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

FORM 10-Q

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

For the quarterly period ended June 30, 2018

or

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

For the transition period from to

Commission file number 000-26422

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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 ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒
Emerging growth company ☐	

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

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

As of August 3, 2018, there were outstanding 3,769,088 shares of the registrant's common stock, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

PART II - OTHER INFORMATION

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc., and its wholly owned, presently inactive subsidiary, Discovery Laboratories, 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, and the time during which our existing cash and other resources may support our continued operation as a going concern. Forward-looking statements also include our expectations about our research and development programs, including planned development activities, anticipated timing of clinical trials and potential development milestones; the timing and anticipated outcomes of submitting regulatory filings in the United States and other markets; manufacturing plans for our KL4 surfactant, active pharmaceutical ingredients (APIs) and our proprietary aerosol delivery system (ADS); and our plans regarding potential collaborations and alliances, including potential licensing opportunities, and 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 the risks and uncertainties include, but are not limited to:

Risks Related to Capital Resource Requirements

- we require significant additional capital to maintain operations and continue as a going concern. As of August 3, 2018, we have sufficient cash and cash equivalents to maintain our operations through mid-August 2018. We are currently engaged in discussions for a potential strategic transaction that could bring additional capital and diversify our assets; however, there can be no assurance that we will be able to reach agreement within an acceptable time frame, if at all, and on terms acceptable to all parties. As we work to complete the strategic transaction, Lee's Pharmaceutical Holdings Limited (Lee's), which owns a majority interest in our Company, has indicated to us that it will provide us interim financial support while we work to complete the strategic transaction; however, we have not executed agreements for any additional advances at this time and there can be no assurance that additional interim support will be forthcoming and, as such, there is substantial doubt about our ability to continue as a going concern;

- we seek to identify potential strategic transactions and/or additional equity offerings to enhance and diversify our product offerings and support our development activities and operations. If we are successful in completing such a strategic transaction, we may be exposed to potentially significant risks and uncertainties related to the transaction, the expansion of our product offerings and diversion of management's attention and other resources from our core development activities, and we may require additional capital to support our expanded operations; if we are not successful in completing a strategic transaction, we will nevertheless have incurred potentially significant legal, accounting and other professional fees that will require additional capital;

- we recently completed design verification testing and related development activities for our new AEROSURF® phase 3 aerosol delivery system (ADS, which we previously referred to as "NextGen ADS"). However, in 2017, our AEROSURF phase 2b clinical trial did not meet its primary endpoint due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype ADS. In response, we planned to conduct an additional AEROSURF bridge clinical study that is designed, among other things, to clinically evaluate the design and performance of our new phase 3 ADS. These events and the resulting delay in the AEROSURF clinical development program have made it difficult to raise additional capital in the securities markets and, as such, we have depended primarily upon the support of Lee's and two previously announced loans from Panacea Venture Management Company Ltd. There can be no assurance that such support will continue, however; moreover, we will require additional capital beyond that provided by Lee's and Panacea to fund our bridge clinical study and there can be no assurance that we will be able to raise such additional capital through equity offerings in the securities markets, if at all;

- to restore investor confidence and attract sustained financial support, we believe that we must timely advance our AEROSURF development program through our planned device bridging clinical study and be in a position to initiate an AEROSURF phase 3 clinical program; even if our AEROSURF development efforts are successful, we expect that we will incur ongoing significant losses and will require significant additional capital to support our late-stage development, regulatory and business activities. In addition, our ability to raise such capital may be adversely impacted by future unforeseen adverse developments;

- our common stock has been quoted on the OTC Markets Group Inc.'s OTCQB® Market (OTCQB) tier since May 5, 2017, and has experienced, over time, lower trading volumes and reduced analyst interest. In addition, effective December 22, 2017, we implemented a share combination (1-for-20 reverse split) that had the effect of reducing the number of shares outstanding and further lowering our trading volumes. These conditions may make it more difficult to raise capital when needed. Our stockholders also may find it more difficult to trade our securities on the OTCQB, and the value and liquidity of our common stock may be adversely affected, which could have a material adverse effect on our ability to raise the additional capital that we require. Moreover, even if we are successful in raising the required capital, any equity financings could result in substantial equity dilution of stockholders' interests;

- if our AEROSURF development program is unduly delayed or should other complications arise, given our limited cash resources, we may be unable to implement the corrective actions that we might like, which potentially could adversely impact our planned development timelines. Under such circumstances, we may find it difficult to raise additional capital when needed to continue our development programs and support our operations;

- to manage our cash resources and closely monitor cash outflows, we aggressively monitor our payables and work closely with our vendors, suppliers and service providers to assure that investment and spending decisions advance our corporate objectives at any time. During periods of limited cash resources, our paced or delayed payment practices potentially could impair our relationships with important vendors, suppliers and servicers, which could have a material adverse effect on our business, operation and development programs;

Risks related to Development Activities

- our AEROSURF development program could be adversely affected by such risks as: our new ADS may not perform in a consistent and predictable manner; we may miscalculate the treatment effect or comparator performance or underpower the size of a clinical study; variability in patient management among physicians, institutions and countries may adversely affect the results of our clinical study or we could experience adverse events that impact the benefit/risk profile; our efforts to manufacture, test and release lyophilized KL4 surfactant and ADS devices and procure other supplies, will also require that we initiate, conduct and monitor clinical programs in clinical sites in multiple jurisdictions and could be adversely affected by unforeseen events and requirements or delayed, which potentially could have a material adverse effect on our development programs, business and operations;

- we participate in rigorous regulatory processes to potentially gain approval for any drug, medical device or combination drug/device product candidate; in that regard, FDA or other regulatory authorities may withhold or delay consideration of our applications, may not agree with us on matters raised during the review process, or may require us to conduct significant unanticipated activities to advance our product candidates; FDA or other regulatory authorities may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- our efforts to gain regulatory approval in a timely manner for our drug and combination drug/device products in the U.S. and in international markets may be adversely affected by unforeseen developments and changed circumstances, including in the national or international political and regulatory environment and may make it more difficult to gain FDA or international regulatory approvals;

Risks Related to Strategic and Other Transactions

- we may be unable to identify and enter into strategic alliances, collaboration agreements or other strategic transactions that would provide capital to support our AEROSURF development activities, or resources and expertise to support the registration and commercialization of AEROSURF in various markets, and potentially support the development and, if approved, commercialization, of our other potential KL4 surfactant pipeline products; or such strategic alliances, collaboration agreements and other strategic transactions may be delayed, terminated or fail, which could prevent us from advancing our development programs in accordance with our plan;

- we believe that, even if our AEROSURF development efforts are successful, we also must seek to identify and pursue development of additional product candidates, including other KL4 surfactant product candidates, to potentially leverage our capabilities, maximize our resources, reduce our dependency upon a single product candidate, and attract the significant capital that we will require;

Risks related to Manufacturing

- our contract manufacturing organizations (CMOs) or any of our third-party suppliers, most of which are single-source providers, may encounter problems in manufacturing our KL4 surfactant, active pharmaceutical ingredients (APIs) and other materials used in the manufacture of our KL4 surfactant, and the ADS, related components and other materials, on a timely basis or in an amount sufficient to support our needs;

- we have transferred the manufacturing process for our KL4 surfactant to our CMO, with elements of the final process validation pending. Such technology transfers and the related process validation may be time consuming and expensive and may experience problems, delays and setbacks;

- our drug product must be produced in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, which are conducted by our own analytical laboratory, third-party laboratories, most of which are also single-source providers, and our CMO, and which are expensive and could produce results that do not meet our specifications;

