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

FORM 10-Q

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

For the quarterly period ended September 30, 2019

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	**2600 Kelly Road, Suite 100**	**94-3171943**
(State or other jurisdiction of incorporation or organization)	**Warrington, Pennsylvania 18976-3622** (Address of principal executive offices)	(I.R.S. Employer Identification Number)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). YES ☒ NO ☐

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

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 November 11, 2019, there were outstanding 32,188,855 shares of the registrant's common stock, par value $0.001 per share.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Windtree Therapeutics, Inc., and its wholly-owned subsidiaries, CVie Investments Limited and its wholly-owned subsidiary, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” 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. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, future milestones, goals and objectives, and our financial plans and future financial condition, including the period of time during which our existing resources will enable us to fund our operations and continue as a going concern. Forward-looking statements also include our expectations about the timing and anticipated outcomes of submitting regulatory filings in the United States (US) and other markets for our products under development; our research and development programs, including planned development activities, anticipated timing of clinical trials and potential development milestones; manufacturing plans for our drug products, active pharmaceutical ingredients, materials and our aerosol delivery system (ADS); and our plans regarding potential strategic alliances, collaboration agreements, including licensing opportunities, and other potential strategic transactions (including without limitation, by merger, acquisition or other corporate transaction).

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 include, but are not limited to the following:

- our immediate and long-term capital resource requirements and our ability to raise funds to meet such requirements;
- our ability to successfully execute product development activities;
- our ability to successfully identify and enter into strategic and other non-dilutive transactions;
- risks related to manufacturing active pharmaceutical ingredients (APIs), drug product, medical devices and other materials; and
- other risks and uncertainties detailed in Risk Factors and elsewhere in our Annual Report on Form 10-K, and in the documents incorporated by reference therein.

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.

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,437	$ 11,187
Available-for-sale marketable securities	-	13,959
Prepaid expenses and other current assets	826	507
Total current assets	5,263	25,653
Property and equipment, net	877	802
Restricted cash	154	171
Operating lease right-of-use assets	1,566	-
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 100,632	$ 119,398
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 607	$ 3,420
Collaboration and device development payable, net	1,873	2,576
Accrued expenses	5,235	6,465
Operating lease liabilities - current portion	781	-
Deferred revenue	-	198
Loans payable	7,782	7,974
Total current liabilities	16,278	20,633
Operating lease liabilities - non-current portion	953	-
Restructured debt liability - contingent milestone payments	15,000	15,000
Deferred tax liabilities	15,224	15,476
Other liabilities	106	175
Total liabilities	47,561	51,284
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2019 and December 31, 2018	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at September 30, 2019 and December 31, 2018; 32,188,929 and 32,133,263 shares issued at September 30, 2019 and December 31, 2018, respectively; 32,188,855 and 32,133,189 shares outstanding at September 30, 2019 and December 31, 2018, respectively	32	32
Additional paid-in capital	733,840	728,783
Accumulated deficit	(677,747)	(657,647)
Accumulated other comprehensive income	-	-
Treasury stock (at cost); 74 shares	(3,054)	(3,054)
Total stockholders' equity	53,071	68,114
Total liabilities & stockholders' equity	$ 100,632	$ 119,398

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Grant revenue	$ -	$ 70	$ -	$ 765
License revenue with affiliate	-	159	198	719
Total revenues	-	229	198	1,484
Expenses:				
Research and development	3,792	2,197	10,547	8,194
General and administrative	3,395	1,500	9,990	4,634
Total operating expenses	7,187	3,697	20,537	12,828
Operating loss	(7,187)	(3,468)	(20,339)	(11,344)
Other income / (expense):				
Interest income	25	1	124	9
Interest expense	(105)	(460)	(358)	(642)
Other income, net	141	-	473	486
Other income / (expense), net	61	(459)	239	(147)
Net loss	$ (7,126)	$ (3,927)	$ (20,100)	$ (11,491)
Net loss per common share				
Basic and diluted	$ (0.22)	$ (1.04)	$ (0.62)	$ (3.21)
Weighted average number of common shares outstanding				
Basic and diluted	32,189	3,769	32,173	3,585

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (7,126)	$ (3,927)	$ (20,100)	$ (11,491)
Other comprehensive income:				
Unrealized gain (loss) on marketable securities	(12)	-	-	-
Comprehensive loss	$ (7,138)	$ (3,927)	$ (20,100)	$ (11,491)

See notes to condensed consolidated financial statements

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

(in thousands)

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2017	**3**	**$ -**	**3,227**	**$ 3**	**$ 616,245**	**$ (637,114)**	**$ -**	**-**	**$ (3,054)**	**$ (23,920)**
Net Loss						(4,512)				(4,512)
Share Purchase Agreement, April 2018					(52)					(52)
Stock-based compensation expense					418					418
Balance - March 31, 2018	**3**	**$ -**	**3,227**	**$ 3**	**$ 616,611**	**$ (641,626)**	**$ -**	**-**	**$ (3,054)**	**$ (28,066)**
Net Loss						(3,052)				(3,052)
Issuance of common stock, Share Purchase Agreement, April 2018			542	1	2,593					2,594
Stock-based compensation expense					140					140
Balance - June 30, 2018	**3**	**$ -**	**3,769**	**$ 4**	**$ 619,344**	**$ (644,678)**	**$ -**	**-**	**$ (3,054)**	**$ (28,384)**
Net Loss						(3,927)				(3,927)
Issuance of warrants, equity consideration in debt issuance					833					833
Stock-based compensation expense					145					145
Balance - September 30, 2018	**3**	**$ -**	**3,769**	**$ 4**	**$ 620,322**	**$ (648,605)**	**$ -**	**-**	**$ (3,054)**	**$ (31,333)**

	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	**-**	**$ -**	**32,133**	**$ 32**	**$ 728,783**	**$ (657,647)**	**$ -**	**-**	**$ (3,054)**	**$ 68,114**
Net Loss						(6,537)				(6,537)
Vesting of restricted stock units			56							-
Withholding tax payments related to net share settlements of restricted stock units					(151)					(151)
Stock-based compensation expense					1,530					1,530
Unrealized gain (loss) on marketable securities							40			40
Balance - March 31, 2019	**-**	**$ -**	**32,189**	**$ 32**	**$ 730,162**	**$ (664,184)**	**$ 40**	**-**	**$ (3,054)**	**$ 62,996**
Net Loss						(6,437)				(6,437)
Stock-based compensation expense					1,739					1,739
Unrealized gain (loss) on marketable securities							(28)			(28)
Balance - June 30, 2019	**-**	**$ -**	**32,189**	**$ 32**	**$ 731,901**	**$ (670,621)**	**$ 12**	**-**	**$ (3,054)**	**$ 58,270**
Net Loss						(7,126)				(7,126)
Stock-based compensation expense					1,939					1,938
Unrealized gain (loss) on marketable securities							(12)			(12)
Balance - September 30, 2019	**-**	**$ -**	**32,189**	**$ 32**	**$ 733,840**	**$ (677,747)**	**$ -**	**-**	**$ (3,054)**	**$ 53,071**

