Table of Contents

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

FORM 10-Q

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

For the quarterly period ended June 30, 2020

or

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

For the transition period from to

Commission file number 000-26422

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
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 August 13, 2020, there were outstanding 16,886,482 shares of the registrant's common stock, par value $0.001 per share.

Table of Contents

PART I - FINANCIAL INFORMATION

PART II - OTHER INFORMATION

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will,” “should,” “could,” “targets,” “projects,” “contemplates,” “predicts,” “potential” or “continues” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of such risks and uncertainties, which potentially could have a material adverse effect on our development programs, business and/or operations, include, but are not limited to the following:

- our estimates regarding future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- how long we can continue to fund our operations with our existing cash and cash equivalents;
- delays in our anticipated clinical timelines and milestones associated with COVID-19;
- the results, cost and timing of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- our plans and ability to successfully execute development activities and commercialize our product candidates;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices and other materials we need;
- the size and growth of the potential markets for our product candidates, the rate and degree of market acceptance of our product candidates and our ability to serve those markets;
- the success of competing therapies and products that are or become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- recently enacted and future legislation regarding the healthcare system, including changes to the Patient Protection and Affordable Care Act;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties upon which we depend, including third-party contract research organizations, contract manufacturing organizations, contractor laboratories and independent contractors;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers; and
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyberattacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption.

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

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

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

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 31,515	$ 22,578
Prepaid expenses and other current assets	2,121	1,283
Total current assets	33,636	23,861
Property and equipment, net	727	798
Restricted cash	154	154
Operating lease right-of-use assets	1,034	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 128,323	$ 118,975
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,223	$ 1,708
Collaboration and device development payable, net	968	1,972
Accrued expenses	3,676	3,226
Operating lease liabilities - current portion	651	750
Loans payable - current portion	5,714	161
Total current liabilities	12,232	7,817
Operating lease liabilities - non-current portion	506	794
Loans payable - non-current portion	-	4,608
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	1,000	-
Deferred tax liabilities	16,129	15,821
Total liabilities	44,867	44,040
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2020 and December 31, 2019; 16,868,756 and 13,697,419 shares issued at June 30, 2020 and December 31, 2019, respectively; 16,868,732 and 13,697,395 shares outstanding at June 30, 2020 and December 31, 2019, respectively	17	14
Additional paid-in capital	787,707	763,097
Accumulated deficit	(701,214)	(685,122)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	83,456	74,935
Total liabilities & stockholders' equity	$ 128,323	$ 118,975

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
License revenue with affiliate	$ -	$ 158	$ -	$ 198
Total revenues	-	158	-	198
Expenses:				
Research and development	4,495	3,413	7,956	6,755
General and administrative	3,453	3,240	6,695	6,595
Total operating expenses	7,948	6,653	14,651	13,350
Operating loss	(7,948)	(6,495)	(14,651)	(13,152)
Other income (expense):				
Interest income	5	39	94	99
Interest expense	(31)	(117)	(75)	(253)
Other (expense) income, net	(1,584)	136	(1,460)	332
Total other (expense) income, net	(1,610)	58	(1,441)	178
Net loss	$ (9,558)	$ (6,437)	$ (16,092)	$ (12,974)
Net loss per common share				
Basic and diluted	$ (0.63)	$ (0.60)	$ (1.12)	$ (1.21)
Weighted average number of common shares outstanding				
Basic and diluted	15,091	10,730	14,394	10,722

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (9,558)	$ (6,437)	$ (16,092)	$ (12,974)
Other comprehensive income:				
Unrealized (loss) gain on marketable securities	-	(28)	-	12
Comprehensive loss	$ (9,558)	$ (6,465)	$ (16,092)	$ (12,962)

See notes to condensed consolidated financial statements

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

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2018	**-**	**$ -**	**10,711**	**$ 11**	**$ 728,804**	**$ (657,647)**	**$ -**	**-**	**$ (3,054)**	**$ 68,114**
Net loss						(6,537)				(6,537)
Vesting of restricted stock units			18							-
Withholding tax payments related to net share settlements of restricted stock units					(151)					(151)
Stock-based compensation expense					1,530					1,530
Unrealized gain on marketable securities							40			40
Balance - March 31, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 730,183**	**$ (664,184)**	**$ 40**	**-**	**$ (3,054)**	**$ 62,996**
Net loss						(6,437)				(6,437)
Stock-based compensation expense					1,739					1,739
Unrealized loss on marketable securities							(28)			(28)
Balance - June 30, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 731,922**	**$ (670,621)**	**$ 12**	**-**	**$ (3,054)**	**$ 58,270**

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2019	**-**	**$ -**	**13,697**	**$ 14**	**$ 763,097**	**$ (685,122)**	**$ -**	**-**	**$ (3,054)**	**$ 74,935**
Net loss						(6,534)				(6,534)
Stock-based compensation expense					1,689					1,689
Balance - March 31, 2020	**-**	**$ -**	**13,697**	**$ 14**	**$ 764,786**	**$ (691,656)**	**$ -**	**-**	**$ (3,054)**	**$ 70,090**
Net loss						(9,558)				(9,558)
Issuance of common stock and common stock warrants, net of issuance costs			3,172	3	20,243					20,246
Modification of warrants					1,112					1,112
Stock-based compensation expense					1,566					1,566
Balance - June 30, 2020	**-**	**$ -**	**16,869**	**$ 17**	**$ 787,707**	**$ (701,214)**	**$ -**	**-**	**$ (3,054)**	**$ 83,456**

See notes to condensed consolidated financial statements

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

(in thousands)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (16,092)	$ (12,974)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	-	(198)
Depreciation	82	139
Amortization of debt discount	3	92
Stock-based compensation	3,255	3,269
Non-cash expense related to warrant modifications	1,112	-
Non-cash lease expense	356	436
Realized gain on investments	-	(61)
Changes in:		
Prepaid expenses and other current assets	218	(68)
Accounts payable	(485)	(2,696)
Collaboration and device development payable	(1,007)	(1,187)
Accrued expenses	425	(1,726)
Operating lease liabilities	(387)	(465)
Other liabilities	-	59
Net cash used in operating activities	(12,520)	(15,380)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	-	11,488
Purchase of property and equipment	(12)	(226)
Net cash (used in) provided by investing activities	(12)	11,262
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	20,246	-
Proceeds from research and development funding arrangement	1,000	-
Proceeds from Payroll Protection Program loan	547	-
Principle payments on Payroll Protection Program loan	(547)	-
Principle payments on loans payable	(199)	(474)
Payment for taxes related to net share settlements of restricted stock units	-	(151)
Net cash provided by (used in) financing activities	21,047	(625)
Effect of exchange rate changes on cash and cash equivalents	422	(338)
Net increase (decrease) in cash, cash equivalents and restricted cash	8,937	(5,081)
Cash, cash equivalents and restricted cash - beginning of period	22,732	11,358
Cash, cash equivalents and restricted cash - end of period	$ 31,669	$ 6,277
Prepayment of insurance through 3rd party financing	$ 1,056	$ 708

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

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

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

In May 2020, upon completing a public financing and meeting listing requirements for The Nasdaq Stock Market LLC, our common stock began trading on the Nasdaq Capital Market.