- we are engaged in a technology transfer of our manufacturing processes for our ADS to a device manufacturer and assembler, which is expected to produce ADSs and disposable components for use in our planned clinical programs. In executing the technology transfer, we may experience problems, delays and setbacks that could affect our timeline for further development and clinical activities;

- our device manufacturer and assembler, whom we expect to support further ADS development and manufacturing process enhancements, and manufacture and assemble our ADS for our continuing clinical programs and, if approved, commercial activities, may experience problems, delays and materials shortages;

- our CMOs and suppliers of our APIs may experience problems in manufacturing our drug product, APIs and medical device components from time to time; ultimately, if our products are approved, they may experience problems complying with the final drug and medical device approval specifications;

Other Risks Affecting Our Business

- in the third quarter of 2017, Lee's acquired a controlling interest in us through a wholly-owned subsidiary, LPH Investments Limited, and as such holds sufficient voting power to approve transactions that may not be in the best interests of other stockholders or recommended by management, or to take control of the Board of Directors by nominating and electing its own directors; in addition, we have entered into a License Agreement with Lee's Pharmaceutical (HK) Ltd. (Lee's (HK)), a subsidiary of Lee's, granting Lee's (HK) rights to develop and commercialize our products in a specific Asian territory and Lee's could use its voting power to benefit Lee's (HK), which could give rise to potential or apparent conflicts of interest; and

- other risks and uncertainties detailed in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, and in the documents incorporated by reference in this report, other risks and uncertainties detailed in "Risk Factors" in our most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on April 17, 2018, and our 2018 Quarterly Reports and filings with the SEC and any amendments thereto.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, 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, 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 SUBSIDIARY
Condensed Consolidated Balance Sheets
(in thousands, except share data)

	June 30, 2018	December 31, 2017
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 638	$ 1,815
Prepaid expenses and other current assets	397	422
Total current assets	1,035	2,237
Property and equipment, net	804	885
Restricted cash	140	225
Total assets	$ 1,979	$ 3,347
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 4,258	$ 3,048
Collaboration payable	3,718	3,624
Accrued expenses	3,974	4,204
Deferred revenue - current portion	731	884
Loan payable	2,500	-
Total current liabilities	15,181	11,760
Restructured debt liability - contingent milestone payments	15,000	15,000
Deferred revenue - non-current portion	-	407
Other liabilities	182	100
Total liabilities	30,363	27,267
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 2,701 shares issued and outstanding at June 30, 2018 and December 31, 2017	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at June 30, 2018 and December 31, 2017; 3,769,162 shares issued at June 30, 2018 and December 31, 2017; 3,769,088 shares outstanding at June 30, 2018 and December 31, 2017	4	3
Additional paid-in capital	619,344	616,245
Accumulated deficit	(644,678)	(637,114)
Treasury stock (at cost); 74 shares	(3,054)	(3,054)
Total stockholders' equity	(28,384)	(23,920)
Total liabilities & stockholders' equity	$ 1,979	$ 3,347

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Grant revenue	$ 695	$ 1,147	$ 695	$ 1,366
License revenue with affiliate	356	-	560	-
Total revenues	1,051	1,147	1,255	1,366
Expenses:				
Research and development	2,879	5,483	5,997	11,896
General and administrative	1,208	1,804	3,134	3,726
Total operating expense	4,087	7,287	9,131	15,622
Operating loss	(3,036)	(6,140)	(7,876)	(14,256)
Other income / (expense):				
Interest income	4	3	8	6
Interest expense	(92)	(615)	(182)	(1,226)
Other income	72	-	486	-
Other income / (expense), net	(16)	(612)	312	(1,220)
Net loss	$ (3,052)	$ (6,752)	$ (7,564)	$ (15,476)
Deemed dividend on Series A preferred stock	-	(532)	-	(4,136)
Net loss attributable to common shareholders	$ (3,052)	$ (7,284)	$ (7,564)	$ (19,612)
Net loss per common share				
Basic and diluted	$ (0.81)	$ (14.37)	$ (2.17)	$ (40.96)
Weighted average number of common shares outstanding				
Basic and diluted	3,751	507	3,491	479

See notes to condensed consolidated financial statements

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

(in thousands)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (7,564)	$ (15,476)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	(560)	-
Depreciation and amortization	82	101
Stock-based compensation and 401(k) plan employer match	558	660
Amortization of prepaid interest	-	543
Gain on sale of property and equipment	(9)	-
Changes in:		
Prepaid expenses and other current assets	25	194
Accounts payable	1,210	2,231
Collaboration payable	94	(37)
Accrued expenses	(148)	(1,077)
Net cash used in operating activities	(6,312)	(12,861)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	9	-
Purchase of property and equipment	-	(24)
Net cash used in investing activities	9	(24)
Cash flows from financing activities:		
Proceeds from loan payable, net of expenses	2,500	-
Proceeds from Private Placement issuance of securities, net of expenses	2,542	8,789
Proceeds from ATM Program, net of expenses	-	1,036
Net cash provided by financing activities	5,042	9,825
Net increase/(decrease) in cash and cash equivalents	(1,262)	(3,060)
Cash, cash equivalents and restricted cash - beginning of year	2,040	5,813
Cash, cash equivalents and restricted cash - end of year	$ 778	$ 2,753
Supplementary disclosure of cash flows information:		
Interest paid	$ -	$ 514

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 company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies, including our proprietary aerosol delivery system (ADS), being developed to enable noninvasive administration of aerosolized KL4 surfactant. We recently completed design verification for our new phase 3 ADS (which we previously referred to as the "NextGen ADS"), which we plan to use in our remaining AEROSURF® clinical development activities and, if approved, initial commercial activities. We believe that our proprietary technologies may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of respiratory distress syndrome (RDS) in premature infants who may require surfactant therapy to sustain life. The currently-available surfactants in the United States (U.S.) are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support such as nasal continuous positive airway pressure (nCPAP). Because nCPAP does not address the underlying surfactant deficiency, many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require delayed surfactant therapy administered with invasive intubation (an outcome referred to as "nCPAP failure"). If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to premature infants earlier in their course of treatment and without exposing them to the risks associated with invasive endotracheal intubation and mechanical ventilation.

AEROSURF is designed to administer aerosolized KL4 surfactant noninvasively and potentially meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, will allow for earlier treatment of premature infants who currently receive delayed surfactant therapy, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy following nCPAP failure. We also believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. Consistent with our belief, FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

In addition to advancing AEROSURF, we are assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant may potentially provide benefits related to use, including longer shelf life, reduced cold-chain requirements and lower viscosity. We have discussed with the FDA a potential development plan, trial design and regulatory plan for approval. If we can define an acceptable development program that is achievable from a cost, timing and resource perspective, we might seek approval to treat premature infants who, because they are unable to breathe on their own or other reason, cannot benefit from AEROSURF.

We also believe that our KL4 surfactant technology may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have received support, and plan to seek additional support, from the National Institutes of Health (NIH) and other government funding sources to explore the utility of our KL4 surfactant to address a variety of such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI; as well as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). Although there can be no assurance, we may in the future support development activities to establish a proof-of-concept and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or pursue other financial alternatives to fund further development and, if approved, commercialization of additional KL4 surfactant indications.