See notes to condensed consolidated financial statements

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

(in thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (20,100)	$ (11,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	(198)	(789)
Depreciation	178	121
Amortization of operating lease right-of-use assets	741	-
Amortization of debt discount	127	303
Stock-based compensation	5,208	703
Realized gain on investments	(75)	-
Gain on sale of property and equipment	-	(9)
Changes in:		
Prepaid expenses and other current assets	389	23
Accounts payable	(2,813)	1,471
Collaboration and device development payable	(830)	146
Accrued expenses	(1,166)	(68)
Operating lease liabilities	(784)	-
Other liabilities	119	-
Net cash used in operating activities	(19,204)	(9,590)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	13,988	-
Purchase of property and equipment	(129)	-
Proceeds from sale of property and equipment	-	9
Net cash provided by investing activities	13,859	9
Cash flows from financing activities:		
Proceeds from loan payable, net of expenses	-	4,280
Proceeds from private placement issuance of securities, net of expenses		2,541
Proceeds from convertible note payable	-	1,500
Principle payments on loans payable	(820)	-
Payment for taxes related to net share settlements of restricted stock units	(151)	-
Net cash (used in) / provided by financing activities	(971)	8,321
Effect of exchange rate changes on cash and cash equivalents	(451)	-
Net decrease in cash and cash equivalents	(6,767)	(1,260)
Cash, cash equivalents and restricted cash - beginning of period	11,358	2,040
Cash, cash equivalents and restricted cash - end of period	$ 4,591	$ 780
Supplementary disclosure of non-cash activity:		
Prepayment of director and officer insurance through 3rd party financing	$ 708	$ -

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a biotechnology and medical device company focused on developing drug product candidates and medical device technologies to address acute cardiovascular and pulmonary diseases. Through 2018, we focused on the development of our proprietary KL4 surfactant technology and aerosol delivery system (ADS) technology for the treatment and/or prevention of respiratory distress syndrome (RDS) in premature infants. In December 2018, we entered into an Agreement and Plan of Merger (the CVie Acquisition) with CVie Investments Limited (CVie Investments), an exempted company with limited liability incorporated under the laws of the Cayman Islands. We have operated CVie Investments, and its wholly-owned subsidiary, CVie Therapeutics Limited (CVie Therapeutics), a Taiwan corporation organized under the laws of the Republic of China, as a business division (these entities may be collectively referred to herein as CVie) focused on development of drug product candidates for cardiovascular diseases, including acute heart failure and hypertension and associated organ dysfunction.

Our four lead development programs are (1) istaroxime for treatment of (a) acute heart failure (AHF) and (b) early cardiogenic shock, (2) AEROSURF® (lucinactant for inhalation) for non-invasive delivery of our lyophilized KL4 surfactant to treat RDS in premature infants, (3) lyophilized KL4 surfactant intratracheal suspension for RDS, and (4) rostafuroxin for genetically associated hypertension. We are currently preparing for a study assessing the utility of istaroxime in early cardiogenic shock, as well as phase 2 clinical studies of istaroxime in acute heart failure and AEROSURF in RDS potentially to transition thereafter to phase 3. We also continue with our preclinical activities for follow-on oral and intravenous SERCA 2a heart failure compounds; however, we have slowed the pace of these activities while we seek the additional capital required to support our development activities and operations. *See*, "Note 3 – Liquidity Risks and Management's Plans."

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, 2018 that we filed with the Securities and Exchange Commission (SEC) on April 16, 2019, as amended by the Form 10-K/A that we filed with the SEC on April 23, 2019 (collectively, 2018 Form 10-K), and our Quarterly Reports on Form 10-Q filed thereafter, which contain discussions 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 US (US GAAP) for interim financial information in accordance with the instructions to Form 10-Q and include accounts of Windtree 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. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. When necessary, the prior year interim unaudited condensed consolidated financial statements have been reclassified to conform to the current year presentation. Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. There have been no changes to our critical accounting policies since December 31, 2018. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with annual audited financial statements and related notes as of and for the year ended December 31, 2018 contained in our 2018 Form 10-K and our Quarterly Reports on Form 10-Q filed thereafter.

Note 3 – Liquidity Risks and Management's Plans

As of September 30, 2019, we had cash and cash equivalents of $4.4 million and current liabilities of $16.3 million, including $7.8 million of Loans payable (*see*, Note 7 - Loans Payable). On October 24, 2019, LPH II Investments Ltd. (LPH II), an affiliate of Lee's Pharmaceutical Holdings Limited, agreed to lend the Company $1.0 million to fund the Company's operations, on an interim basis. We believe that, including the LPH II loan, we currently have cash and cash equivalent resources to fund our business operations through late-November 2019 while maintaining minimum cash resources to provide for an orderly shutdown of operations, if required.

We have an immediate need for additional capital to continue our operations. Even if we are able to secure such additional capital in the near term, we expect to continue to incur significant losses and will require significant additional capital to support our operations, advance our clinical development programs, and satisfy existing obligations. We currently only have cash and cash equivalent resources to fund our business operations through late-November 2019, and we do not currently have sufficient cash and cash equivalents for at least the next year following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans, and is currently actively engaged in discussions with various parties, including our largest shareholders, seeking to secure additional capital, potentially through one or a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be able to raise the required capital before our cash is exhausted, with acceptable terms and in an amount required to support our plans and operations, or identify and enter into any strategic transactions that would provide the capital that we will require or, if we do raise capital, it may not be in an amount sufficient to support all of our planned activities and we would therefore need to prioritize and potentially curtail certain programs. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, our current cash and cash equivalent resources is only adequate to fund our business operations through late-November 2019 and we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date that the financial statements are issued. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

As of September 30, 2019, there were 120.0 million shares of common stock and 5.0 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 72.0 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

Note 4 – Summary of Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the US (US GAAP) and include accounts of Windtree Therapeutics, Inc. and its wholly-owned subsidiaries, CVie Investments, CVie Therapeutics, and a presently inactive subsidiary, Discovery Laboratories, Inc.

Business Combinations

We follow the acquisition method for an acquisition of a business where the purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values at the dates of acquisition. The excess of the fair value of purchase consideration over the fair value of the assets acquired and liabilities assumed is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Management's estimate of fair value is based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and as such, actual results may differ materially from estimates.

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 (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 September 30, 2019 and December 31, 2018:

(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. We perform an annual impairment test for goodwill and evaluate the recoverability whenever events or changes in circumstances indicate that the carrying value of goodwill may not be fully recoverable. In making such an assessment, qualitative factors are used to determine whether it is more likely than not that our fair value is less than our carrying value. If the estimated fair value is less than our carrying value, then an impairment loss is recorded.

Foreign Currency Transactions

The functional currency for our foreign subsidiaries is US dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income (expense). Foreign currency transactions resulted in gains of approximately $0.1 million and $0.4 million for the three and nine months ended September 30, 2019. There were no foreign currency transaction gains or losses for the three and nine months ended September 30, 2018.

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.

Marketable Securities

Marketable securities consist of investments in US Treasury securities. Management determines the appropriate classification of these securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. We classify investments as available-for-sale pursuant to Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 320, Investments—Debt and Equity Securities. Investments are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders' equity and a component of total comprehensive loss in the condensed consolidated statements of comprehensive loss, until realized. Realized gains and losses are included in other income (expense) on a specific-identification basis. For the three months ended September 30, 2019, we had $14,000 in realized gains and $12,000 in unrealized losses on marketable securities. For the nine months ended September 30, 2019, we had $75,000 in realized gains and our unrealized gains and losses on marketable securities netted to zero. There were no realized or unrealized gains or losses on investments for the three and nine months ended September 30, 2018.

