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

FORM 10-Q

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

For the quarterly period ended March 31, 2017

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 May 11, 2017, there were outstanding 10,301,287 shares of the registrant's common stock, par value $0.001 per share.

Table of Contents

PART I - FINANCIAL 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, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations and continue as a going concern. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to our development and potential regulatory plans to secure marketing authorization for AEROSURF®, if approved, and other potential future products that we may develop; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant product candidates, our aerosol delivery system (ADS) based on our proprietary aerosol technology for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs), materials and medical devices; plans regarding potential strategic alliances and collaborative arrangements to develop, manufacture and market our products, and other potential strategic transactions.

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

- the risk that our ability to continue as a going concern in the near-term is highly dependent upon our successfully completing the AEROSURF phase 2b clinical trial in mid-2017 and obtaining results that are sufficiently positive to support a strategic transaction and/or equity financing immediately thereafter. If we obtain results that are suboptimal or present an unacceptable benefit/risk profile, we may be unable to secure the additional required capital, which likely would prevent us from continuing as a going concern;

- the risk that, as a development company, with limited resources and no operating revenues, we currently have sufficient capital resources to fund our AEROSURF development program, support our business operations and pay our debt service obligations on a timely basis to mid-year 2017, and, if for any reason we are unable to raise additional capital before our resources are exhausted, we likely would be unable to continue as a going concern;

- the risk that, even if we successfully complete the AEROSURF phase 2b clinical trial in accordance with our plan, we will continue to require significant additional infusions of capital to support our business operations and efforts to potentially identify and secure significant strategic transactions, pay our debt service obligations, and advance our development activities, including additional AEROSURF clinical development programs; and the risk that our ability to raise such capital may be adversely impacted by future developments;

- the risk that our transition to the OTC Markets’ OTCQB® market tier, which was effective on May 5, 2017, following suspension of our common stock from The Nasdaq Capital Market® on the same date may adversely affect our ability to raise the additional capital that we will require and, in turn, adversely affect the ability of our stockholders to trade our securities and may negatively impact the value and liquidity of our common stock, which could have a material and adverse effect on our ability to raise the additional capital that we will require;

- the risk that our ability to raise additional capital is subject to certain other risks, including (i) limitations on the amount that we can raise under our 2014 universal shelf registration statement on Form S-3 (2014 Universal Shelf), which in any event will expire on June 12, 2017 and will not be replaced; (ii) the risk that our "at-the-market" equity sales program (ATM Program), our only arrangement to efficiently secure additional capital in the public market, has been suspended effective with the delisting of our common stock from The Nasdaq Capital Market; (iii) the risk that our stockholders may not approve a capital transaction for which stockholder approval is required under Delaware law; (iv) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (iv) that unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution of stockholders' interests;

- risks relating to our pledge of substantially all of our assets to secure our obligations under a $25 million secured loan with affiliates of Deerfield Management Company, L.P. (Deerfield), which could make it more difficult for us to secure additional capital, including to satisfy our Deerfield debt obligations, with respect to which a principal payment in the amount of $12.5 million is payable in February 2018, and require us to dedicate cash flow to pay debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;

- risks relating to our ability to manage our limited resources effectively and timely modify our business strategy as needed to respond to developments in our research and development activities, as well as in our business, our industry and other factors;

Risks related to Development Activities

- risks related to our AEROSURF clinical development program, which involves significant risks and uncertainties that are inherent in clinical development. Our clinical trials may be delayed, terminated early due to safety or other concerns, subjected to conditions imposed by the FDA or other regulatory body, or fail. Failure to achieve positive results from our ongoing phase 2b clinical trial, for any reason, will harm our business prospects and have a material adverse effect on our business and operations;

- risks related to our AEROSURF development program, including with respect to our aerosol delivery system (ADS), lyophilized KL4 surfactant and clinical development activities, that might arise and could affect the AEROSURF development program and potential future research and development activities, and potentially have a material adverse effect on our business and operations;

- risks related to our efforts to gain regulatory approval in a timely and successful manner, in the U.S. and in international markets, for our drug products and combination drug/device product candidates, including AEROSURF, including that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or international regulatory approvals for our product candidates;

- risks relating to the rigorous regulatory approval processes required for approval of any drug, medical device or combination drug/device product that we may develop, whether independently, with strategic partners or pursuant to collaboration arrangements, including that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we may submit; or that the FDA or other regulatory authorities may not agree on matters raised during the review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates; or that the 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;

Risks Related to Strategic and Other Transactions

- the risk that 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 and 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;