To leverage our capabilities, maximize the use of our resources and potentially reduce our dependency on a single product candidate, we also seek to enter into strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction). We are currently engaged in discussions for a potential strategic transaction that could diversify our assets and bring in additional capital. There can be no assurance, however, that we will be able to reach agreement on terms and within the time frame acceptable to all parties. Moreover, even if we reach agreement and complete a transaction, there can be no assurance that we will have sufficient resources to fund the continued development of AEROSURF or any other product candidates, that any of our development efforts would be successful, or that we would obtain regulatory approvals needed to commercialize our product candidates in the world's markets.

Note 2 – Liquidity Risks and Management's Plans

As of June 30, 2018, we had cash and cash equivalents of $0.6 million and current liabilities of $15.2 million. On July 2, 2018, we were able to secure $1.5 million in additional capital (see below), and as of August 3, 2018 we had cash and cash equivalents of $0.7 million, which we believe is sufficient to maintain our operations through mid-August 2018. We are currently engaged in discussions for a potential strategic transaction that could diversify our assets and bring in additional capital to fund our activities. As we seek to finalize that transaction, Lee's Pharmaceutical Holdings Limited (Lee's), the majority holder of our common stock, has indicated to us that it will provide us interim financial support while we work to complete a strategic transaction; however, we have not executed agreements for any additional advances at this time and there can be no assurance that additional interim support will be forthcoming. Moreover, in connection with these activities, we are incurring and will continue to incur potentially significant legal, accounting, and other professional fees that represent an additional financial burden for which we will require additional capital.

We expect to continue to incur significant losses and will require significant additional capital to support our operations, advance our AEROSURF clinical development program, and satisfy existing obligations, 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 to raise additional capital through one or more of the following: (i) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through private placements of our equity securities, although there can be no assurance that we will be able to secure such transactions or complete a private placement on acceptable terms, if at all. Although we are currently engaged in active diligence and discussions for a potential strategic transaction, there is no guarantee we will be able to complete the strategic transaction. In addition, if none of the other alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, 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.

In April 2018, we completed a $2.6 million private placement offering with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee's, from which we received net proceeds of approximately $2.5 million. In June 2018, we entered into a Guaranty and Replenishment Agreement with Lee's pursuant to which Lee's agreed to replenish amounts up to $1 million expended by us that reduce our cash resources to an amount that is less than our planned minimum cash (the amount that would otherwise be required to cover estimated wind-down costs should we be unable at any time to continue as a going concern). Lee's secured its obligation to us by delivering an Irrevocable Stand-by Letter of Credit (the Letter of Credit) in the amount of $1 million in favor of the Company, which expires on October 31, 2018. As of August 3, 2018, we have not drawn on the Letter of Credit.

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea), a Secured Convertible Promissory Note (the Note) with respect to a loan facility in the aggregate amount of up to $1.5 million. In connection with the issuance of the Note, Panacea made two loans (individually, each a Loan and collectively, the Loans) to us, the first of which was in the amount of $1.0 million and paid on the date of the Note and the second of which was in the amount of $500,000 and received on July 23, 2018. The Loans bear interest on the outstanding principal amount at a rate of 15% per annum until the Note is paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea may deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, may participate. There can be no assurance that such a private placement will be completed. In connection with these Loans, we granted to Panacea a security interest in substantially all our assets. The proceeds of these Loans are being used to support our operations while we pursue a potential strategic transaction that could diversify our assets and bring in additional capital.
(S*ee,* "– Note 12 – Subsequent Events").

As of June 30, 2018, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 113.5 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

Note 3 – Basis of Presentation

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. There have been no changes to our critical accounting policies since December 31, 2017. For a discussion of our accounting policies, *see*, "– Note 4 – Summary of Significant Accounting Policies" in this Quarterly Report on Form 10-Q, and, in the Notes to Consolidated Financial Statements in our 2017 Form 10-K, "– Note 4 – Accounting Policies and Recent Accounting Pronouncements." Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Note 4 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements, in conformity with U.S. 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.

Restructured debt liability – contingent milestone payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*See*, "– Note 9 – 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.

Deferred revenue

Deferred revenue represents amounts received prior to satisfying the revenue recognition criteria (*see*, Revenue recognition) and are recognized as deferred revenue in our balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as Deferred revenue – current portion. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as Deferred revenue, non-current portion.

Deferred revenue primarily consists of amounts related to an upfront license fee received in July 2017 in connection with the License Agreement with Lee's. The revenue will be recognized as our performance obligations under the contract are met (*see*, Note 11 – Out-Licensing Agreement).

Revenue recognition

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, we recognize the cumulative effect of initially adopting ASC Topic 606, if any, as an adjustment to the opening balance of retained earnings. Additionally, under this method of adoption, we apply the guidance to all incomplete contracts in scope as of the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 606, we recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the we determine are within the scope of ASC Topic 606, we perform the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, we assess the goods or services promised within a contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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 Accounting Standards Codification (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 June 30, 2018 and 2017, the number of shares of common stock potentially issuable upon the conversion of preferred stock or exercise of certain stock options and warrants was 1.1 million and 1.2 million shares, respectively. For the three and six months ended June 30, 2018 and 2017, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

Net loss per common share – basic and diluted and weighted average number of common shares outstanding for the three and six months ended June 30, 2017 have been corrected for immaterial calculation errors related to the conversion of preferred stock to common stock during those periods.

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

Beneficial Conversion Feature

The issuance of Series A Convertible Preferred Stock (Preferred Shares) in the second quarter of 2017 (*see*, "– Note 5 – Stockholders' Equity") resulted in a beneficial conversion feature, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor (or in the money) at inception due to the conversion option having an effective conversion price that is less than the fair value of the underlying stock at the commitment date. We recognized the beneficial conversion feature by allocating the relative fair value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital, resulting in a discount on the Preferred Shares. As the Preferred Shares are immediately convertible by the holders, the discount allocated to the beneficial conversion feature was immediately accreted and recognized as a $3.6 million one-time, non-cash deemed dividend to the preferred shareholders during the first quarter of 2017.

An additional discount to the Preferred Shares of $4.5 million was created due to the allocation of proceeds to the Warrants which were issued with the Preferred Shares. This discount is amortized proportionately as the Preferred Shares are converted. No Preferred Shares were converted during the three or six months ended June 30, 2018. For the three months ended June 30, 2017, we recognized a non-cash deemed dividend to the preferred shareholders of $0.5 million related to the Preferred Shares converted during the period.

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.

On December 22, 2017, the U.S. government enacted the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act), which significantly revises U.S. tax law by, among other provisions, lowering the U.S. federal statutory income tax rate to 21%, imposing a mandatory one-time transition tax on previously deferred foreign earnings, and eliminating or reducing certain income tax deductions. As of December 31, 2017, we recorded the provisional impact from the 2017 Tax Act in accordance with SAB 118. As of June 30, 2018, we have not adjusted any of our provisional amounts that were recorded as of December 31, 2017. We will finalize our adjustments during 2018.