We review investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the condensed consolidated statements of operations if we have experienced a credit loss, have the intent to sell the investment, or if it is more likely than not that we will be required to sell the investment before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

Available-for-sale marketable securities are classified as marketable securities, current or marketable securities, non-current depending on the contractual maturity date of the individual available-for-sale security.

Leases

Effective January 1, 2019, we adopted ASC Topic 842, *Leases* (ASC 842), using the modified retrospective transition approach and utilizing the effective date as the date of initial application. Consequently, prior period balances and disclosures have not been restated and are presented in accordance with the previous guidance in ASC Topic 840, *Leases*.

At the inception of an arrangement, we determine whether an arrangement is, or contains, a lease based on the unique facts and circumstances present in the arrangement. An arrangement is, or contains, a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Leases with a term greater than one year are generally recognized on the balance sheet as operating lease right-of-use assets and current and non-current operating lease liabilities, as applicable. We elected not to recognize on the balance sheet leases with terms of 12 months or less. We typically only include the initial lease term in our assessment of a lease arrangement. Options to extend a lease are not included in our assessment unless there is reasonable certainty that we will renew.

Operating lease liabilities and their corresponding operating lease right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in our leases is typically not readily determinable. As a result, we utilize our incremental borrowing rate, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, we utilized the remaining lease term of our leases in determining the appropriate incremental borrowing rates.

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 established a $15 million long-term liability for contingent AEROSURF regulatory and commercial milestone payments, beginning with the filing for marketing approval in the United States, potentially due under the Exchange and Termination Agreement dated as of October 27, 2017 (Exchange and Termination Agreement), between ourselves and affiliates of Deerfield Management Company L.P. (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) clinical 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 ASC Topic 730, *Research and Development*.

Net Loss per Common Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. As of September 30, 2019 and 2018, the number of shares of common stock potentially issuable upon the conversion of preferred stock or exercise of certain stock options and warrants was 15.6 million and 1.3 million shares, respectively. For the three and nine months ended September 30, 2019 and 2018, 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.

Recently Adopted Accounting Standards

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 establishes ASC 842 which amends ASC 840, *Leases*, by introducing a lessee model that requires balance sheet recognition for most leases and the disclosure of key information about leasing arrangements. ASC 842 was subsequently amended during 2018. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. We adopted the new standard using the required modified retrospective approach on January 1, 2019 and used the effective date as its date of initial application. Consequently, financial information is not updated and the disclosures required under the new standard are not provided for dates and periods prior to January 1, 2019. Instead, the requirements of ASC 840 are presented for these prior periods.

ASC 842 provides several optional practical expedients in transition. We elected the package of practical expedients which allowed us to not reassess our existing conclusions on lease identification, classification, and initial direct costs. Further, we elected to utilize the short-term lease exemption for all leases with an original term of 12 months or less, for purposes of applying the recognition and measurement requirements of the new standard. We also elected the practical expedient to not separate lease and non-lease components for all our leases.

The adoption of this standard resulted in the recognition of operating lease liabilities and related right-of-use assets on our condensed consolidated balance sheets of $2.2 million and $2.0 million, respectively, related to our operating leases. The adoption of ASC 842 also resulted in the elimination of deferred rent of approximately $72,000 and $139,000 in accrued expenses and other long-term liabilities, respectively, in our condensed consolidated balance sheets. The adoption of the standard did not have a material impact on our condensed consolidated statements of operations and comprehensive loss or condensed consolidated statements of cash flows. Refer to Note 10 – Leases, for our current lease commitments.

In January 2017, the FASB issued ASU No. 2017-04, "Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment." The new standard simplifies the subsequent measurement of goodwill by eliminating the second step of the goodwill impairment test. This ASU will be applied prospectively and is effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019 with early adoption permitted. We adopted this guidance on January 1, 2019 and will apply it to our annual impairment test, and any interim impairment tests during the year ending December 31, 2019.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement" (ASU 2018-13), which removes, adds and modifies certain disclosure requirements for fair value measurements in Topic 820. Companies will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy as well as the valuation processes of Level 3 fair value measurements. However, companies will be required to additionally disclose the changes in unrealized gains and losses included in other comprehensive income for recurring Level 3 fair value measurements and the range and weighted average of assumptions used to develop significant unobservable inputs for Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments relating to additional disclosure requirements will be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments will be applied retrospectively to all periods presented upon their effective date. We are currently evaluating the impact that the adoption of ASU 2018-13 will have on our condensed consolidated financial statements.

Note 5 – License Revenue with Affiliate

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
License revenue with affiliate	$ -	$ 159	$ 198	$ 719

License revenue with affiliate represents revenue from a License Agreement with Lee’s Pharmaceutical (HK) Ltd. (Lee’s (HK)), an affiliate of our largest shareholder, Lee’s Pharmaceutical Holdings Limited (Lee’s), and constitutes a contract with a customer accounted for in accordance with ASC Topic 606. As of June 30, 2019, all revenue related to the License Agreement was recognized and no future material performance obligations are due.

Note 6 – 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 September 30, 2019	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 4,437	$ 4,437	$ -	$ -
U.S. Treasury notes	-	-	-	-
Certificate of deposit	154	154	-	-
Total Assets	$ 4,591	$ 4,591	$ -	$ -

(in thousands)	Fair Value December 31, 2018	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 5,234	$ 5,234	$ -	$ -
U.S. Treasury notes	19,912	19,912	-	-
Certificate of deposit	171	171	-	-
Total Assets	$ 25,317	$ 25,317	$ -	$ -

Note 7 – Loans Payable

In January 2018 and March 2018, LPH Investments Limited (LPH), an affiliate of Lee's, agreed to lend us $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we sought to identify and advance one or more potential strategic initiatives as defined in the related loan agreements (Funding Event). The loans accrued interest at a rate of 6% per annum and would mature upon the earlier of the closing date of the Funding Event or December 31, 2018. To secure our obligations under these loans, we granted LPH a security interest in substantially all our assets pursuant to the terms of a Security Agreement dated March 1, 2018 (LPH Security Agreement). Effective December 5, 2018, LPH assigned all outstanding loans to us to LPH II Investment Limited (LPH II), a subsidiary of Lee's. In connection with the Private Placement Financing, we converted to equity $6.0 million of the then outstanding loan payable obligations to LPH II on the same terms as those of the investors in the private placement. Included in the conversion were the $1.5 million and $1.0 million loans and following this conversion of the loans into equity securities, the security interest granted under the LPH Security Agreement was discharged.

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 due in March 2020.

In September 2016, CVie entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd. (O-Bank) to finance operating activities. The facility was later renewed and increased to approximately $5.8 million in September 2017. The credit facility was guaranteed by Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. The guaranty was part of the 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 90-day TAIBOR (the Taipei Interbank Offer Rate) plus 0.91%. The credit facility expired on September 11, 2019 and the loans mature six months after the expiration date, on March 11, 2020. We have initiated a process with O-Bank potentially to extend the maturity date of the facility into 2021.

As of September 30, 2019, the outstanding principal was approximately $4.5 million.

Assumption of Lee's debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $3.5 million of debt payable to Lee's Pharmaceutical International Limited (Lee's International).

From April 24, 2018 to November 16, 2018, CVie entered into four separate agreements to borrow an aggregate of approximately $3.5 million from Lee's International. The terms of the loan agreements are identical with interest, payable in cash upon maturity, at a rate of 4% per annum and maturing one year from the effective date of the respective loan agreement as follows: $0.5 million in April 2019; $0.3 million in September 2019; $0.2 million in October 2019; and $2.5 million in November 2019. Due to our current cash position, Lee's recently agreed in principle to defer payment of these loans until we have adequate cash resources to satisfy the outstanding obligations or no later than April 30, 2021.

