERAL, IN THE "FOREGOUND OUTCOME" OF THE SCIENTIFIC COLLABORATION.

1. BACKGROUND PATENTS:
   All the following filed and granted patents, including all continuations, continuations-in-part or divisions thereof, patent applications claiming priority thereto, any granted patent resulting from such applications and any supplemental protection certificate (SPC) thereof:

[***]

2. BACKGROUND PAPERS: All the following papers:

[***]

3. BACKGROUND KNOW-HOW
   I. All molecules, compounds and products, patented or applied for patent or invented and secret but non-patented, that fall within the license agreement executed between [***].

   II. In more general terms, belong to the Background Know-How all molecules, compounds and products that fall within the [***] herein described

[***]

ANNEX A2

Background SERCA2a Compounds

[***]

BACKGROUND PATENTS:

[***]

BACKGROUND KNOW-HOW

[***]

ANNEX B:

For the next **12 months**, the Study and Research Program shall perform the following activities:

[***]

Budget plan

The budget for the Project, including Physiology and Chemistry costs for 12 months funding (starting from the date of signing of the Agreement to which this document is attached, for the following 12 months), is as follows:

Budget (Keuro) for 12 months

	Physiology & Chemistry Units
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
TOT (Keuro)	

ANNEX C:

Resources made available by Company

[***]

Resources made available by University

[***]

ANNEX D:

Premises and related floor plans of the laboratory made available by University to Company for exclusive use of the collaboration.

[***]

ANNEX E:

ACT OF COMMITMENT OF RESEARCHERS AT THE UNIVERSITY OF MILANO-BICOCCA

The Undersigned

- Prof. Antonio Zaza, Professor at the Department of Biotechnology and Bioscience - Università degli Studi di Milano-Bicocca;
- Prof. Francesco Peri, Professor at the Department of Biotechnology and Bioscience - Università degli Studi di Milano-Bicocca;
- Prof.ssa Marcella Rocchetti, Professor at the Department of Biotechnology and Bioscience - Università degli Studi di Milano-Bicocca;
- Prof.ssa Cristina Airoldi, Professor at the Department of Biotechnology and Bioscience - Università degli Studi di Milano-Bicocca;

by virtue of their participation in the study and research program covered by the Agreement for Scientific Collaboration to which this document is attached (hereinafter "the Agreement") concerning discovery and development of compounds to modulate SERCA2a activity, to be carried out at the Department of Biotechnology and Bioscience-University Milano-Bicocca and under their scientific responsibility,

DECLARE

that they have read the contents of the agreement between the University and the Company, relating to the program of study and research in the subject, and abide by the conditions set out in the full text of the Agreement.

In particular, the undersigned accept and agree to abide by the provisions contained in the following articles:

- **Article 4** Secrecy;
- **Article 5** Results of the Scientific Collaboration. In reference to that provision, the undersigned, hereby give the University, each for their own part, and then for the whole, all the future inventive and non-inventive results, which will be obtained from the program of study and research, as well as any industrial property rights connected to them;
- **Article 6** Publication of the results.

/s/ Antonio Zaza Milan, *26-02-21*
Prof. Antonio Zaza

/s/ Francesco Peri Milan, *26-02-21*
Prof. Francesco Peri

/s/ Marcella Rocchetti Milan, *25-02-21*
Prof. Marcella Rocchetti

/s/ Cristina Airoldi Milan, *26-02-21*
Prof. Cristina Airoldi

ANNEX F:

ACT OF COMMITMENT OF RESEARCHERS OF THE COMPANY

The Undersigned

Dr. BARASSI PAOLO, collaborator

Dr.ssa FERRANDI MARA, collaborator

by virtue of their participation in the research program covered by the Agreement for Scientific Cooperation to which this document is attached (hereinafter "the agreement"), concerning discovery and development of compounds to modulate SERCA2a activity, to be carried out at the Department of Biotechnology and Bioscience-University Milano-Bicocca and under the scientific responsibility of Profs. Antonio Zaza, Francesco Peri, Marcella Rocchetti and Cristina Airoli,

DECLARE

that they have read the contents of the Agreement between the University and Company, relating to the program of study and research in the subject, and abide by the conditions set out in the full text of the Agreement.

In particular, the undersigned accept and agree to abide by the provisions contained in the following articles:

- **Article 4** Secrecy;
- **Article 5** Results of the Scientific Collaboration. In reference to that provision, the undersigned, hereby give the Company, each for their own part, and then for the whole, all the future inventive and non-inventive results, which will be obtained from the program of study and research, as well as any industrial property rights connected to them;
- **Article 6** Publication of the results.

Milan, 02/02/2021

Dr. BARASSI PAOLO */s/ P. Barassi*

Dr.ssa FERRANDI MARA /s/ *M. Ferrand*

Exhibit 31.1

CERTIFICATION

I, Craig Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 13, 2021

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

Exhibit 31.2

CERTIFICATION

I, John P. Hamill, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 13, 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 March 31, 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: May 13, 2021

/s/ Craig Fraser
Craig 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.