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was subsequently amended by several other ASUs related to Topic 606 to, among other things, defer the effective date and clarify various aspects of the new revenue guidance including principal versus agent considerations, identifying performance obligations, and licensing, and include other improvements and practical expedients. We adopted ASU 2014-09, as amended, effective January 1, 2018 using the modified retrospective transition method. In July 2017, we entered into a License Agreement with Lee's (HK), granting Lee's (HK) rights to develop and commercialize our products in a specific Asian territory. The consideration we are eligible to receive under this agreement includes an upfront payment, contingent revenues in the form of regulatory and commercial milestones, and sales-based milestone and royalty payments. We evaluated the License Agreement under ASU 2014-09 and determined that there was no material impact to revenues for any of the years presented upon adoption. Additionally, there were no revisions to any balance sheet components of revenues such as deferred revenues or beginning retained earnings as a result of the adoption of the modified retrospective method. The primary impact on our financial statements is related to revised or additional disclosures with respect to revenues and cash flows arising from contracts with customers, which are included in Note 11 – Out-Licensing Agreement.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718), Scope of Modification Accounting*. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The ASU is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. We adopted ASU 2017-09 effective January 1, 2018 and the adoption did not have a material impact on our unaudited condensed consolidated financial statements and is not expected to have a material impact on the annual 2018 financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*. This ASU clarifies clarify how entities should classify certain cash receipts and cash payments related to eight specific cash flow issues, including debt prepayment or extinguishment costs, with the objective of reducing diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The ASU is effective retrospectively for the annual period ending December 31, 2018 and interim periods within that annual period. We adopted ASU 2016-15 effective January 1, 2018 and the adoption did not have a material impact on our unaudited condensed consolidated financial statements and is not expected to have a material impact on the annual 2018 financial statements.

Note 5 – Stockholders' Equity

On April 4, 2018, we completed a private placement offering pursuant to a Securities Purchase Agreement (SPA) and Registration Rights Agreement with LPH II Investments Limited (LPH II), a Cayman Islands company and wholly-owned subsidiary of Lee's. Under this SPA, LPH II invested $2.6 million and acquired 541,667 shares of our common stock and warrants to purchase 135,417 shares of our common stock at an exercise price of $5.52 per share. The purchase price per share was $4.80. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date. In addition, under the Registration Rights Agreement, we agreed to file an initial resale registration statement with the SEC to register for subsequent resale the shares and the warrant shares. We are required to seek registration of 25% of the shares and warrant shares on such initial resale registration statement. From time to time, following the 180th day from March 30, 2018, LPH II or a majority of the holders of the shares and warrant shares may require us to file additional registration statement(s) to register the resale of the balance of the shares and warrant shares, subject to certain limitations.

Note 6 – License Revenue with Affiliate

(in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
License revenue with affiliate	$ 356	$ -	$ 560	$ -

License revenue with affiliate for the three and six months ended June 30, 2018 represents revenue from a License Agreement with Lee's (HK) and constitutes a contract with a customer accounted for in accordance with ASC Topic 606, which we adopted effective January 1, 2018 (*see*, Note 4 – Summary of Significant Accounting Policies – Recently Adopted Accounting Standards and Note 11 – Out-Licensing Agreement). There was no impact to License revenue with affiliate previously recognized as a result of the adoption of ASC Topic 606.

Note 7 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

(in thousands)	Fair Value June 30, 2018	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 638	$ 638	$ -	$ -
Certificate of deposit	140	140	-	-
Total Assets	$ 778	$ 778	$ -	$ -

(in thousands)	Fair Value December 31, 2017	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 1,815	$ 1,815	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 2,040	$ 2,040	$ -	$ -

Note 8 – Loan Payable

In January 2018 and March 2018, LPH agreed to lend us $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we seek to identify and advance one or more potential strategic initiatives as defined in the related loan agreements (Funding Event). To secure our obligations under these loans, we granted LPH a security interest in substantially all our assets. The loans accrue interest at a rate of 6% per annum and mature upon the earlier of the closing date of the Funding Event or December 31, 2018. We expect to apply the outstanding principal balance of the loans in satisfaction of a like amount of cash consideration payable by LPH for its participation in the Funding Event, and the loans will thereby be fully discharged.

Note 9 – Restructured debt liability

(in thousands)	June 30, 2018	December 31, 2017
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 – Restructured debt liability – contingent milestone payment).

Note 10 – Stock Options and Stock-Based Employee Compensation

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

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2018	84	$ 163.20	
Granted	-	-	
Forfeited or expired	(1)	693.45	
Outstanding at June 30, 2018	83	$ 158.88	7.3
Vested and exercisable at June 30, 2018	65	$ 195.43	7.0
Vested and expected to vest at June 30, 2018	82	$ 159.40	7.3

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2018	190	$ 4.33
Awarded	-	-
Vested	-	-
Unvested at June 30, 2018	190	$ 4.33

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

	Six Months Ended June 30, 2017
Weighted average expected volatility	79%
Weighted average expected term	6.6
Weighted average risk-free interest rate	2.22%
Expected dividends	-

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

(in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Research and development	$ 30	$ 124	$ 140	$ 283
Selling, general and administrative	110	130	418	271
Total	$ 140	$ 254	$ 558	$ 554

Note 11 – Out-Licensing Agreement

Lee's Pharmaceutical (HK) Ltd.

In June 2017, we entered into a License, Development and Commercialization Agreement ("License Agreement") with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong (**"**Lee's"). Under the License Agreement, we granted to Lee's an exclusive license with a right to sublicense, (i) to develop and commercialize our KL4 surfactant products, including SURFAXIN®, which was approved by the U.S. Food and Drug Administration ("FDA") in 2012 for the prevention of respiratory distress syndrome ("RDS") in premature infants, SURFAXIN LS™, the lyophilized dosage form of SURFAXIN; and AEROSURF®, an investigative combination drug/device product that is designed to deliver aerosolized KL4 surfactant noninvasively, and (ii) to register and manufacture SURFAXIN and SURFAXIN LS for use in the Licensed Territory, which includes the People's Republic of China ("PRC"), Hong Kong, Thailand, Taiwan and 12 other countries (the "Licensed Territory"). In addition, we granted Lee's options to potentially add Japan to the Licensed Territory and to manufacture our ADS in the Licensed Territory, in each case subject to conditions set forth in the License Agreement.

Under the License Agreement, Lee's made an upfront payment to us of $1 million. We also may receive up to $37.5 million in potential clinical, regulatory and commercial milestone payments and will share in any sublicense income Lee's may receive at a rate equal to low double digits. In addition, Lee's will be responsible for all costs and expenses in and for the Licensed Territory related to development activities, including a planned AEROSURF phase 3 clinical trial, regulatory activities, and commercialization activities.

In August 2017, we entered into a Loan Agreement, pursuant to which Lee's (HK) agreed to lend us up to $3.9 million to support our activities through October 31, 2017, while we and Lee's worked to complete a $10 million securities purchase agreement (Lee's SPA) pursuant to which Lee's acquired a controlling interest in our Company effective on November 1, 2017. In connection with Lee's SPA, we amended the License Agreement (Amendment No. 1) to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. As a result, the additional amounts for potential clinical, regulatory and commercial milestone were reduced to $35.8 million.

Accounting Analysis under ASC 606

In evaluating the License Agreement in accordance with ASC Topic 606, we concluded that the contract counterparty, Lee's (HK), is a customer. We identified the following performance obligations: (i) a bundled performance obligation consisting of licensing rights to develop and commercialize our KL4 surfactant products and a technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS; and (ii) a technology transfer process for the manufacture of our ADS. We determined that participation in the Joint Steering Committee (and other committees under its authority) and our ongoing product development, regulatory, and commercialization activities under the License Agreement were deemed immaterial in the context of the contract. Consistent with the guidance under ASC 606-10-25-16A, we disregarded immaterial promised goods and services when determining performance obligations.

We concluded that the licensing rights were not distinct within the context of the contract (i.e. separately identifiable) because the licensing rights do not have stand-alone value from other promised goods and services as Lee's (HK) could not benefit from the licensing rights without the completion of the technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS. The technology transfer process for the manufacture of our ADS is distinct within the context of the contract because it has stand-alone value from other promised goods and services as Lee's (HK) could benefit from this right on a stand-alone basis. However, we determined that the ADS manufacturing right has a nominal stand-alone selling price at the time of Amendment No. 1 as the ADS is not yet verified and there is uncertainty with regard to the commercial value of the ADS given that the AEROSURF combination drug/device product is currently in clinical development.