During the quarter ended March 31, 2019, we made payments of $0.45 million against the April 2018 loan and paid the remaining $50,000 balance plus accrued interest in April 2019. As of September 30, 2019, the outstanding principal of the loans with Lee's International was $3.0 million.

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 (Bank Direct). Under the agreement, we have financed $0.7 million of certain premiums at a 5.35% annual interest rate. Payments of approximately $80,000 are due monthly through March 2020. As of September 30, 2019, the outstanding principal of the loan was $0.4 million.

Note 8 – Restructured Debt Liability

(in thousands)	September 30, 2019	December 31, 2018
Restructured debt liability - contingent milestone payments	$ 15,000	$ 15,000

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. (Deerfield Loan) in the aggregate principal amount of $25 million and (ii) warrants to purchase up to 25,000 shares of our common stock at an exercise price of $786.80 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) 71,111 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 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 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement (*see*, Note 4 – Summary of Significant Accounting Policies). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

Note 9 – Stock Options and Stock-Based Employee Compensation

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

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

(in thousands, except for weighted-average data) Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2019	4,417	$ 6.73	
Granted	1,144	4.20	
Forfeited or expired	(5)	467.57	
Outstanding at September 30, 2019	5,556	$ 5.80	9.2
Vested and exercisable at September 30, 2019	70	$ 128.45	6.3
Vested and expected to vest at September 30, 2019	5,245	$ 5.79	9.2

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2019	151	$ 4.29
Awarded	249	3.95
Vested	(95)	3.95
Cancelled	(144)	4.33
Unvested at September 30, 2019	161	$ 4.04

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:

	Nine Months Ended September 30, 2019
Weighted average expected volatility	95%
Weighted average expected term (in years)	6.6
Weighted average risk-free interest rate	2.6%
Expected dividends	-

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

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Research and development	$ 574	$ 29	$ 1,613	$ 169
General and administrative	1,365	116	3,595	534
Total	$ 1,939	$ 145	$ 5,208	$ 703

Note 10 – Leases

Our operating leases consist primarily of facility leases for our operations in Warrington, Pennsylvania and Taipei, Taiwan.

We maintain our corporate headquarters and operations in Warrington, Pennsylvania, with a remaining non-cancelable term of approximately three years. The facility serves as the main operating facility for drug and device development, regulatory, analytical technical services, research and development, and administration. We also maintain offices in Taipei, Taiwan, the former headquarters of CVie Therapeutics, where we perform certain manufacturing development and preclinical activities related to our cardiovascular drug product candidates.

Throughout the term of our leases, we are responsible for paying certain variable lease costs, in addition to the rent, as specified in the lease, including a proportionate share of applicable taxes, operating expenses and utilities.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to our operating leases for the three and nine months ended September 30, 2019:

(in thousands)	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	$ 212	$ 677
Variable lease cost	5	17
Total lease cost	$ 217	$ 694
Other Information		
Operating cash flows used for operating leases	$ 227	$ 721
Operating lease liabilities arising from obtaining right-of-use assets	$ 232	$ 364
Weighted average remaining lease term (in years)	2.4	2.4
Weighted average incremental borrowing rate	9.00%	9.00%

Future minimum lease payments under our non-cancelable operating leases as of September 30, 2019, are as follows:

(in thousands)	As of September 30, 2019
2019 (excluding the nine months ended September 30, 2019)	$ 230
2020	849
2021	638
2022	179
2023	23
Thereafter	-
Total lease payments	1,919
Less imputed interest	(184)
Total operating lease liabilities at September 30, 2019	1,735

Note 11 – Subsequent Event

Effective as of October 24, 2019, we entered into a Loan Agreement (“Loan Agreement”) with LPH II. Under the Loan Agreement, LPH II agreed to lend us $1.0 million (the “Loan”) to support our operations while we seek to complete a financing or Strategic Transaction (as defined in the Loan Agreement). The Loan, which was funded in a single installment on October 28, 2019, will accrue interest at a rate of 6% per annum and will mature upon the earlier of (i) the closing date for the Strategic Transaction on terms defined in the Loan Agreement, or (ii) December 31, 2019. If we are unable to complete the Strategic Transaction for any reason, based on our resources currently available to us, we likely will have insufficient resources to repay the Loan and may be forced to curtail some or all of our activities, and, ultimately, may be compelled to cease operations.

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

Some of the information contained in this Management’s 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 and uncertainties. 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, 2018 that we filed with the Securities and Exchange Commission (SEC) on April 16, 2019, as amended by the Form 10-K/A that we filed with the SEC on April 23, 2019 (collectively, our 2018 Form 10-K), our Quarterly Reports on Form 10-Q filed thereafter, and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

This MD&A is provided as a supplement to the accompanying 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), the 2018 Form 10-K and our Quarterly Reports on Form 10-Q filed thereafter. 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

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a biotechnology and medical device company focused on developing drug product candidates and medical device technologies to address acute cardiovascular and pulmonary diseases. Through 2018, we focused on the development of our proprietary KL4 surfactant technology and aerosol delivery system (ADS) technology for the treatment and/or prevention of respiratory distress syndrome (RDS) in premature infants. In December 2018, we entered into an Agreement and Plan of Merger (the CVie Acquisition) with CVie Investments Limited (CVie Investments), an exempted company with limited liability incorporated under the laws of the Cayman Islands. We have operated CVie Investments, and its wholly-owned subsidiary, CVie Therapeutics Limited (CVie Therapeutics), a Taiwan corporation organized under the laws of the Republic of China, as a business division (these entities may be collectively referred to herein as CVie) focused on development of drug product candidates for cardiovascular diseases, including acute heart failure and hypertension and associated organ dysfunction.

Our four lead development programs are (1) istaroxime for treatment of (a) acute heart failure (AHF) and (b) early cardiogenic shock, (2) AEROSURF® (lucinactant for inhalation) for non-invasive delivery of our lyophilized KL4 surfactant to treat RDS in premature infants, (3) lyophilized KL4 surfactant intratracheal suspension for RDS, and (4) rostafuroxin for genetically associated hypertension. We are currently preparing for a study assessing the utility of istaroxime in early cardiogenic shock, as well as phase 2 clinical studies of istaroxime in acute heart failure and AEROSURF in RDS potentially to transition thereafter to phase 3. We also continue with our preclinical activities for follow-on oral and intravenous SERCA 2a heart failure compounds; however, we have slowed the pace of these activities while we seek the additional capital required to support our development activities and operations. *See*, "Note 3 – Liquidity Risks and Management's Plans."

Heart failure is a chronic, progressive disease resulting from structural or functional cardiac abnormalities and is characterized by inadequate pumping function of the heart that results in fluid accumulation manifesting as pulmonary congestion, peripheral edema and congestion in other parts of the body. Insufficient cardiac output can result in inadequate peripheral perfusion that increases the risk of other organ dysfunction such as renal failure. Heart failure commonly but episodically worsens to a point of decompensation, a condition called AHF. Istaroxime is an investigational drug product, which has a dual mechanism of action referred to as luso-inotropic, that may result in improvement in cardiac function to reduce congestion and edema and preserve other organ function while avoiding the side effects associated with other classes of heart failure therapies. Istaroxime has been evaluated in two phase 2 clinical trials, the results of which suggest that istaroxime may improve cardiovascular physiology as assessed by parameters of pump function, decreases in pulmonary capillary wedge pressure, decreases in heart rate, increases in blood pressure without adverse events such as arrhythmias, cardiac damage (as indicated by elevated troponin values) or adverse impact on kidney function. We have engaged with leading heart failure opinion leaders to inform our plans for the program and have engaged with the FDA to gain alignment on the istaroxime clinical development plan. We believe that istaroxime, if approved, could potentially improve patients' heart failure symptoms and reduce complications and the length of hospital stays when compared to current therapeutic regimens for AHF. In August 2019, the FDA granted Fast Track designation for istaroxime for the treatment of acute heart failure.