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2019 that we filed with the Securities and Exchange Commission, or the SEC, on April 3, 2020, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Note 2 – Basis of Presentation

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or US GAAP, for interim financial information in accordance with the instructions to Form 10-Q and include accounts of Windtree Therapeutics, Inc. and its wholly-owned subsidiaries. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. Intercompany balances and transactions have been eliminated in consolidation. All adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. When necessary, prior year's condensed consolidated financial statements have been reclassified to conform to the current year presentation. Operating results for the three and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. There have been no changes to our significant accounting policies since December 31, 2019. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2019 contained in our Annual Report on Form 10-K for the year ended December 31, 2019.

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

Note 3 – Liquidity Risks and Management's Plans

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

We have incurred net losses since inception. Our net loss was $9.6 million and $6.4 million, respectively, for the three-month periods ended June 30, 2020 and 2019. Our net loss was $16.1 million and $13.0 million, respectively, for the six-month periods ended June 30, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of June 30, 2020, we had an accumulated deficit of $701.2 million. Our future success is dependent on our ability to identify and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

In May 2020, we received net proceeds of approximately $20.2 million related to a public offering of 3,172,413 units, inclusive of 413,793 units related to a fully exercised over-allotment option, at a price per unit of $7.25. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance.

In March 2020, we entered into a binding term sheet, or the Term Sheet, with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF and in August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement. In April 2020, we received the first non-refundable payment of $1.0 million. In August 2020, we received the second non-refundable payment of $1.4 million. The third non-refundable payment of $0.4 million is due by September 15, 2020. In addition, Lee's (HK) will pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. The timing of the receipt of these financing payments by Lee's (HK) may have an impact on the timing, progression and development of our AEROSURF programs. If Lee's (HK) subsequently terminates the PF Agreement, our Board of Directors has approved a plan to suspend or terminate AEROSURF development until such time as we are able to secure the capital required to fund the program.

We believe that our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 are sufficient to fund operations through at least the next twelve months. In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities, and thus they are not considered probable.

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

Note 4 – Summary of Significant Accounting Policies

Principles of Consolidation

The interim unaudited condensed consolidated financial statements are prepared in accordance with US GAAP and include accounts of Windtree Therapeutics, Inc. and its wholly-owned subsidiaries, CVie Investments Limited, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or IPR&D, assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. The following table represents identifiable intangible assets as of June 30, 2020 and December 31, 2019:

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

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate its carrying value may be impaired.

Foreign Currency Transactions

The functional currency for our foreign subsidiaries is US Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income (expense), net. Foreign currency transactions resulted in losses of approximately $0.5 million and gains of approximately $0.1 million for the three-month periods ended June 30, 2020 and 2019. Foreign currency transactions resulted in losses of approximately $0.3 million and gains of approximately $0.3 million for the six-month periods ended June 30, 2020 and 2019.

Use of Estimates

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

Cash and Cash Equivalents

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

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (see, - Note 8 - Restructured Debt Liability), we have established a $15.0 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017, or Exchange and Termination Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

Research and Development

We account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical development programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of June 30, 2020 and 2019, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 9.7 million and 5.2 million shares, respectively. For the three and six months ended June 30, 2020 and 2019, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

Income Taxes

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

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

COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. As of the date of issuance of these interim unaudited condensed consolidated financial statements, our operations, capital and financial resources and overall liquidity position and outlook have not been materially impacted by COVID-19 while our operations have experienced some delays in clinical study initiation and early productivity. The full extent, duration, or full 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, including new information that may emerge concerning the severity of the COVID-19 outbreak, including any regional outbreaks in one or more markets where 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 strategic re-implementation of mitigating COVID-19 measures in one or more markets where our 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 the third quarter of 2020 and beyond.

We are not aware of any specific event or circumstance that would require us to update our estimates, judgments or revise the carrying value of our assets or liabilities as of the date of issuance of these interim unaudited condensed consolidated financial statements. These estimates may change, as new events occur and additional information is obtained. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

Recently Issued Accounting Standards

Recent Accounting Pronouncements

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

Note 5 – Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Fair Value on a Recurring Basis

The tables below categorize assets and liabilities measured at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value June 30, 2020	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 5,355	$ 5,355	$ -	$ -
U.S. Treasury notes	25,243	25,243	-	-
Total Assets	$ 30,598	$ 30,598	$ -	$ -

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

Note 6 – Collaboration and Device Development Payable

Restructuring of the Battelle Payables

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

In April 2020, we made the first milestone payment of $0.8 million to Battelle and announced enrollment of the first patient into the AEROSURF phase 2 bridging study. As of June 30, 2020, the remaining liability of $0.8 million is included in the balance of collaboration and device development payable, net.

Note 7 – Loans Payable

Assumption of bank debt as part of the CVie Acquisition

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

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

As of June 30, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $4.7 million and $4.6 million, respectively. 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. The $4.7 million outstanding under the facility has been classified as a current liability on the balance sheet as of June 30, 2020 given the uncertainty of Lee's commitment to maintain the required collateral.

Loan payable to Bank Direct Capital Finance

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

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 are due monthly from July 2020 through March 2021. As of June 30, 2020, the outstanding principal of the loan was $1.1 million.

Note 8 – Restructured Debt Liability

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P., or Deerfield Loan, in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 8,333 shares of our common stock at an exercise price of $2,360.40 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) 23,703 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain milestone payments based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15.0 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. We established a $15.0 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement (see, Note 5 - Accounting Policies and Recent Accounting Pronouncements). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of June 30, 2020 and December 31, 2019, the restructured debt liability balance was $15.0 million.