With respect to Amendment No. 1, we elected to use the practical expedient for contract modifications that occur prior to the adoption of ASU 2014-09, and we determined that the impact was immaterial. Allocable arrangement consideration under the practical expedient comprised the upfront payment of $1 million and $0.3 million related to reductions in royalties and milestones in connection with Amendment No. 1. The $1.3 million was attributed in its entirety to the bundled performance obligation of licensing rights to develop and commercialize our KL4 surfactant products and a technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS. Revenue associated with the bundled performance obligation was recognized beginning in November 2017 with the initiation of the technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS and will be recognized over time as services are performed and based on the input method related to the level of effort expended. The expected completion date for the technology transfer is June 2019.

Regulatory and commercialization milestones were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. As part of our evaluation of the constraint, we considered a number of factors in determining whether there is significant uncertainty associated with the future events that would result in the milestone payments. Those factors include: our financial position; ongoing delays in our development activities and with initiating phase 3 clinical trial; our limited experience with successful drug development; our limited experience with clinical trials; our recent failure to achieve primary endpoints in our phase 2b clinical trial; our limited experience with commercialization; our decision in 2015 to cease manufacturing and commercializing of SURFAXIN; and the fact that the uncertainty about the related consideration is not expected to be resolved for a long period of time (*see*, Item 1A – Risk Factors).

Consideration related to sales-based milestones and royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Lee's (HK) and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Note 12 – Subsequent Events

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea), a Secured Convertible Promissory Note (the Note) with respect to Loans (defined below) in the aggregate amount of up to $1.5 million. In connection with the issuance, Panacea made two loans (individually, Loan and collectively, the Loans) to us, the first of which was in the amount of $1.0 million and funded on the date of the Note, and the second of which was in the amount of $500,000 and received on July 23, 2018.

The Loans bear interest on the outstanding principal amount at a rate of 15% per annum until the Note is paid in full or converted into shares of our common stock at a price per share of $4.00, which was the closing price of our common stock as quoted on the OTCQB® trading market operated by the OTC Markets Group on June 29, 2018, the trading day immediately preceding the funding date for the first Loan. In addition, in lieu of converting the Note, Panacea may deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, may participate. There can be no assurance that such a private placement will be completed. To secure our obligations under the Note, we granted to Panacea a security interest in substantially all of our assets. The proceeds of these Loans are being used to support our operations while we pursue a potential strategic transaction that could diversify our assets and bring in additional capital (see, "– Note 2 – Liquidity Risks and Management's Plans").

In connection with the Loans, we issued to Panacea warrants (the "Series D Warrants") to purchase 187,500 shares (the "Warrant Shares") at an exercise price of $4.00 per Warrant Share (the "Exercise Price"). The Warrants may be exercised at any time beginning six months after the date of issuance and through the fifth anniversary of the date of issuance. The Warrants may not be exercised to the extent that the holder thereof would, following such exercise, beneficially own more than 9.99% of the Company's outstanding shares of Common Stock, which percentage may be increased, decreased or waived by such holder upon sixty-one days' notice to the Company. The Warrants also contain customary provisions that adjust the Exercise Price and the number of Warrant Shares in the event of a corporate transaction.

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

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. The reader should review the "Forward-Looking Statements" section, and risk factors discussed in the Risk Factors Section and elsewhere in this Quarterly Report on Form 10-Q, which, together with the earlier Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 that we filed on May 21, 2018, are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2017 that we filed with the Securities and Exchange Commission (SEC) on April 17, 2018 (2017 Form 10-K,) 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 and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) and the 2017 Form 10-K. 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 company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies, including our proprietary aerosol delivery system (ADS), being developed to enable noninvasive administration of aerosolized KL4 surfactant. We recently completed design verification for our new phase 3 ADS (which we previously referred to as the "NextGen ADS"), which we plan to use in our remaining AEROSURF® clinical development activities and, if approved, initial commercial activities. We believe that our proprietary technologies may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of respiratory distress syndrome (RDS) in premature infants who may require surfactant therapy to sustain life. The currently-available surfactants in the United States (U.S.) are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support such as nasal continuous positive airway pressure (nCPAP). Because nCPAP does not address the underlying surfactant deficiency, many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require delayed surfactant therapy administered with invasive intubation (an outcome referred to as "nCPAP failure"). If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to premature infants earlier in their course of treatment and without exposing them to the risks associated with invasive endotracheal intubation and mechanical ventilation.

AEROSURF is designed to administer aerosolized KL4 surfactant noninvasively and potentially meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, will allow for earlier treatment of premature infants who currently receive delayed surfactant therapy, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy following nCPAP failure. We also believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. Consistent with our belief, FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

In addition to advancing AEROSURF, we are assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant may potentially provide benefits related to use, including longer shelf life, reduced cold-chain requirements and lower viscosity. We have discussed with the FDA a potential development plan, trial design and regulatory plan for approval. If we can define an acceptable development program that is achievable from a cost, timing and resource perspective, we might seek approval to treat premature infants who, because they are unable to breathe on their own or other reason, cannot benefit from AEROSURF.

We also believe that our KL4 surfactant technology may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have received support, and plan to seek additional support, from the National Institutes of Health (NIH) and other government funding sources to explore the utility of our KL4 surfactant to address a variety of such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI; as well as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). Although there can be no assurance, we may in the future support development activities to establish a proof-of-concept and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or pursue other financial alternatives to fund further development and, if approved, commercialization of additional KL4 surfactant indications.

To leverage our capabilities, maximize the use of our resources and potentially reduce our dependency on a single product candidate, we also seek to enter into strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction). We are currently engaged in discussions for a potential strategic transaction that could diversify our assets and bring in additional capital. There can be no assurance, however, that we will be able to reach agreement on terms and within the time frame acceptable to all parties. Moreover, even if we reach agreement and complete a transaction, there can be no assurance that we will have sufficient resources to fund the continued development of AEROSURF or any other product candidates, that any of our development efforts would be successful, or that we would obtain regulatory approvals needed to commercialize our product candidates in the world's markets.

In 2017, our AEROSURF phase 2b clinical trial did not meet its primary endpoint due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype ADS. In response we planned to conduct an additional AEROSURF bridge clinical study that is designed, among other things, to clinically evaluate the design and performance of our new phase 3 ADS. These events and the resulting delay in the AEROSURF clinical development program have made it difficult to attract investors and raise additional capital in the securities markets at this time and, as such, we have depended primarily upon the continuing support of Lee's Pharmaceutical Holdings Limited (Lee's), our majority stockholder and licensee in the Asia Pacific markets, and two previously announced loans from Panacea Venture Management Company Ltd. to support our operations while we pursue the potential strategic transaction currently under discussion. There can be no assurance that such support will continue, however. We believe that our ability to continue as a going concern in the near term is highly dependent upon continuing support from Lee's, and our ability to continue as a going concern in the long term will be highly dependent upon our ability to secure the capital necessary to timely advance our AEROSURF development program, including plans to execute the AEROSURF bridge study and be in a position to initiate an AEROSURF phase 3 clinical program.

Business and Pipeline Program Updates

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business – Company Overview" and "– Business Strategy," in the 2017 Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and potential KL4 pipeline initiatives.