In addition, after assessing the regulatory landscape and data from the istaroxime phase 2 clinical program in acute heart failure, we held discussions with our advisors and added to our istaroxime development program a study in early cardiogenic shock. Cardiogenic shock is a severe presentation of heart failure characterized by very low blood pressure and hypo-perfusion to critical organs. It is associated with high mortality and morbidity and is not well treated with current therapies. We believe that istaroxime may fulfill an unmet need in early cardiogenic shock based on the profile observed in prior phase 2 clinical studies in acute heart failure. In those studies, istaroxime increased systolic blood pressure by approximately 15 mmHg (1.5 ug/kg/min dose group), suggesting that istaroxime could potentially contribute to the clinical improvement of select patients in cardiogenic shock due to heart failure. In addition, there may be opportunities for an abbreviated regulatory pathway and review. According to an FDA published position paper, we believe that approval for early cardiogenic shock potentially could be based on blood pressure changes alone (assuming comparable mortality compared to control patients at 30 days). We plan to execute a small study of istaroxime in early cardiogenic shock patients to evaluate the potential to improve blood pressure and organ perfusion. The study will also evaluate the safety and side effect profile of istaroxime in this patient population. The Company plans to initiate this study in the first half of 2020.

AEROSURF (lucinactant for inhalation) is an investigational combination drug/device product that we are developing to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. AEROSURF is designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary aerosol delivery systems (ADS) technology, without invasive procedures. This noninvasive method contrasts favorably with surfactants in the US today, which are animal-derived and must be administered using endotracheal intubation, frequently with mechanical ventilation, invasive procedures that may result in serious respiratory conditions and other complications.

In 2017, we completed a phase 2b clinical trial, which did not meet the primary endpoint of reduction in the rate of nasal continuous airway pressure (nCPAP) failure at 72 hours, due in large part, we believe, to an unexpected rate of treatment interruptions that occurred in about 24% of active enrollments, predominantly in the 50-minute dose group. We believe the interruptions were primarily related to certain of the prototype phase 2 ADS devices with specific lots of disposable cartridge filters that had a higher tendency to clog. After excluding patients in the 50-minute dose group whose dose was interrupted, in accordance with the predesignated statistical plan, we observed a meaningful treatment effect in line with our desired targeted outcome. AEROSURF appears to reduce both the rate of nCPAP failure and the need for intubation in premature infants being treated for RDS when dosed as intended. The phase 2 program has also produced positive initial data suggesting that AEROSURF may have the potential to lower the incidence and severity of bronchopulmonary dysplasia (BPD).

The overall data suggest that the safety and tolerability profile of AEROSURF was generally comparable to the control group. Reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS and comparable to the control group.

We are also assessing potential development pathways to secure marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant is the drug product component of AEROSURF and a lyophilized dosage form of liquid KL4 surfactant, which was approved by the FDA in 2012 (SURFAXIN®). We have opened an Investigational New Drug (IND) application for lyophilized KL4 surfactant as an intratracheal instillate in the US and are interacting with the FDA to determine if we can define an acceptable development plan that is achievable from a cost, timing and resource perspective. If we are successful, we may seek approval to treat premature infants who, because they are unable to breathe on their own or other reason, are not candidates for AEROSURF.

We also believe that our lyophilized KL4 surfactant may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have pursued a number of early exploratory research efforts to identify potential product candidates, including a collaboration with Eleison Pharmaceuticals, Inc., a specialty pharmaceutical company developing life-saving therapeutics for rare cancers, to assess the feasibility of using our ADS potentially to deliver Eleison's inhaled lipid cisplatin (ILC), and, with support from the National Institutes of Health (NIH), to address certain respiratory conditions. Once we have secured additional funding to further advance our lead development programs, we plan to assess the status of these programs and potentially redouble our efforts to advance one or more of these opportunities.

Our fourth product candidate is rostafuroxin for the treatment of genetically associated hypertension. Rostafuroxin targets resistant hypertensive patients with a specific genetic profile, which is found in approximately 20% to 25% of the adult hypertensive population. We believe that rostafuroxin may reduce or normalize blood pressure in this genetically identified subset of patients and may reduce the risk of hypertension-related sequelae beyond the level normally associated with the absolute reduction of blood pressure, per se, because the molecular mechanism blocked by rostafuroxin may also be involved in organ damage. CVie Therapeutics completed three clinical trials assessing rostafuroxin, including a phase 2b clinical trial which was conducted in two parts, one in Caucasian patients in Italy and one in Chinese patients in Taiwan. While the blood pressure reduction in Caucasians was notable, there was no blood pressure response in Chinese patients. We are analyzing the results of these studies potentially to understand the reasons for the limited response in Chinese patients. We currently are working to finalize the drug formulation and define drug product analytical methods. If successful, we then plan to engage in business development activities potentially to out-license rostafuroxin to a larger company that has an interest in and/or operates in the very large and broad anti-hypertension market.

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, 2018 that we filed with the Securities and Exchange Commission (SEC) on April 16, 2019, as amended by the Form 10-K/A that we filed with the SEC on April 23, 2019 (collectively, 2018 Form 10-K), and each of our Quarterly Reports on Form 10-Q filed thereafter, which contain discussions of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Istaroxime

On May 30, 2019, we announced new data from the phase 2b study of istaroxime which was presented at a late-breaker session of the European Society of Cardiology (ESC) 2019 Heart Failure Congress. The study achieved its primary endpoint by demonstrating a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses. The study further showed that stroke volume, a key secondary endpoint, was substantially increased. Importantly, certain toxicities and complications experienced with many existing acute heart failure therapies were not observed in istaroxime-treated patients, including no signals of increased arrhythmias or increased troponin levels, a common marker of heart muscle damage. Istaroxime significantly increased or maintained systolic blood pressure during treatment which may have contributed to short term trend toward improvement in renal function.

The phase 2b study was conducted with 120 patients and was designed to assess the safety and efficacy of 24-hour infusions of two doses of istaroxime (0.5 and 1.0 µg/kg/min), compared to placebo, in the treatment of patients with acute heart failure. The primary endpoint of this study was a change from baseline to 24 hours after start of infusion (Day 1) in E/e' with istaroxime 0.5 or 1.0 µg/kg/min vs. placebo. The E/e' ratio is a marker of the function of the left ventricle (LV) of the heart and was measured using doppler echocardiography read by a central laboratory. Secondary endpoints included change in other parameters of cardiac function, such as diastolic function (E/A), stroke volume (SVI), left ventricle ejection fraction (LVEF), LV volumes, left atrial (LA) area, interior vena cava (IVC) diameter. Investigators of the study concluded that a 24-hour infusion of istaroxime was associated with significant improvements in cardiac function, in both dosing groups, with a mean E/e' of -4.55 for the 0.5 µg/kg/min group and -3.16 for the 1.0 µg/kg/min group, compared with mean placebo E/e' ratios of -1.55 and -1.08, respectively.