Note 9 – Stockholders' Equity

Warrant Amendments

On April 24, 2020, we and each of the holders of our Series F Warrants dated as of December 24, 2018, or the Series F Warrants, entered into Amendment No. 1 to the Series F Warrant to Purchase Common Stock whereby the expiration date of the Series F Warrants was extended from June 24, 2020 to December 24, 2020 in consideration for the holders agreeing to be bound by a lock-up provision with respect to any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by the holders. The lock-up provision provides that the holders will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by the holders for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020. The lock-up provision commenced on May 22, 2020 upon closing of the public offering discussed below.

On May 6, 2020, we and certain holders of our Series I Warrants dated as of December 6, 2019, or the Series I Warrants, entered into Amendment No. 1 to the Series I Warrant to Purchase Common Stock pursuant to which the exercise price of the Series I Warrants was amended from $12.09 to $9.67 if the Series I Warrants are exercised, in whole or in part, prior to December 5, 2021. In addition, the certain holders of the Series I Warrants agreed to be bound by a lockup provision with respect to any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by such holders for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020. During the lock-up period, the certain holders of the Series I Warrants will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock. The lock-up provision commenced on May 22, 2020 upon closing of the public offering discussed below.

While there is no specific guidance that addresses the modification of an equity-classified contract, such as the amendments to the Series F Warrants and the Series I Warrants, it is the practice to determine the accounting for such modifications based on analogy to the share-based compensation guidance.

The model for a modified share-based payment award that is classified as equity and remains classified in equity after the modification is addressed in ASC 718-20, *Compensation – Stock Compensation*, or ASC 718-20. Pursuant to that guidance, the incremental fair value from the modification (the change in the fair value of the instrument before and after the modification) is recognized as an expense in the income statement to the extent the modified instrument has a higher fair value.

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

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

May 2020 Public Offering

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

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

The closing of the Offering occurred on May 22, 2020, inclusive of the Overallotment Option. The offering price to the public was $7.25 per unit. After deducting underwriting discounts and commissions and offering expenses of $2.8 million payable by us, and excluding the proceeds, if any, from the exercise of the Warrants issued pursuant to this Offering, the net proceeds to the Company were approximately $20.2 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 Warrants issued in the Offering as equity. We have also determined that the 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 Offering based on the relative fair value of the common stock and the Warrants.

Note 10 – Stock Options and Stock-Based Employee Compensation

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

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2020	1,772	$ 17.61	
Granted	5	9.74	
Forfeited or expired	(15)	38.12	
Outstanding at June 30, 2020	1,762	$ 17.41	8.5
Vested and exercisable at June 30, 2020	645	$ 25.72	8.4
Vested and expected to vest at June 30, 2020	1,696	$ 17.37	8.5

As of June 30, 2020, there were 35,000 unvested restricted stock units. There was no activity with respect to restricted stock units during the six months ended June 30, 2020.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula based on the following weighted average assumptions:

	Six Months Ended June 30,	
	2020	2019
Weighted average expected volatility	98%	95%
Weighted average expected term (in years)	6.0	6.6
Weighted average risk-free interest rate	2.60%	2.60%
Expected dividends	-	-

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

(in thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Research and development	$ 596	$ 550	$ 1,310	$ 1,039
General and administrative	970	1,189	1,945	2,230
Total	$ 1,566	$ 1,739	$ 3,255	$ 3,269

Note 11 – 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) will provide financing for the development of AEROSURF and in August 2020, we entered into the PF Agreement with Lee's (HK). In April 2020, we received the first non-refundable payment of $1.0 million. In August 2020, we received the second non-refundable payment of $1.4 million. The third non-refundable payment of $0.4 million is due by September 15, 2020. In addition, Lee's (HK) will pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. The timing of the receipt of these financing payments by Lee's (HK) may have an impact on the timing, progression and development of our AEROSURF programs. If Lee's (HK) subsequently terminates the PF Agreement, our Board of Directors has approved a plan to suspend or terminate AEROSURF development until such time as we are able to secure the capital required to fund the program.

The PF Agreement also provides that, until such time as we have repaid 125% of the amounts funded by Lee's (HK) for the development of AEROSURF, we will pay to Lee's (HK) 50% of all revenue amounts and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, excluding (i) payments for bona fide research and development services; (ii) reimbursement of patent expenses and (iii) all amounts paid to us under the License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the License Agreement, 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).

We retain the right to develop and commercialize AEROSURF, Surfaxin, Surfaxin LS and any KL4 Surfactant-containing product as a mono-substance or combination with any other active ingredient, or collectively, the Products, outside of the Licensed Territory (as defined in the License Agreement, which includes China, Japan, Hong Kong, South Korea, Thailand and other countries), including, without limitation, determining marketing and regulatory strategies for the approval to use and commercialize the Products. Pursuant to the PF Agreement, we will be responsible for all costs and expenses incurred by us in connection with the development and commercialization of the Products outside of the Licensed Territory.

Either party may terminate the PF Agreement for any material breach by the other party that is not cured within certain specified time periods.

We have determined that the Term Sheet is within the scope of ASC 730-20, *Research and Development Arrangements*, or ASC 730-20. We concluded that there has not been a substantive and genuine transfer of risk related to the Term Sheet as there is a presumption that we are obligated to repay Lee's (HK) based on the significant related party relationship that exists at the time the parties entered into the Term Sheet, including Lee's (HK)'s approximate 29% ownership of the outstanding shares of our common stock.

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

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

As of June 30, 2020, the liability balance related to the non-refundable payment was $1.0 million and is recorded in other liabilities.

Note 12 – Subsequent Events

O-Bank Facility Debt Repayment

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.

Executive Severance

In July 2020, John A. Tattory and the Company mutually agreed that he would cease serving as our Senior Vice President and Chief Financial Officer effective July 20, 2020. Also in July 2020, Kathryn Cole and the Company mutually agreed that she would cease serving as our Senior Vice President, Human Resources effective July 20, 2020. In connection with these departures, Mr. Tattory and Ms. Cole each entered into a separation agreement with the Company, which provide that the former employee will be 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, or the Severance Period and (ii) a pro rata bonus, or the 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. If at the time the Pro Rata Bonus is paid Mr. Tattory is employed or providing services on a full-time basis as a chief financial officer or principal financial officer of any entity, the Pro Rata Bonus shall not be paid to Mr. Tattory. The severance amount related the departure of Mr. Tattory and Ms. Cole is approximately $0.9 million and will be paid ratably through August 2021.

AEROSURF Project Financing Agreement

In August 2020, we and Lee's (HK) entered into the PF Agreement dated and effective as of August 12, 2020, formalizing the terms of the Term Sheet. Refer to Note 11 – Collaboration, Licensing and Research Funding Agreements for further discussion of the PF Agreement.