The following are business and development program updates for the second quarter ending June 30, 2018:

- On April 4, 2018, we completed a private placement offering pursuant to a Securities Purchase Agreement (SPA) and Registration Rights Agreement dated as of March 30, 2018, with LPH II Investments Limited (LPH II), a Cayman Islands company and wholly-owned subsidiary of Lee's. Under this SPA, LPH II invested $2.6 million and acquired 541,667 shares of our common stock and warrants to purchase 135,417 shares of our common stock at an exercise price of $5.52 per share. The purchase price per share was $4.80. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date. In addition, under the Registration Rights Agreement, we agreed to file within 90 days from March 30, 2018, an initial resale registration statement with the SEC to register for subsequent resale the shares and the warrant shares. We are required to seek registration of 25% of the shares and warrant shares on such initial resale registration statement. From time to time, following the 180th day from March 30, 2018, LPH II or a majority of the holders of the shares and warrant shares may require us to file additional registration statement(s) to register the resale of the balance of the shares and warrant shares, subject to certain limitations.

- In June 2018, we entered into a Guaranty and Replenishment Agreement with Lee's pursuant to which Lee's agreed to replenish amounts up to $1 million expended by us that reduce our cash resources to an amount that is less than our planned minimum cash (the amount that would otherwise be required to cover estimated wind-down costs should we be unable at any time to continue as a going concern). Lee's secured its obligation to us by delivering an Irrevocable Stand-by Letter of Credit (the Letter of Credit) in the amount of $1 million in favor of the Company. As of August 3, 2018, we have not drawn on the Letter of Credit.

- On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea), a Secured Convertible Promissory Note (the Note) with respect to Loans (defined below) in the aggregate amount of up to $1.5 million. In connection with the issuance of the Note, Panacea made two loans (individually, each a Loan and collectively, the Loans) to us, the first of which was in the amount of $1.0 million and paid on the date of the Note, and the second of which was in the amount of $500,000 and received on July 23, 2018. The Loans bear interest on the outstanding principal amount at a rate of 15% per annum until the Note is paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea may deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, may participate. There can be no assurance that such a private placement will be completed. The proceeds of these Loans are being used to support our operations while we pursue a potential strategic transaction that could diversify our assets and bring in additional capital. In connection with the Loans, we issued to Panacea warrants (the "Series D Warrants") to purchase 187,500 shares (the "Warrant Shares") at an exercise price of $4.00 per Warrant Share (the "Exercise Price") (see, "– Note 12 – Subsequent Events").

- 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. 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, 2017. 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 2017 Form 10-K, "Note 4 – Accounting Policies and Recent Accounting Pronouncements." Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended June 30, 2018 and 2017 was $3.0 million and $6.1 million, respectively. The decrease in operating loss from 2017 to 2018 was due to a $3.2 million decrease in operating expenses and a $0.4 million increase in license revenue with affiliate, partially offset by a $0.5 million decrease in grant revenue.

The operating loss for the six months ended June 30, 2018 and 2017 was $7.9 million and $14.3 million, respectively. The decrease in operating loss from 2017 to 2018 was due to a $6.5 million decrease in operating expenses and a $0.6 million increase in license revenue with affiliate, partially offset by a $0.7 million decrease in grant revenue.

The net loss for the three months ended June 30, 2018 and 2017 was $3.1 million and $6.8 million, respectively. Included in the net loss is interest expense of $0.1 million and $0.6 million in 2018 and 2017, respectively.

The net loss for the six months ended June 30, 2018 and 2017 was $7.6 million and $15.5 million, respectively. Included in the net loss is interest expense of $0.2 million and $1.2 million in 2018 and 2017, respectively.

The net loss attributable to common shareholders for the three and six months ended June 30, 2018 was $3.1 million (or $0.81 basic net loss per common share) and $7.6 million (or $2.17 basic net loss per common share). The net loss attributable to common shareholders for the three and six months ended June 30, 2017 was $7.3 million (or $14.37 basic net loss per common share) and $19.6 million (or $40.96 basic net loss per common share). Included in the net loss attributable to common shareholders for the three and six months ended June 30, 2017 is a $0.5 million and a $4.1 million non-cash deemed dividend on preferred stock, respectively (*see*, "Note 4 – Summary of Significant Accounting Policies – Beneficial Conversion Feature").

Grant revenue

For the three months ended June 30, 2018 and 2017, we recognized grant revenue of $0.7 million and $1.1 million, respectively.

Grant revenue for the three months ended June 30, 2018 consists of $0.7 million of funds received and expended under a Phase II Small Business Innovation Research Grant (SBIR) from the National Heart, Lung, and Blood Institute (NHLBI) of the NIH to support the AEROSURF phase 2b clinical trial (AEROSURF Grant). Grant revenue for the three months ended June 30, 2017 includes $0.9 million of funds received and expended under the AEROSURF Grant and $0.2 million of funds under a Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (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).

For the six months ended June 30, 2018 and 2017, we recognized grant revenue of $0.7 million and $1.4 million, respectively. Grant revenue for the six months ended June 30, 2018 consists of $0.7 million of funds received and expended under the AEROSURF Grant. Grant revenue for the six months ended June 30, 2017 includes $1.1 million of funds received and expended under the AEROSURF Grant and $0.3 million of funds under the Radiation Grant.

As of June 30, 2018, all funding under the AEROSURF Grant and the Radiation Grant has been received and $0.1 million related to the Radiation Grant is currently recorded as deferred revenue and will be recognized as grant revenue when the funds are expended.

License Revenue with Affiliate

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, we recognize the cumulative effect of initially adopting ASC Topic 606, if any, as an adjustment to the opening balance of retained earnings. Additionally, under this method of adoption, we apply the guidance to all incomplete contracts in scope as of the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 606, we recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the we determine are within the scope of ASC Topic 606, we perform the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, we assess the goods or services promised within a contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

For the three and six months ended June 30, 2018, we recognized license revenue with affiliates of $0.4 million and $0.6 million, respectively, which had previously been included in deferred revenue – current portion.

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 form the foundation for the development of our KL4 surfactant and drug delivery technologies, 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 six months ended June 30, 2018 and 2017 are as follows:

(in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Product development and manufacturing	$ 1,691	$ 1,830	$ 3,282	$ 3,707
Clinical, medical and regulatory operations	966	1,569	2,196	3,377
Direct preclinical and clinical programs	222	2,084	519	4,812
Total Research and Development Expenses	$ 2,879	$ 5,483	$ 5,997	$ 11,896

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.1 and $0.2 million for the three months ended June 30, 2018 and 2017, respectively, and $0.2 and $0.4 million for the six months ended June 30, 2018 and 2017, respectively.

Product Development and Manufacturing

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

Product development and manufacturing expenses decreased $0.1 million for the three months ended June 30, 2018 and $0.4 million for the six months ended June 30, 2018 compared to the same periods in 2017 due to (i) our ongoing efforts to conserve cash and reduce costs and (ii) a July 2017 workforce reduction.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses decreased $0.6 million for the three months ended June 30, 2018 and $1.2 million for the six months ended June 30, 2018 compared to the same periods in 2017 due to (i) our ongoing efforts to conserve cash and reduce costs and (ii) a July 2017 workforce reduction.

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 decreased $1.9 million for the three months ended June 30, 2018 and $4.3 million for the six months ended June 30, 2018 compared to the same periods in 2017 due to a decrease in AEROSURF phase 2 clinical development program costs following the completion of enrollment in the phase 2a and phase 2b clinical trials during the second quarter of 2017.