Twenty-four-hour infusions of istaroxime were also associated with substantial increases in stroke volume in both dosing groups, with a mean SVI value of 5.33 ml/beat/m^2 for the 0.5 µg/kg/min group and 5.49 ml/beat/m^2 for the 1.0 µg/kg/min group, compared with the mean placebo SVI of 1.65 ml/beat/m^2 and 3.18 ml/beat/m^2, respectively. Importantly, subjects also maintained or increased systolic blood pressure (SBP), with a mean change in SBP of 2.82 mmHg for the 0.5 µg/kg/min group and 6.1 mmHg for the 1.0 µg/kg/min group, compared with the mean placebo SBP values of -2.47 mmHg and 2.7 mmHg, respectively.

Istaroxime was generally well tolerated. Istaroxime did not appear to be associated with an increase in risk for arrhythmias or increases in cardiac troponin T. Cardiovascular-related adverse events were 23 percent for placebo, 10 percent for istaroxime low dose, and 18 percent for istaroxime high dose with cardiac failure occurring in 3 percent, 5 percent and 8 percent of placebo, low and high dose of istaroxime patients, respectively. These cases of cardiac failure were reported by the investigator as “worsening of heart failure” symptoms that occurred approximately 10-14 days after study drug administration and were not considered to be drug related. The most common adverse drug reactions reported included pain at infusion site, generally associated with use of short catheters, and dose-related gastrointestinal adverse events in 5 percent, 10 percent and 35 percent of placebo, low and high dose istaroxime respectively.

Based on feedback from the FDA in June 2019 and discussions with our scientific advisors, we are preparing for a phase 2 clinical trial focused on patients with low systolic blood pressure (SBP) and those who are diuretic resistant. These two, difficult-to-treat patient groups have limited treatment options and could particularly benefit from the istaroxime unique profile and potential ability to increase cardiac function, increase blood pressure and improve renal function. We plan to initiate this next phase 2 study in the second half of 2020 and plan to extend dosing beyond that previously studied and include clinical outcome measures that may be acceptable for registration.

AEROSURF

With respect to our AEROSURF® development program, on May 9, 2019, we announced that we had presented a new post-hoc analysis from our phase 2b AEROSURF clinical trial suggesting that AEROSURF may reduce the overall incidence and severity of bronchopulmonary dysplasia (BPD) in premature infants with RDS, regardless of whether the infant was ultimately intubated. The new data were presented in May 2019 at the Pediatric Academic Societies (PAS) Meeting, the leading event for academic pediatrics and child health research.

We have completed the planned design verification activities and other performance testing for the new ADS that is intended for use in the planned bridging study and the phase 3 clinical program and, if approved, initial commercial activity. We have completed design verification activities and have conducted extensive performance testing in which the ADS demonstrated consistent performance under rigorous testing and design verification protocols. In addition, the new ADS has been designed for ease of use and rapid setup, both of which may lead to faster time to treatment and may potentially support better clinical outcomes.

To complete the phase 2 clinical program and transition to phase 3, we are preparing to execute a small bridging study that is designed, among other things, to clinically evaluate the design and performance of our new ADS. Going forward, we expect to advance AEROSURF at a reduced cost by leveraging development opportunities in China (the largest RDS and surfactant market) with our partner in the region. We currently plan to conduct the bridging study globally and expect to begin in the first quarter of 2020. This trial will not be powered to establish statistical significance but will generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial.

Other Programs

We continue to advance our preclinical follow-on oral and intravenous SERCA 2a heart failure compounds and are actively exploring partnership opportunities for these potential product candidates. For rostafuroxin, we continue formulation development and development of an enhanced assay for pharmacokinetic measurement of drug concentration, which we expect will support an out-licensing initiative planned for 2020.

Manufacturing

We are currently in discussions with Pharma Services Group, Patheon, part of Thermo Fisher Scientific (Patheon), concerning the winddown of our Master Services Agreement dated as of October 24, 2013 for the manufacture of lyophilized KL4 surfactant for AEROSURF. Patheon has indicated that it will continue to manufacture lyophilized KL4 surfactant to support the planned AEROSURF clinical trial and will assist us with the technology transfer to another contract manufacturing organization. We plan to seek proposals for the technology transfer and future manufacturing of lyophilized KL4 surfactant from certain entities that we have identified that we believe have appropriate experience to support this program.

KL4 surfactant is comprised of four active pharmaceutical ingredients (API’s). Bachem Americas has been our supplier of KL4 (sinapultide) since 2008. We received a notice of nonrenewal from Bachem in June 2019 indicating their intent to discontinue the current manufacturing process. We discussed with them potential development of a new manufacturing process for KL4 to meet our future needs. Bachem has agreed to continue manufacturing with the current process thru 2020 and to produce an adequate supply of KL4 to satisfy our needs for the currently planned clinical programs for AEROSURF and lyophilized KL4 surfactant. We have received two comprehensive proposals for the development and validation of a new process for manufacturing KL4 (including one from Bachem). Following initial feasibility studies of the new process, we expect to determine our go forward manufacturer.

This Quarterly Report on Form 10-Q includes information concerning our AEROSURF clinical and device development programs. The AEROSURF phase 2b clinical trial has been supported to date, in part, by a $2.6 million Phase IIb award under a Small Business Innovation Research (SBIR) grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) under parent award number R44HL107000. In addition, we received funding under a Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) under parent grant number R44AI102308. The content of this Quarterly Report on Form 10-Q is solely our responsibility and does not necessarily represent the official views of the NIH.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2018. 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 2018 Form 10-K, 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 September 30, 2019 and 2018 was $7.2 million and $3.5 million, respectively. The increase in operating loss from 2018 to 2019 was due to a $3.5 million increase in operating expenses, a $0.1 million decrease in grant revenue, and a $0.1 million decrease in license revenue with affiliate.

The operating loss for the nine months ended September 30, 2019 and 2018 was $20.3 million and $11.3 million, respectively. The increase in operating loss from 2018 to 2019 was due to a $7.7 million increase in operating expenses, a $0.8 million decrease in grant revenue, and a $0.5 million decrease in license revenue with affiliate.

The net loss for the three months ended September 30, 2019 and 2018 was $7.1 million and $3.9 million, respectively. The net loss for the nine months ended September 30, 2019 and 2018 was $20.1 million and $11.5 million, respectively.

Grant revenue

For the three and nine months ended September 30, 2018, we recognized grant revenue of $0.1 million and $0.7 million, respectively. Grant revenue for the three months ended September 30, 2018 consists of funds received and expended under a Phase II SBIR grant from NIAID to support continued development of our aerosolized KL4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (Radiation Grant). Grant revenue for the nine months ended September 30, 2018 consists of funds received and expended under the Radiation Grant and a Phase II SBIR grant from the NHLBI of the NIH to support the AEROSURF phase 2b clinical trial.

License Revenue with Affiliate

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
License revenue with affiliate	$ -	$ 159	$ 198	$ 719

License revenue with affiliate represents revenue from a License Agreement with Lee's Pharmaceutical (HK) Ltd. (Lee's (HK)), an affiliate of Lee's Pharmaceutical Holdings Limited (Lee's), which together with its affiliates is our largest shareholder, and constitutes a contract with a customer accounted for in accordance with ASC Topic 606. As of June 30, 2019, all revenue related to the License Agreement was recognized and no future material performance obligations are due.