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

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the Forward-Looking Statements section, any risk factors discussed in the "Risk Factors" Section and elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2019 that we filed with the Securities and Exchange Commission, or SEC, on April 3, 2020, our Quarterly Report on Form 10-Q that we filed with the SEC on May 13, 2020, and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

This Management's Discussion and Analysis, or MD&A, is provided as a supplement to the accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) to help provide an understanding of our financial condition and changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) and our Annual Report on Form 10-K for the year ended December 31, 2019. Unless otherwise specified, references to Notes in this MD&A shall refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

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

Business and Program Updates

The reader is referred to, and encouraged to read in its entirety, Item 1 – Business in our Annual Report on Form 10-K for the year ended December 31, 2019 that we filed with the SEC on April 3, 2020, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Istaroxime (AHF)

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

Istaroxime (Cardiogenic Shock)

We are also planning to study istaroxime for the treatment of early cardiogenic shock, a severe presentation of heart failure characterized by very low blood pressure and hypo-perfusion to critical organs which is associated with high mortality and morbidity and is not well treated with current therapies. We believe istaroxime may fulfill an unmet need in cardiogenic shock based on the profile observed in our phase 2 clinical studies in AHF. Because of the unmet need in the treatment of early cardiogenic shock, we believe there may be an opportunity with a breakthrough therapy designation, which may provide an expedited development program. Receipt of either Fast Track or breakthrough therapy designation may increase the likelihood of receiving priority review of a marketing application, which would provide for an expedited review timeframe.

We had planned to initiate a small study of istaroxime in early cardiogenic shock patients to evaluate the potential to improve blood pressure and organ perfusion by mid-year 2020, but due to the recent COVID-19 outbreak have experienced some delays in the initiation of the clinical study. As a result, we expect to initiate this study by the end of the third quarter of 2020. The study will also evaluate the safety and side effect profile of istaroxime in this patient population. Due to the recent global outbreak of COVID-19, our study may be impacted and we may experience delays in anticipated timelines and milestones.

AEROSURF (lucinactant for inhalation)

In April 2020, as part of the phase 2 clinical program, we enrolled the first patient and commenced our small, approximately 90-patient, phase 2b bridging study in premature infants with RDS and prepare to transition to our phase 3 clinical program by demonstrating the performance of our new ADS, in the neonatal intensive care unit, or NICU, as well as a more intensive dosing regimen. This trial will not be powered to establish statistical significance but will generate clinical experience with the ADS as well as additional higher dose treatment data to augment data previously obtained in the phase 2b clinical trial. The AEROSURF phase 2b bridging study is a multicenter, randomized, controlled study with masked treatment assignment in up to 90 premature infants 26 to 32 weeks gestational age, or GA, receiving nasal continuous airway pressure, or nCPAP, for RDS. The trial will leverage the favorable safety profile from the previous phase 2 studies to evaluate higher and more frequent dosing of aerosolized KL4 surfactant compared to premature infants receiving standard care of nCPAP alone. The trial will utilize the new ADS and bridge to data generated in the phase 2 program utilizing a prototype device on the following endpoints: time to nCPAP failure (the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. In June 2020, we announced that all initial European trial sites are active and enrolling or able to enroll patients into the phase 2b bridging study. In addition, we announced that select patients in the phase 2b bridging study may be co-enrolled in an investigator-sponsored study, being run in parallel to the phase 2b bridging study. Due to the recent global outbreak of COVID-19, our phase 2b bridging study may be impacted and we may experience delays in anticipated timelines and milestones.

Lyophilized KL4 Surfactant – Lung Injury and Other Studies

We are developing plans to study our proprietary KL4 surfactant for the treatment of lung injury resulting from severe COVID-19 infection, if we are able to secure the required regulatory approval to initiate the study. We plan to file an investigational new drug, or IND, application with the FDA in the third quarter of 2020 for an initial pilot clinical trial to assess the ability of our proprietary KL4 surfactant to impact key respiratory parameters in ventilated COVID-19 patients with a targeted start date in the second half of 2020. We recently applied to Biomedical Advanced Research and Development Authority, or BARDA, requesting funding for our development plans of KL4 surfactant in COVID-19 patients and we were granted a meeting to review our proposal with BARDA representatives.

Reverse Stock Split

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

Impact of COVID-19

The COVID-19 pandemic continues to evolve and we are closely monitoring the situation, including its potential impact on our clinical development plans and timelines. As of the date of the filing of this Quarterly Report on Form 10-Q, however, our operations, capital and financial resources and overall liquidity position and outlook have not been materially impacted by COVID-19 while our operations have experienced some delays in clinical study initiation and early productivity. The full extent, duration, or full 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, including new information that may emerge concerning the severity of the COVID-19 outbreak, including any regional outbreaks in one or more markets where 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 strategic re-implementation of mitigating COVID-19 measures in one or more markets where our 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 the third quarter of 2020 and beyond.

Payroll Protection Program Loan

On April 9, 2020, we applied to Newtek Small Business Finance, LLC, or the Lender, under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020, or the CARES Act, for a loan of $0.5 million, or the PPP Loan. On April 20, 2020, we entered into a promissory note in favor of the Lender. We had planned to use the loan proceeds for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. On April 30, 2020, we announced that we would repay the PPP Loan and on May 12, 2020 the loan was repaid in full.

CRITICAL ACCOUNTING POLICIES

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

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended June 30, 2020 and 2019 was $7.9 million and $6.5 million, respectively. The increase in operating loss from 2019 to 2020 was due to a $1.3 million increase in operating expenses and a $0.1 million decrease in license revenue with affiliate.

The operating loss for the six months ended June 30, 2020 and 2019 was $14.7 million and $13.2 million, respectively. The increase in operating loss from 2019 to 2020 was due to a $1.3 million increase in operating expenses and a $0.2 million decrease in license revenue with affiliate.

The net loss for the three months ended June 30, 2020 and 2019 was $9.6 million and $6.4 million, respectively. The net loss for the six months ended June 30, 2020 and 2019 was $16.1 million and $13.0 million, respectively. Included in the net loss for the three and six months ended June 30, 2020 is $1.1 million in non-cash expenses related to the modification of certain warrants.