General and Administrative Expenses

(in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
General and Administrative Expenses	$ 1,208	$ 1,804	$ 3,134	$ 3,726

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

General and administrative expenses decreased $0.6 million in each of the three and six month periods ended June 30, 2018 compared to the same periods in 2017 due to (i) our ongoing efforts to conserve cash and reduce costs and (ii) a July 2017 workforce reduction.

Other Income and (Expense)

(in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Interest income	$ 4	$ 3	$ 8	$ 6
Interest expense	(92)	(615)	(182)	(1,226)
Other income	72	-	486	-
Other income / (expense), net	$ (16)	$ (612)	$ 312	$ (1,220)

For 2018, interest expense consists of interest expense associated with the Battelle payables and on the $2.5 million in Loans Payable. For 2017, interest expense primarily consists of interest expense associated with the Deerfield Loan (*see*, "Note 9 – Restructured debt liability").

Other income primarily consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2018, we had cash and cash equivalents of $0.6 million and current liabilities of $15.2 million. On July 2, 2018, we secured $1.5 million in additional capital, and as of August 3, 2018, we had cash and cash equivalents of $0.7 million, which we believe is sufficient to maintain our operations through mid-August 2018. We are currently engaged in discussions for a potential strategic transaction that could diversify our assets and bring in additional capital to fund our activities. As we seek to finalize that transaction, Lee's Pharmaceutical Holdings Limited (Lee's), the majority holder of our common stock, has indicated to us that it will provide us interim financial support while we work to complete the strategic transaction; however, we have not executed agreements for any additional advances at this time and there can be no assurance that additional interim support will be forthcoming. Moreover, in connection with these activities, we are incurring and will continue to incur potentially significant legal, accounting, and other professional fees that represent an additional financial burden for which we will require additional capital.

We expect to continue to incur significant losses and will require significant additional capital to support our operations, advance our AEROSURF clinical development program, and satisfy existing obligations, 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 to raise additional capital through one or more of the following: (i) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through private placements of our equity securities, although there can be no assurance that we will be able to secure such transactions or complete a private placement on acceptable terms, if at all. Although we are currently engaged in active diligence and discussions for a potential strategic transaction, there is no guarantee we will be able to complete the strategic transaction. In addition, if none of the other alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, 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.

In April 2018, we completed a $2.6 million private placement offering with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee’s, from which we received net proceeds of approximately $2.5 million. In June 2018, we entered into a Guaranty and Replenishment Agreement with Lee’s pursuant to which Lee’s agreed to replenish amounts expended by us that reduce our cash resources to an amount that is less than our planned minimum cash (the amount that would otherwise be required to cover estimated wind-down costs should we be unable at any time to continue as a going concern). Lee’s secured its obligation to us by delivering an Irrevocable Stand-by Letter of Credit (the Letter of Credit) in the amount of $1 million in favor of the Company, which expires on October 31, 2018. As of August 3, 2018, we have not drawn on the Letter of Credit.

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea), a Secured Convertible Promissory Note (the Note) with respect to a loan facility in the aggregate amount of up to $1.5 million. In connection with the issuance of the Note, Panacea made two loans (individually, each a Loan and collectively, the Loans) to us, the first of which was in the amount of $1.0 million and paid on the date of the Note and the second of which was in the amount of $500,000 and received on July 23, 2018. The Loans bear interest on the outstanding principal amount at a rate of 15% per annum until the Note is paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea may deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, may participate. There can be no assurance that such a private placement will be completed. In connection with these Loans, we granted to Panacea a security interest in substantially all our assets. The proceeds of these Loans are being used to support our operations while we pursue a potential strategic transaction that could diversify our assets and bring in additional capital.

In 2017, our AEROSURF phase 2b clinical trial did not meet its primary endpoint due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype ADS. In response, in November 2017, we planned to conduct an additional AEROSURF bridge clinical study that is designed, among other things, to clinically evaluate the design and performance of our new phase 3 ADS. These events and the resulting delay in the AEROSURF clinical development program have made it difficult to attract investors and raise additional capital in the securities markets at this time and, as such, we have depended primarily upon the continuing support of Lee’s Pharmaceutical Holdings Limited (Lee’s), our majority stockholder and licensee in the Asia Pacific markets, and two previously announced loans from Panacea Venture Management Company Ltd. to support our operations while we pursue the potential strategic transaction currently under discussion. There can be no assurance that such support will continue, however. We believe that our ability to continue as a going concern in the near term is highly dependent upon continuing support from Lee’s, and our ability to continue as a going concern in the long term will be highly dependent upon our ability to secure the capital necessary to timely advance our AEROSURF development program, including plans to execute the AEROSURF bridge study and be in a position to initiate an AEROSURF phase 3 clinical program, and achieve results that can attract investor interest. Our AEROSURF development program activities are subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing these activities in accordance with our plans, or at all. If our AEROSURF development program activities should be delayed for any reason, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and potentially the results of our clinical programs. Even if we complete our AEROSURF development program activities as planned, if the results are inconclusive, or present an unacceptable benefit/risk profile, we may be unable to secure the additional capital that we will require to continue our development activities and operations, which could have a material adverse effect on our business. In that event, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders’ interests and, in such event, the market price of our common stock may decline.

As we seek to secure the needed capital through strategic transactions and private placement equity offerings, we will be subject to regulatory and other restrictions, including that our status as a smaller reporting company makes us ineligible to use a registration statement on Form S-3 to register our securities and will have to use a long-form Form S-1, the preparation of which would be more time-consuming and costly; our controlling stockholder may not approve a strategic transaction recommended by our Board, or agree to increase the number of shares of common stock authorized under our Certificate of Incorporation, which could impair our ability in the future to conduct equity financings or enter into certain strategic transactions; and our efforts may be adversely affected by potentially unfavorable credit and financial markets. Under these circumstances, we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise.

As of June 30, 2018, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 113.5 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 six months ended June 30, 2018, consist of $6.3 million used for ongoing operating activities offset by cash inflows for the six months ended June 30, 2018 of $5.0 million for financing activities.

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2018 and 2017 was $6.3 million and $12.9 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The decrease in net cash used in operating activities is due to our ongoing efforts to conserve cash as well the completion of enrollment in the phase 2a and phase 2b clinical trials during the second quarter of 2017.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2018 represents $9,000 in proceeds from the sale of property and equipment. Net cash used in investing activities for the six months ended June 30, 2017 represents capital expenditures of $24,000.

Financing Activities

Net cash provided by financing activities for six months ended June 30, 2018 was $5.0 million and represents loan proceeds of $1.5 million and $1.0 million related to loan agreements with LPH, an affiliate of Lee’s, and $2.6 million from a private placement offering with LPH II, a wholly-owned subsidiary of Lee’s, from which we received net proceeds of approximately $2.5 million.

Net cash provided by financing activities for six months ended June 30, 2017 was $9.8 million and represents net cash proceeds from both the February 2017 private placement of $8.8 and the use of the ATM Program of $1.0 million.

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

Private Placement Offerings

April 2018 Private Placement

In April 2018, we completed a private placement with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee's, for the purchase of $2.6 million of our common stock and warrants at a purchase price per share of $4.80. In connection with this offering, we issued 541,667 shares of common stock and warrants to purchase 135,417 shares of common stock at an exercise price of $5.52 per share. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date.