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 for the three and nine months ended September 30, 2019 and 2018 are as follows:

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Product development and manufacturing	$ 1,165	$ 1,053	$ 3,262	$ 4,335
Clinical, medical and regulatory operations	1,734	966	5,339	3,162
Direct preclinical and clinical programs	893	178	1,946	697
Total research and development expenses	$ 3,792	$ 2,197	$ 10,547	$ 8,194

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.6 and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $1.7 and $0.3 million for the nine months ended September 30, 2019 and 2018, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with contract manufacturing organizations (CMOs), technology transfer and validation activities, quality assurance and analytical chemistry capabilities that support the manufacture of our drug product candidates used in research and development activities, including istaroxime, KL4 surfactant and rostafuroxin, 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, including development of a lyophilized dosage form of our KL4 surfactant and rostafuroxin. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses were consistent for the three months ended September 30, 2019 compared to the same period in 2018. The decrease of $1.1 million for the nine months ended September 30, 2019 compared to the same period in 2018 is due to a reduction of design and development activities on the phase 3 ADS following completion of the design verification activities in mid-2018.

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 product candidates under development. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Clinical, medical and regulatory operations expenses increased $0.8 million and $2.2 million, respectively, for the three and nine months ended September 30, 2019 compared to the same periods in 2018 primarily due to (i) an increase of $0.4 million and $1.2 million, respectively, in non-cash, stock compensation expense as a result of employee stock option grants in the fourth quarter of 2018 and the first quarter of 2019; (ii) an increase in employee-related incentive bonus accruals of $0.1 million and $0.4 million, respectively; and (iii) an increase of $0.2 million and $0.4 million, respectively, in personnel costs.

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 $0.7 million and $1.2 million, respectively, for the three and nine months ended September 30, 2019 compared to the same periods in 2018 due to costs associated with continued clinical development of istaroxime and AEROSURF and preclinical activities related to potential follow-on product candidates in acute heart failure.

Research and Development Projects – Updates

For our lead clinical programs, istaroxime and AEROSURF, we have been engaged in start-up activities related to the next planned clinical studies. With respect to rostafuroxin, we continue to focus on product development work for final formulation to potentially support our planned business development activities.

General and Administrative Expenses

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
General and administrative expenses	$ 3,395	$ 1,500	#	$ 9,990	$ 4,634

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

General and administrative expenses increased $1.9 million and $5.4 million, respectively, for the three and nine months ended September 30, 2019 compared to the same periods in 2018 primarily due to (i) an increase of $1.2 million and $3.0 million, respectively, in non-cash, stock compensation expense as a result of employee stock option grants in the fourth quarter of 2018 and the first quarter of 2019; (ii) an increase of $0.2 million and $0.8 million, respectively, in employee-related incentive bonus accruals; and (iii) an increase of $0.3 million and $1.2 million, respectively, in professional fees, taxes, and insurance.

Other Income and (Expense)

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Interest income	25	1	124	9
Interest expense	(105)	(460)	(358)	(642)
Other income	141	-	473	486
Other income, net	$ 61	$ (459)	$ 239	$ (147)

The increase in interest income for the three and nine months ended September 30, 2019 compared to the same periods in 2018 is due to the increase in cash and marketable securities available-for-sale as a result of the Private Placement Financing.

For the three and nine months ended September 30, 2019, interest expense consists of interest expense associated with collaboration and device development payables and with loans payable. For the three and nine months ended September 30, 2018, interest expense primarily consists of interest expense associated with a $1.5 million convertible note payable, collaboration and device development payables and interest expense related to $2.5 million in loans payable to LPH. The decrease in interest expense for the three and nine months ended September 30, 2019 compared to the same periods in 2018 is primarily due to non-cash amortization of the debt discount on the convertible note payable in 2018. The convertible note was paid in its entirety in December 2018.

For the three and nine months ended September 30, 2019, other income primarily consists of $0.1 million and $0.3 million, respectively, in gains on foreign currency translation. For the nine months ended September 30, 2018, other income primarily consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had cash and cash equivalents of $4.4 million and current liabilities of $16.3 million, including $7.8 million of Loans payable (see, Note 7 - Loans Payable). On October 24, 2019, LPH II Investments Ltd. (LPH II), an affiliate of Lee's Pharmaceutical Holdings Limited, agreed to lend the Company $1.0 million to fund the Company's operations on an interim basis. We believe that, including the LPH II loan, we currently have cash and cash equivalent resources to fund our business operations through late-November 2019 while maintaining minimum cash resources to provide for an orderly shutdown of operations, if required.

We have an immediate need for additional capital to continue our operations. Even if we are able to secure such additional capital in the near term, we expect to continue to incur significant losses and will require significant additional capital to support our operations, advance our clinical development programs, and satisfy existing obligations. We currently only have cash and cash equivalent resources to fund our business operations through late-November 2019, and we do not currently have sufficient cash and cash equivalents for at least the next year following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans, and is currently actively engaged in discussions with various parties, including our largest shareholders, seeking to secure additional capital, potentially through one or a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be able to raise the required capital before our cash is exhausted, with acceptable terms and in an amount required to support our plans and operations, or identify and enter into any strategic transactions that would provide the capital that we will require or, if we do raise capital, it may not be in an amount sufficient to support all of our planned activities and we would therefore need to prioritize and potentially curtail certain programs. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, our current cash and cash equivalent resources is only adequate to fund our business operations through late-November 2019 and we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date that the financial statements are issued. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

As of September 30, 2019, there were 120.0 million shares of common stock and 5.0 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 72.0 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

Cash Flows

Cash outflows for the nine months ended September 30, 2019, consist of $19.2 million used for operating activities and $1.0 million used for financing activities, offset by cash inflows for the nine months ended September 30, 2019 of $13.9 million for investing activities.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2019 and 2018 was $19.2 million and $9.6 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The increase in net cash used in operating activities is due to the payment of CVie Acquisition costs and Private Placement Financing costs, the payment of pre-existing obligations with the proceeds of the Private Placement Financing, and continued development of our clinical programs.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2019 represents $14.0 million related to the sale of marketable securities, partially offset by $0.1 million in purchase of property and equipment.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2019 was $1.0 million and represents $0.8 million in principal payments on our Loans Payable and $0.2 million related to withholding tax payments for net share settlements of restricted stock units.

Net cash provided by financing activities for the nine months ended September 30, 2018 was $8.3 million and represents net loan proceeds of $4.3 million related to loan agreements with LPH, $2.5 million in net proceeds from a private placement offering with LPH II, a wholly-owned subsidiary of Lee’s, and $1.5 million in proceeds from a convertible note payable.

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

Loans Payable

In January 2018 and March 2018, LPH Investments Limited (LPH), an affiliate of Lee’s, agreed to lend us $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we sought to identify and advance one or more potential strategic initiatives as defined in the related loan agreements (Funding Event). The loans accrued interest at a rate of 6% per annum and would mature upon the earlier of the closing date of the Funding Event or December 31, 2018. To secure our obligations under these loans, we granted LPH a security interest in substantially all our assets pursuant to the terms of a Security Agreement dated March 1, 2018 (LPH Security Agreement). Effective December 5, 2018, LPH assigned all outstanding loans to us to LPH II Investment Limited (LPH II), a subsidiary of Lee's. In connection with the Private Placement Financing, we converted to equity $6.0 million of the then outstanding loan payable obligations to LPH II on the same terms as those of the investors in the private placement. Included in the conversion were the $1.5 million and $1.0 million loans and following this conversion of the loans into equity securities, the security interest granted under the LPH Security Agreement was discharged.