Research and Development Expenses

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

Research and development expenses by category are as follows:

(in thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Product development and manufacturing	$ 1,544	$ 1,104	$ 2,608	$ 2,097
Clinical, medical and regulatory operations	1,700	1,917	3,418	3,605
Direct preclinical and clinical programs	1,251	392	1,930	1,053
Total research and development expenses	$ 4,495	$ 3,413	$ 7,956	$ 6,755

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.6 million for each of the three-month periods ended June 30, 2020 and 2019, respectively, and $1.4 million and $1.1 million, respectively, for the six months ended June 30, 2020 and 2019.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with contract manufacturing organizations, or CMOs, validation activities, quality assurance and analytical chemistry capabilities that support the manufacture of our drug products used in research and development activities, and our medical devices, including our ADS, (ii) design and development activities related to our ADS for use in our AEROSURF clinical development program; and (iii) pharmaceutical and manufacturing development activities of our drug product candidates including development of istaroxime, lyophilized KL4 surfactant, and rostafuroxin. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses increased $0.4 million and $0.5 million, respectively, for the three and six months ended June 30, 2020 compared to the same periods in 2019 primarily due to the purchase of raw materials during the second quarter of 2020.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses decreased $0.2 million in each of the three and six month periods ended June 30, 2020 compared to the same periods in 2019 due to (i) a decrease of $0.2 million and $0.3 million, respectively, in personnel and travel costs and (ii) a decrease of $0.1 million and $0.2 million, respectively, in employee-related incentive bonus expense, partially offset by (iii) an increase of $0.1 million and $0.3 million, respectively, in non-cash, stock compensation expense.

Direct Preclinical and Clinical Development Programs

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

Direct preclinical and clinical development programs expenses increased $0.9 million in each of the three and six months ended June 30, 2020 compared to the same periods in 2019 due to an increase in costs related to our continued clinical development of istaroxime and AEROSURF.

General and Administrative Expenses

(in thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
General and administrative expenses	$ 3,453	$ 3,240	$ 6,695	$ 6,595

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 $0.2 million and $0.1 million, respectively, for the three and six months ended June 30, 2020 compared to the same periods in 2019 due to (i) an increase of $0.6 million and $0.8 million, respectively, in professional fees, taxes, and insurance and (ii) an increase in personnel costs of $0.1 million in each period; partially offset by (iii); a decrease of $0.3 million and $0.5 million, respectively, in employee-related incentive bonus expense; and (iv) a decrease of $0.2 million and $0.3 million, respectively, in non-cash, stock compensation expense.

Other Income (Expense)

(in thousands)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Interest income	5	39	94	99
Interest expense	(31)	(117)	(75)	(253)
Other (expense) income, net	(1,584)	136	(1,460)	332
Total other (expense) income, net	$ (1,610)	$ 58	$ (1,441)	$ 178

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

For the three and six months ended June 30, 2020 and 2019, interest expense consists of interest expense associated with the collaboration and device development payables and with the loans payable. The decrease of $0.1 million and $0.2 million, respectively, in interest expense for the three and six months ended June 30, 2020 to the comparable period in 2019 is related to the repayment of $2.1 million in loans payable during the year ended December 31, 2019.

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

For the three and six months ended June 30, 2019, other income (expense) primarily consists $0.1 million and $0.3 million, respectively, in gains on foreign currency translation.

LIQUIDITY AND CAPITAL RESOURCES

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

We have incurred net losses since inception. Our net loss was $9.6 million and $6.4 million, respectively, for the three-month periods ended June 30, 2020 and 2019. Our net loss was $16.1 million and $13.0 million, respectively, for the six-month periods ended June 30, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of June 30, 2020, we had an accumulated deficit of $701.2 million. Our future success is dependent on our ability to identify and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

In May 2020, we received net proceeds of approximately $20.2 million related to a public offering of 3,172,413 units, inclusive of 413,793 units related to a fully exercised over-allotment option, at a price per unit of $7.25. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance.

In March 2020, we entered into a binding term sheet, or the Term Sheet, with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF and in August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement. In April 2020, we received the first non-refundable payment of $1.0 million. In August 2020, we received the second non-refundable payment of $1.4 million. The third non-refundable payment of $0.4 million is due by September 15, 2020. In addition, Lee's (HK) will pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. The timing of the receipt of these financing payments by Lee's (HK) may have an impact on the timing, progression and development of our AEROSURF programs. If Lee's (HK) subsequently terminates the PF Agreement, our Board of Directors has approved a plan to suspend or terminate AEROSURF development until such time as we are able to secure the capital required to fund the program.

We believe that our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 are sufficient to fund operations through at least the next twelve months. In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities, and thus they are not considered probable.

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

Cash Flows

Cash outflows for the six months ended June 30, 2020, consist of $12.5 million used in ongoing operating activities and $21.0 million provided by financing activities. Cash outflows for the six months ended June 30, 2019, consist of $15.4 million used for ongoing operating activities and $0.6 million used for financing activities, offset by cash inflows for the six months ended June 30, 2019 of $11.3 million for investing activities.

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2020 and 2019 was $12.5 million and $15.4 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The decrease in net cash used in operating activities from 2019 to 2020 is due to costs related to the acquisition of CVie Investments Limited, or the CVie Acquisition, costs from the December 2018 private placement financing and the payment of pre-existing obligations with the proceeds of the December 2018 private placement financing during the six months ended June 30, 2019.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2019 represents $11.5 million related to the sale of marketable securities, partially offset by $0.2 million in purchase of property and equipment compared with a de minimis amount of cash used in investing for the six months ended June 30, 2020.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 was $21.0 million and includes the following: (i) $20.2 million in net proceeds from the May 2020 public offering; (ii) $1.0 million in proceeds from our research and development funding arrangement with Lee's (HK); and (iii) $0.2 million of principal payments on loans payable – current portion. Net cash used in financing activities for the six months ended June 30, 2019 was $0.6 million and represents $0.5 million in principal payments on our loans payable – current portion and $0.1 million related to withholding tax payments for net share settlements of restricted stock units.

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

Loans Payable

Assumption of bank debt as part of the CVie Acquisition

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

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

As of June 30, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $4.7 million and $4.6 million, respectively. 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. The $4.7 million outstanding under the facility has been classified as a current liability on the balance sheet as of June 30, 2020 given the uncertainty of Lee's commitment to maintain the required collateral.

Loan payable to Bank Direct Capital Finance

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

In June 2020, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 4.26% annual interest rate. Payments of approximately $117,000 are due monthly from July 2020 through March 2021. As of June 30, 2020, the outstanding principal of the loan was $1.1 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at June 30, 2020 or 2019 or during the periods then ended.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

Our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

ITEM 1A. RISK FACTORS

Investing in our securities involves risks. In addition to any risks and uncertainties described below and 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, 2019 and Part II, Item 1A Risk Factors in our Quarterly Report on Form 10-Q for the quarter ended March 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, 2019 or our Quarterly Report on Form 10-Q for the quarter ended March 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*.