Loan Payable

In January 2018 and March 2018, we entered into loan agreements with LPH, an affiliate of Lee's, for loan proceeds of $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain its operations while the parties seek to identify and advance one or more potential strategic initiatives (Funding Event). To secure our obligations under these loans, we granted LPH a security interest in substantially all of our assets. The loans will accrue interest at a rate of 6% per annum and mature upon the earlier of the closing date of the Funding Event or December 31, 2018. The parties expect that, upon the closing of the Funding Event, the outstanding principal balance of the loans will be applied in full satisfaction of a like amount of cash consideration payable by LPH for its participation in such Funding Event, and the loans will be discharged in full thereby.

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea), a Secured Convertible Promissory Note (the Note) with respect to Loans (defined below) in the aggregate amount of up to $1.5 million. In connection with the issuance of the Note, Panacea made two loans (individually, each a Loan and collectively, the Loans) to us, the first of which was in the amount of $1.0 million and paid on the date of the Note, and the second of which was in the amount of $500,000 and received on July 23, 2018. The Loans bear interest on the outstanding principal amount at a rate of 15% per annum until the Note is paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea may deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, may participate. There can be no assurance that such a private placement will be completed. In connection with these Loans, we granted to Panacea a security interest in substantially all our assets. The proceeds of these Loans are being used to support our operations while we pursue the potential strategic transaction that could diversify our assets and bring in additional capital. (*See*, "– Overview – Business and Pipeline Program Updates.")

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 June 30, 2018 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 2017 Form 10-K. The risks and uncertainties described in our 2017 Form 10-K and as may be supplemented in our Quarterly Reports on Form 10-Q are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. Should any of the risks and uncertainties described in our 2017 Form 10-K and Quarterly Reports on Form 10-Q 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."

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 June 30, 2018, we had cash and cash equivalents of $0.6 million and current liabilities of $15.2 million. In early July 2018, we issued a Secured Convertible Promissory Note to Panacea Venture Management Company Ltd. (Panacea) with respect to two loans in the aggregate totaling $1.5 million. As of August 3, 2018, and before any additional financings, including in connection with potential strategic transactions, we believe that we will only have sufficient cash resources available to support our operations through mid-August 2018. We are currently engaged in discussions for a potential strategic transaction that could provide additional capital to fund our activities. Lee's Pharmaceutical Holdings Limited (Lee's), the majority holder of our common stock, has indicated to us that it will provide us interim financial support while we work to complete the strategic transaction; however, we have not executed agreements for any additional advances at this time and there can be no assurance that additional interim support will be forthcoming. Moreover, in connection with these activities, we are incurring and will continue to incur potentially significant legal, accounting, and other professional fees that represent an additional financial burden for which we will require additional capital.

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, to fund our research and development programs, support our business operations and pay our existing obligations on a timely basis. However, in 2017, our AEROSURF phase 2b clinical trial did not meet its primary endpoint due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype ADS. In response, we planned to conduct an additional AEROSURF bridge clinical study that is designed, among other things, to clinically evaluate the design and performance of our new phase 3 ADS. These events and the resulting delay in the AEROSURF clinical development program have made it difficult to attract investors and raise additional capital in the securities markets at this time and, as such, we have depended primarily upon the continuing support of Lee's Pharmaceutical Holdings Limited (Lee's), our majority stockholder and licensee in the Asia Pacific markets, and two previously announced loans from Panacea Venture Management Company Ltd. while we pursue the potential strategic transaction currently under discussion.

We believe that our ability to continue as a going concern in the near term is highly dependent upon continuing support from Lee's, and our ability to continue as a going concern in the long term will be highly dependent upon our ability to secure the capital necessary to timely advance our AEROSURF development program, including plans to execute the AEROSURF bridge study and be in a position to initiate an AEROSURF phase 3 clinical program. Our longer-term plans include securing the additional capital through a combination of public or private equity offerings, and strategic transactions, including potential alliances and collaborations focused on various individual markets, as well as potential combinations (including by merger or acquisition) or other corporate transactions. We are currently engaged in discussions with respect to a specific strategic transaction. If such transactions are not available, or if available, we are unable to raise sufficient capital through such transaction, 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 all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

We seek to enter into strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction) that could potentially provide additional capital and access to additional pipeline products under development that we believe could diversify our portfolio, leverage our capabilities, and improve our ability to attract renewed investor interest and the significant capital that we will require to advance our development programs. Such strategic transactions expose us to risks and uncertainties that could have a material adverse effect on our business and the AEROSURF® development program.

We seek to enter into strategic alliances, collaboration agreements and other strategic transactions that potentially could provide the additional capital that we need, leverage our capabilities, maximize the use of our resources and reduce our dependency on a single product candidate. We also seek licensing arrangements for AEROSURF and our other KL4 surfactant products in select geographic markets that could bring strategic partners with local development and commercial expertise to support development of AEROSURF in various markets outside the U.S., and financial resources to support our AEROSURF development program. We are currently focused on completing a strategic transaction that could allow us to diversify our product offerings and provide additional capital.

The identification, evaluation, and negotiation of potential strategic transactions may divert the attention of management and entail various expenses, whether or not such transactions are ultimately completed. We also have limited experience in acquiring other businesses. In addition to transaction and opportunity costs, these transactions involve large challenges and risks, whether or not such transactions are completed, any of which could harm our business and our results of operations, including risks that:

- the transaction ultimately may not advance our business strategy;
- we may spend time and resources on opportunities that we are unable to consummate on terms acceptable to us;
- the transaction may not close or may be delayed;
- we may incur significant acquisition costs and transition costs;
- we may experience disruptions on our ongoing operations and divert management's attention;
- we expect to assess our newly-diversified product portfolio and potentially adjust our business plan and priorities based on the potential of each product and the resources available to us;
- we may not realize the expected benefits from the transaction in the expected time period, or at all;
- we may be unable to retain key personnel;
- we may experience difficulty and may not be successful in integrating technologies, IT systems, data processing methods and policies, accounting systems, culture, or personnel;
- businesses we acquire may not have adequate controls, processes and procedures to ensure compliance with laws and regulations, and our due diligence process may not identify compliance issues or other liabilities;
- we may incur substantial liabilities, whether known or unknown, associated with the transaction;
- we may assume additional financial or legal exposure, including exposure that is known to us;
- we may have difficulty entering and operating in new markets or product segments;
- we may be unable to retain the key relationships and partners of acquired businesses;
- there may be unknown, underestimated, or undisclosed commitments or liabilities, including actual or threatened litigation;
- acquisitions could result in dilutive issuances of equity securities or the incurrence of debt; and
- our business, the acquired business, or the integrated business may be adversely affected by other political, business, and general economic conditions.

The occurrence of any of these risks could have a material adverse effect on our business, operations, financial condition, or cash flows. In addition, we may enter into strategic partnerships with third parties with the goal of gaining access to new and innovative products and technologies. Strategic partnerships pose many of the same risks as acquisitions or investments.

We cannot guarantee that we will be able to complete the strategic transaction on which we are currently focused or that we will realize any anticipated benefits if we do complete it. If we do not complete the strategic transaction, it is unlikely that we would be able to find another suitable opportunity that is available at attractive valuations, if at all, within a time for which we may have adequate funding. Moreover, the relative illiquidity of our common stock may make it more difficult and expensive to initiate or complete any strategic transaction on commercially acceptable terms.

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.

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: August 14, 2018

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

Date: August 14, 2018

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

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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 June 30, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2018 and June 30, 2017 (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2018 and June 30, 2017, 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.

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: August 14, 2018

/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: August 14, 2018

/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 June 30, 2018 (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: August 14, 2018

/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.