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 due in March 2020.

In September 2016, CVie entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd. (O-Bank) to finance operating activities. The facility was later renewed and increased to approximately $5.8 million in September 2017. The credit facility was guaranteed by Lee’s, which pledged bank deposits in the amount of 110% of the actual borrowing amount. The guaranty was part of the 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 90-day TAIBOR (the Taipei Interbank Offer Rate) plus 0.91%. The credit facility expired on September 11, 2019 and the loans mature six months after the expiration date, on March 11, 2020. We have initiated a process with O-Bank potentially to extend the maturity date of the facility into 2021.

As of September 30, 2019, the outstanding principal was approximately $4.5 million.

Assumption of Lee's debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $3.5 million of debt payable to Lee's Pharmaceutical International Limited (Lee's International).

From April 24, 2018 to November 16, 2018, CVie entered into four separate agreements to borrow an aggregate of approximately $3.5 million from Lee's International. The terms of the loan agreements are identical with interest, payable in cash upon maturity, at a rate of 4% per annum and maturing one year from the effective date of the respective loan agreement as follows: $0.5 million in April 2019; $0.3 million in September 2019; $0.2 million in October 2019; and $2.5 million in November 2019. Due to our current cash position, Lee's recently agreed in principle to defer payment of these loans until we have adequate cash resources to satisfy the outstanding obligations or no later than April 30, 2021.

During the quarter ended March 31, 2019, we made payments of $0.45 million against the April 2018 loan and paid the remaining $50,000 balance plus accrued interest in April 2019. As of September 30, 2019, the outstanding principal of the loans with Lee's International was $3.0 million.

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 (Bank Direct) . Under the agreement, we have financed $0.7 million of certain premiums at a 5.35% annual interest rate. Payments of approximately $80,000 are due monthly through March 2020. As of September 30, 2019, the outstanding principal of the loan was $0.4 million.

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 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 September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

ITEM 1A. RISK FACTORS

Investing in our securities involves risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in Item 1A. Risk Factors in our 2018 Form 10-K and our Quarterly Reports on Form 10-Q filed thereafter. These risks are not the only risks that could materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations and development activities. Should any of the risks and uncertainties described in our 2018 Form 10-K and our Quarterly Reports on Form 10-Q filed thereafter actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.

Risks Related to Capital Resource Requirements

As of November 10, 2019, we believe our cash resources are only sufficient to fund our business operations through the end of November 2019 while maintaining minimum cash resources to provide for an orderly shutdown of operations if required. If we do not secure additional capital to support our future activities before our existing cash resources are exhausted, we likely will be unable to continue as a going concern.

As of September 30, 2019, we had cash and cash equivalents of $4.4 million. On October 24, 2019, LPH II, an affiliate of Lee's Pharmaceutical Holdings Limited, agreed to lend us $1.0 million to fund the Company's operations. We believe that, with the LPH II loan, we currently have sufficient cash and cash equivalent resources to fund our business operations through late-November 2019. We expect to continue to incur significant losses and require significant additional capital to advance our development programs, support our operations and business development efforts, and satisfy existing obligations. These conditions raise substantial doubt about our ability to continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital. We plan, and are currently actively engaged in discussions with various parties, to secure the additional capital that we require potentially from a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time and there can be no assurance that we will be successful in identifying and completing such a transaction in the future. If we are unable to complete one or more transactions on terms that are acceptable to us, or if we are unable to raise sufficient capital through any such transactions, or within a time that would support our capital requirements, we likely will not have sufficient cash resources and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. If we are unable to raise the required capital, we may be forced to curtail our activities and, ultimately, cease operations.

Risks Related to Manufacturing Development and Manufacturing

We depend on third party contract manufacturing organizations (CMOs) to manufacture our drug products and APIs, and manufacture and assemble our medical devices. In addition, we are currently contemplating process changes and/or technology transfers with certain of our CMOs to support our clinical development activities. If we undertake to transition to a new manufacturer or supplier, this exposes us to risks that may affect our ability to maintain inventory supplies of our clinical materials and could potentially delay our research and development activities.

We depend upon single-source suppliers to provide our requirements for AEROSURF drug product and APIs and are currently working with our CMOs to assure that we will have sufficient inventory to support our planned AEROSURF clinical activities. In addition, we are currently discussing the winddown of our AEROSURF drug product manufacturing agreement. In that regard, our CMO has indicated a willingness to continue manufacturing on an interim basis to build drug product inventory to support our planned AEROSURF clinical bridging study. However, there can be no guarantee that they will remain willing or able to do so. Furthermore, there can be no guarantee that we will be able to find a successor when needed or enter into agreements on terms and conditions favorable to us, and in a timely manner. If our inventory supplies of lyophilized KL4 surfactant drug product or APIs are insufficient to satisfy demand, there could be an adverse impact on our current clinical development programs, our development activities and our business.

- If we undertake a technology transfer of our manufacturing process to a new CMO, we could be subject to delay or unanticipated problems, including that a CMO or supplier that we choose may be unable to successfully complete the technology transfer and thereafter manufacture our drug product or APIs, or assemble our medical devices in accordance with our plan;

- CMOs and suppliers might be unable to manufacture our drug and medical device products, APIs, excipients and materials in the volume and to our specifications to meet our clinical requirements, or we may have difficulty scheduling the production of drug product, APIs and devices in a timely manner to meet our timing requirements;

- CMOs and suppliers may not perform as agreed, or may unexpectedly exit the business, or may refuse to renew an expiring agreement as expected, or may fail to timely produce a sufficient supply to meet our clinical requirements;

- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Body(ies), the Drug Enforcement Administration, and/or corresponding state agencies to ensure strict compliance with cGMP and/or QSR and other government regulations and corresponding international standards. The failure of a CMO to have a compliance status acceptable to the FDA or other regulatory authorities could delay approval of our product candidates; and

- if we seek to make our clinical drug products and/or medical devices available outside the US, our CMOs would become subject to, and would have to comply with, corresponding manufacturing and quality system regulations or standards of the various foreign regulators having jurisdiction over our activities abroad. If for any reason a CMO failed to so comply, such failures could adversely affect our ability to provide our products and medical devices in all jurisdictions as planned.

If any of the foregoing risks were to arise, our development programs could be delayed, or ability to maintain continuity of supply could be impaired, which could have a material adverse impact on our operations and our business.

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101.1	The following condensed consolidated financial statements from the Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of September 30, 2019 (unaudited) and December 31, 2018, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2019 and September 30, 2018, (iii) Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2019 and September 30, 2018, (iv) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2019 and September 30, 2018, 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: November 14, 2019

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

Date: November 14, 2019

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

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Windtree Therapeutics, Inc. (the "Company);

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 Company as of, and for, the periods presented in this report;

4. I am 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 Company 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 Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

(c) Evaluated the effectiveness of the Company'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 Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: November 14, 2019

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

Exhibit 31.2

CERTIFICATIONS

I, John Tattory, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Windtree Therapeutics, Inc. (the "Company);

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 Company as of, and for, the periods presented in this report;

4. I am 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 Company 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 Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

(c) Evaluated the effectiveness of the Company'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 Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: November 14, 2019

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

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Windtree Therapeutics, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2019

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

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

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to us and will be retained by us and furnished to the SEC or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.