Risks Related to the Ownership of our Securities

Our common stock was relisted for trading on the Nasdaq Capital Market, or Nasdaq, on May 20, 2020. We may not be able to maintain our listing on Nasdaq, or trading in our common stock may be limited, which may make it more difficult for investors to sell shares of our common stock and consequently may negatively impact the price of our common stock.

Our common stock was relisted for trading on Nasdaq on May 20, 2020, after previously being delisted from Nasdaq in May 2017. Prior to the relisting of our common stock on Nasdaq, trading of our common stock was conducted on The OTCQB® Market. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by potential delays in the timing of certain clinical or product development milestones and reduction in security analysts' and the media's coverage of us, if at all.

The foregoing factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and as a result, the trading price of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his or her investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the price at which our common stock will trade at any given time.

There is also no assurance that we will be able to maintain compliance with Nasdaq's continued listing standards, such as the corporate governance requirements or the minimum closing bid price requirement and Nasdaq has the ability to suspend trading in our common stock or remove our common stock from listing on Nasdaq for a variety of reasons under its continued listing standards. Any delisting from Nasdaq could result in further reductions in the market prices of our common stock, substantially limit the liquidity of our common stock, and materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from Nasdaq could also have other negative results, including the potential loss of institutional investor interest, including those that are not permitted to own securities of non-listed companies that may be required to sell their shares, and fewer business development opportunities, both of which could adversely affect the market price of our common stock. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

AEROSURF Project Finanicng Agreement

As previously disclosed, we entered into the Term Sheet with Lee's (HK), pursuant to which the parties agreed that Lee's (HK) would provide financing for the continued development of our product candidate, AEROSURF. On August 12, 2020 we and Lee's (HK) entered into the Project Financing Agreement dated and effective as of August 12, 2020, or the PF Agreement, formalizing the terms of the Term Sheet.

The PF Agreement provides that in connection with the development of AEROSURF, Lee's (HK) will make non-refundable payments to us in the amount of (a) $1.0 million no later than April 1, 2020, (b) $1.4 million no later than August 12, 2020 and (c) $0.4 million no later than September 15, 2020. We have currently received $2.4 million from Lee's (HK) pursuant to the PF Agreement. In addition, Lee's (HK) will pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget.

The PF Agreement also provides that, until such time as we have repaid 125% of the amounts funded by Lee's (HK) for the development of AEROSURF, we will pay to Lee's (HK) 50% of all revenue amounts and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, excluding (i) payments for bona fide research and development services; (ii) reimbursement of patent expenses and (iii) all amounts paid to us under the License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the License Agreement, 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).

We retain the right to develop and commercialize AEROSURF, Surfaxin, Surfaxin LS and any KL4 Surfactant-containing product as a mono-substance or combination with any other active ingredient, or collectively, the Products, outside of the Licensed Territory (as defined in the License Agreement, which includes China, Japan, Hong Kong, South Korea, Thailand and other countries), including, without limitation, determining marketing and regulatory strategies for the approval to use and commercialize the Products. Pursuant to the PF Agreement, we will be responsible for all costs and expenses incurred by us in connection with the development and commercialization of the Products outside of the Licensed Territory.

Either party may terminate the PF Agreement for any material breach by the other party that is not cured within certain specified time periods.

The foregoing summary of the terms of the PF Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the PF Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2020.

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation	Incorporated by reference to Exhibit 3.1 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 17, 2018.
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Windtree's Form 8-K filed on April 29, 2020.
4.1	Form of Series F Warrant Amendment dated April 24, 2020.	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 29, 2020.
4.2	Form of Series I Warrant Amendment dated May 6, 2020, to the Series I Warrant dated December 6, 2019.	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 7, 2020.
4.3	Form of Warrant to be issued to purchasers of units and the underwriters pursuant to the Registration Statement on Form S-1, filed on January 27, 2020, as amended	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 22, 2020
4.4	Form of Warrant Agency Agreement between Windtree and Continental Stock Transfer and Trust Company	Incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 22, 2020
10.1	Note dated April 20, 2020, between Windtree and Newtek Small Business Finance, LLC.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 24, 2020.
10.2	Employment Agreement by and between Windtree and John Hamill, dated as of July 20, 2020	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 23, 2020.
10.3	Separation Agreement by and between Windtree and John A. Tattory, dated as of July 29, 2020	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.

101.1	The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2020 (unaudited) and December 31, 2019, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2020 and June 30, 2019, (iii) Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2020 and June 30, 2019, (iv) Statements of Cash Flows (unaudited) for the six months ended June 30, 2020 and June 30, 2019, and (v) Notes to Condensed Consolidated Financial Statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: August 14, 2020

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

Date: August 14, 2020

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

SEPARATION AND RELEASE AGREEMENT

THIS SEPARATION AND RELEASE AGREEMENT (this "***Agreement***") is made by and between John A. Tattory (the "***Executive***") and Windtree Therapeutics, Inc. (the "***Company***").

WHEREAS, the Executive's employment with the Company and its affiliates ceased as of July 20, 2020 (the "***Termination Date***"); and

WHEREAS, the Company has agreed to pay the Executive certain amounts and provide certain benefits in connection with the Executive's termination of his employment, subject to his execution of this Agreement.

NOW THEREFORE, in consideration of these premises and the mutual promises contained herein, and intending to be legally bound hereby, the parties agree as follows:

1. Termination of Employment. Executive hereby agrees and recognizes that, as of the Termination Date, his employment relationship with the Company has been permanently and irrevocably severed and all officer, director and fiduciary positions with the Company or any of its affiliates, including with respect to any benefit plan sponsored by or contributed to by the Company or any of its affiliates, held by the Executive terminated effective as of the Termination Date. Executive shall execute any document reasonably requested to effect his resignation from his officer and other positions with the Company.

2. Consideration; Acknowledgements.

(a) In connection with the cessation of the Executive's employment, and in consideration of the Executive's execution of this Agreement, and this Agreement becoming irrevocable in accordance with its terms:

(1) the Company shall pay Executive a pro rata bonus (the "***Pro Rata Bonus***") equal to target annual bonus amount (A) multiplied by the fraction obtained by dividing the aggregate amount of actual bonuses paid to the Company's other employment contract executives in respect of the Company's 2020 fiscal year by such employment contract executives' aggregate target bonuses for such fiscal year, as determined by the Company's Compensation Committee, multiplied by (B) the fraction obtained by dividing the number of days in the year through the Termination Date by 365 (i.e., 0.554), which amount shall be paid when the Company's other employment contract executives are paid 2020 bonuses in 2021, provided, however, that if at that time Executive is employed or providing services on a full-time basis as a chief financial officer or principal financial officer of any entity, no amounts shall be due to Executive under this Section 2(a)(1);

(2) the Company shall pay Executive an amount equal to his current annual base salary (i.e., $337,764), plus his target annual bonus amount as a percentage of such base salary (i.e., $135,105.60), the aggregate of such amount payable in substantially equal installments in accordance with the Company's regular payroll schedule over the 12-month period commencing as of the Termination Date (the "***Severance Period***"); provided, however, that each installment payable before this Agreement becomes effective shall be paid no later than three weeks following the date this Agreement becomes effective;

(3) if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("***COBRA***"), the Company shall continue to pay during the Severance Period the Company's shared costs of such coverage as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company; provided, however that the Company's obligation under this Section 2(a)(3) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer; and

(4) all outstanding vested stock options to acquire Company stock held by the Executive as of the Termination Date (as listed on ***Attachment A*** hereto) shall continue to be exercisable during the Severance Period.

(b) Executive acknowledges that: (i) any and all entitlement or rights which Executive heretofore has had under any severance or similar arrangement maintained by the Company or any of its affiliates are hereby subsumed into and superseded by this Agreement, and (ii) except as otherwise provided specifically in Section 2 of this Agreement, the Company and its affiliates do not and will not have any other liability or obligation to the Executive in the nature of compensation or severance, including under the Employment Agreement by and between Discovery Laboratories, Inc. (the Company's predecessor) and the Executive dated as of March 21, 2014, including all subsequent amendments (the "***Employment Agreement***"). The Executive further acknowledges that, in the absence of his execution of this Agreement, the payments specified in Section 2(a) would not otherwise be payable.

(c) By July 31, 2020, the Company shall pay to the Executive all amounts due or earned as of the Termination Date in accordance with applicable plans and programs of the Company, including earned and unpaid salary, 2020 earned and unpaid vacation, and earned and unpaid vacation bank.

3. Release of Claims. In consideration of the payments and benefits described in Section 2(a) hereof, to which Executive agrees Executive is not entitled until and unless Executive executes and does not revoke this Agreement, Executive, for and on behalf of himself and his heirs, executors, administrators and assigns, hereby waives and releases any and all complaints, claims, suits, controversies, and actions, whether known or unknown, suspected or claimed, which Executive, or any of the Executive's heirs, executors, administrators or assigns ever had, now has or may have against the Company and/or its respective predecessors, successors, past or present parents or subsidiaries, affiliates, investors, branches or related entities (collectively, including the Company, the "***Entities***") and/or the Entities' past or present stockholders, insurers, assigns, trustees, directors, officers, limited and general partners, managers, joint ventures and venturers, members, employees or agents in their respective capacities as such (collectively with the Entities, the "***Releasees***") by reason of circumstances, acts or omissions which have occurred on or prior to the date Executive signs this Agreement, including, without limitation, (a) any complaint, charge or cause of action arising under (i) federal, state or local laws pertaining to employment or termination of employment, including the Age Discrimination in Employment Act of 1967 (the "***ADEA***," a law which prohibits discrimination on the basis of age), the National Labor Relations Act, as amended, the Civil Rights Act of 1991, as amended, the Americans with Disabilities Act of 1990, as amended, Title VII of the Civil Rights Act of 1964, as amended, the Equal Pay Act of 1963, as amended, the Family and Medical Leave Act of 1993, as amended, the Worker Adjustment Retraining and Notification Act, as amended, the Executive Retirement Income Security Act of 1974, as amended, any applicable Executive Order Programs, the Fair Labor Standards Act, or their state or local counterparts; (ii) any other federal, state or local civil or human rights law; (iii) any other local, state, or federal law, regulation or ordinance; (iv) any public policy, contract and/or quasi-contract or tort (including, but not limited to, claims of breach of the Employment Agreement, an expressed or implied contract, tortious interference with contract or prospective business advantage, breach of the covenant of good faith and fair dealing, promissory estoppel, detrimental reliance, invasion of privacy, nonphysical injury, personal injury or sickness or any other harm, wrongful or retaliatory discharge, fraud, defamation, slander, libel, false imprisonment, negligent or intentional infliction of emotional distress); (v) common law; or (vi) any policies, practices or procedures of the Company; or (b) any claim for costs, fees, or other expenses, including attorneys' fees incurred in these matters (the "***Released Claims***"). By signing this Agreement, Executive acknowledges that he intends to give effect to the above-specified waiver and release of any rights known or unknown that he may have against the Releasees under these and any other laws. Notwithstanding the foregoing, the parties do not intend the above to release, discharge or waive any rights to defense or indemnification that Executive may have under the Employment Agreement, the Company's by-laws or equivalent governing documents of the Company or applicable law, nor any rights to insurance coverage, including without limitation those available under any directors' and officers' personal liability insurance or fiduciary insurance policy. The Executive acknowledges that he has made no assignment or transfer of any right, claim, demand, cause of action, or other matter covered by this Section 3.

4. Proceedings. Executive acknowledges that he has not filed any complaint, charge, claim or proceeding, if any, or assigned to any other person the right to bring any such complaint, charge, claim, or proceeding, relating to the Released Claims against any of the Releasees before any local, state or federal agency, court or other body (each individually a "***Proceeding***"). Executive (a) acknowledges that he will not initiate or cause to be initiated on his behalf any Proceeding and will not participate in any Proceeding, in each case, except as required by law and (b) waives any right he may have to benefit in any manner from any relief (whether monetary or otherwise) arising out of any Proceeding, including any Proceeding conducted by the Equal Employment Opportunity Commission (the "***EEOC***"). Further, Executive understands that, by executing this Agreement, he will be limiting the availability of certain remedies that he may have against the Releasees and limiting also his ability to pursue certain claims against the Releasees. Notwithstanding the above, nothing in Sections 3 or 4 of this Agreement shall prevent Executive from (i) initiating or causing to be initiated on his behalf any complaint, charge, claim or proceeding against any Releasee before any local, state or federal agency, court or other body challenging the validity of the waiver of his claims under the ADEA contained in Section 3 of this Agreement (but no other portion of such waiver) or asserting a breach by Company of this Agreement, (ii) initiating or participating in an investigation or proceeding conducted by the EEOC or (iii) reporting possible violations of federal, state or local law, ordinance or regulation to any governmental agency or entity, or otherwise taking action or making disclosures that are protected under the "whistleblower" provisions of any federal, state or local law, ordinance or regulation. The Executive acknowledges and agrees that the Executive's separation from employment with the Company shall not serve as the basis for any claim or action (including, without limitation, any claim under the ADEA).

5. Time to Consider. Executive acknowledges that he has been advised that he has twenty-one (21) days from the date of receipt of this Agreement to consider all the provisions of this Agreement and, further, that if Executive signs this Agreement prior to the expiration of such twenty-one (21) day period, he does hereby knowingly and voluntarily waive said given twenty-one (21) day period. EXECUTIVE FURTHER ACKNOWLEDGES THAT HE HAS READ THIS AGREEMENT CAREFULLY, HAS BEEN ADVISED BY THE COMPANY TO CONSULT AN ATTORNEY, AND FULLY UNDERSTANDS THAT BY SIGNING BELOW HE IS GIVING UP CERTAIN RIGHTS WHICH HE MAY HAVE TO SUE OR ASSERT A CLAIM AGAINST ANY OF THE RELEASEES, AS DESCRIBED IN SECTIONS 3 AND 4 OF THIS AGREEMENT AND THE OTHER PROVISIONS HEREOF. EXECUTIVE ACKNOWLEDGES THAT NEITHER THE COMPANY NOR ANY RELEASEES, NOR ANY OTHER PARTY, HAVE FORCED OR PRESSURED HIM IN ANY MANNER WHATSOEVER TO SIGN THIS AGREEMENT, AND EXECUTIVE AGREES TO ALL OF ITS TERMS VOLUNTARILY.

6. Revocation. Executive hereby acknowledges and understands that Executive shall have seven (7) days from the date of his execution of this Agreement to revoke this Agreement (including, without limitation, any and all claims arising under the ADEA) and that neither the Company nor any other person is obligated to provide any benefits to Executive pursuant to Section 2(a) of this Agreement nor to otherwise comply with the provisions of this Agreement until the eighth day following Executive's signing of this Agreement without Executive having revoked this Agreement. Any such revocation shall be in writing (which may be by email) and shall be effective when sent by Executive or his attorney or other representative to any Company attorney or officer. If Executive revokes this Agreement, Executive will be deemed not to have accepted the terms of this Agreement, no action or forbearance of action will be required of the Company or the Executive under any section of this Agreement, and Executive shall not be entitled to receive any portion of the severance compensation described in Section 2(a) which is conditioned on the delivery of this Agreement.

7. No Admission. This Agreement does not constitute an admission of liability or wrongdoing of any kind by Executive or the Company.

8. Confidentiality. Executive agrees that, unless and until the Company publicly files this Agreement, Executive will not communicate or disclose the terms of this Agreement to any persons with the exception of members of Executive's immediate family and Executive's attorney and financial advisor, or as permitted by Sections 4 or 10 hereof.

9. Return of Company Property. Executive represents that all equipment and other property of the Company, including any documents and files containing Proprietary Information (as such term is defined in the Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement entered into by Executive on April 9, 2014 (the "***Covenants Agreement***")) whether electronically stored or maintained in hard copy, have been returned or will be promptly returned to the Company, and that Executive will not retain any copies of any Proprietary Information.

10. Non-Disparagement. Executive will not disparage any Releasee or otherwise take any action which could reasonably be expected to adversely affect the personal or professional reputation of any Releasee. Neither the Company's officers nor the members of the Board of Directors will disparage the Executive or otherwise take any action which could reasonably be expected to adversely affect the Executive's personal or professional reputation. Nothing in this Agreement is intended to or shall prevent either party from providing or limiting discovery or testimony in any judicial, administrative or legal process or otherwise as required by law, or prevent either party from engaging in discovery or truthful testimony pursuant to any proceeding.

11. Post-Employment Obligations. Executive reaffirms that he will comply with all of his post-employment obligations as set forth in the Covenants Agreement, including, without limitation, his non-competition and non-solicitation covenants.

12. Cooperation. Executive will cooperate fully with the Company and its advisors with respect to any litigation or investigations in which Executive was in any way involved during his employment with the Company. Separately and additionally, and in consideration of the payments and other benefits described herein and without any further consideration, the Executive agrees to be reasonably available to the Company for the three months following the Termination Date as may be reasonably requested by the Company to assist with the transition of his duties and responsibilities and any other matters related to his duties with the Company during his employment. The Executive shall render all such cooperation in a timely manner on reasonable notice from the Company. Nothing in this Section shall prevent the Company and Executive reaching an agreement for further such cooperation on mutually acceptable terms.

13. Challenge; Breach. If the Executive violates or challenges the enforceability of any provision of this Agreement or fails to comply with any terms or conditions of the Covenants Agreement, no further payments under Section 2 hereof will be due to Executive.

14. Entire Agreement. Except as explicitly set forth herein, this Agreement constitutes the entire agreement between the parties as to the conditions of termination of Executive's employment with the Company and supersedes any and all prior representations and agreements as to that subject matter, whether written or oral, expressed or implied. This Agreement may not be modified or amended other than by an agreement in writing signed by an officer of the Company and Executive.

15. Assignment. This Agreement shall be binding upon and be for the benefit of the parties as well as Executive's heirs and the Company's successors and assigns.

16. General Provisions. A failure of Executive or any of the Releasees to insist on strict compliance with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision hereof. If any provision of this Agreement is determined to be so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable, and in the event that any provision is determined to be entirely unenforceable, such provision shall be deemed severable, such that all other provisions of this Agreement shall remain valid and binding upon Executive and the Releasees.

17. Governing Law. The validity, interpretations, construction and performance of this Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without giving effect to conflict of laws principles.

18. Counterparts and Facsimiles. This Agreement may be executed and delivered in multiple counterparts (including by facsimile signature and/or Docusign), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. *This Agreement shall not be enforceable if signed by Executive before the Termination Date*.

[*space intentionally left blank; signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its respective duly authorized officer(s), and the Executive has executed this Agreement, on the date(s) below written.

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig Fraser

Name & Title: Craig Fraser, Chief Executive Office

Date: July 29, 2020

JOHN A. TATTORY

/s/ John A. Tattory

Date: July 24, 2020

ATTACHMENT A

to Separation and Release Agreement

Exercisable Options

Exhibit 31.1

CERTIFICATION

I, Craig Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2020

/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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 14, 2020

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

Exhibit 32.1

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report of Windtree Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

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

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

Date: August 14, 2020

/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 Finance Officer)

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