Risks related to Manufacturing

- the risk that we, 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, the active pharmaceutical ingredients (APIs) used in the manufacture of our KL4 surfactant, the ADS and related components, and other materials on a timely basis or in an amount sufficient to support our needs;

- risks relating to the transfer of our KL4 surfactant manufacturing technology to our CMOs, and our CMOs' ability to manufacture our lyophilized KL4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for our research and development activities and, if approved, commercial applications;

- risks related to ongoing manufacturing process development by our suppliers of APIs and our ability to comply with ultimate drug approval specifications;

- risks relating to our ability and our device manufacturer and assembler's ability to develop and manufacture our ADS and related components for preclinical and clinical studies of our combination drug/device product candidates and, if approved, commercial activities;

Other Risks Affecting our Business

- the risk, even if we are able to secure regulatory approval for our products in one or more of the U.S. and international markets, that reimbursement and health care reform may adversely affect our ability to secure appropriate reimbursement; or that market conditions and other factors may make it difficult to gain access to certain markets and patient populations, which could have a material adverse effect on our business;

- the risk that we, our strategic partners or collaborators will be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel, which could have a material adverse effect on our commercial and development activities and our operations;

- the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;

- the risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense; and

- 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 March 31, 2017, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

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.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2017	December 31, 2016
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,022	$ 5,588
Prepaid interest, current portion	1,094	1,094
Prepaid expenses and other current assets	392	512
Total current assets	9,508	7,194
Property and equipment, net	1,018	1,054
Restricted cash	225	225
Prepaid interest, non-current portion	956	1,226
Total assets	$ 11,707	$ 9,699
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,312	$ 1,813
Collaboration payable	4,098	3,967
Accrued expenses	5,926	7,611
Long-term debt, current portion	12,500	-
Total current liabilities	24,836	13,391
Long-term debt, non-current portion	12,500	25,000
Other liabilities	131	138
Total liabilities	37,467	38,529
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 7,049 and 0 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	-	-
Common stock, $0.001 par value; 60,000,000 authorized; 9,592,048 and 8,725,069 shares issued at March 31, 2017 and December 31, 2016, respectively; 9,590,556 and 8,723,577 shares outstanding at March 31, 2017 and December 31, 2016, respectively	10	9
Additional paid-in capital	604,676	592,883
Accumulated deficit	(627,392)	(618,668)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity	(25,760)	(28,830)
Total liabilities & stockholders' equity	$ 11,707	$ 9,699

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 March 31,	
	2017	**2016**
Revenues:		
Grant revenue	$ 219	$ 75
Expenses:		
Research and development	6,413	10,360
General and administrative	1,922	3,657
Total operating expenses	8,335	14,017
Operating loss	(8,116)	(13,942)
Change in fair value of common stock warrant liability	-	223
Other income / (expense):		
Interest income	3	7
Interest expense	(611)	(622)
Other income	-	433
Other income / (expense), net	(608)	(182)
Net loss	$ (8,724)	$ (13,901)
Deemed dividend on preferred stock	(3,604)	-
Net loss attributable to common shareholders	$ (12,328)	$ (13,901)
Net loss per common share		
Basic and diluted	$ (1.37)	$ (1.70)
Weighted average number of common shares outstanding		
Basic and diluted	8,998	8,191

See notes to condensed consolidated financial statements

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

(in thousands)

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (8,724)	$ (13,901)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	76
Stock-based compensation and 401(k) plan employer match	370	658
Fair value adjustment of common stock warrants	-	(223)
Amortization of prepaid interest	270	544
Changes in:		
Prepaid expenses and other current assets	120	(138)
Accounts payable	1,697	2,149
Collaboration payable	131	815
Accrued expenses	(1,252)	835
Net cash used in operating activities	(7,332)	(9,185)
Cash flows from investing activities:		
Purchase of property and equipment	(20)	(137)
Net cash used in investing activities	(20)	(137)
Cash flows from financing activities:		
Proceeds from private placement issuance of securities, net of expenses	8,796	-
Proceeds from ATM Program, net of expenses	990	-
Net cash provided by financing activities	9,786	-
Net increase/(decrease) in cash and cash equivalents	2,434	(9,322)
Cash, cash equivalents and restricted cash - beginning of year	5,813	38,947
Cash, cash equivalents and restricted cash - end of year	$ 8,247	$ 29,625
Supplementary disclosure of cash flows information:		
Interest paid	$ 259	$ 22

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 being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technology platform 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 combines our KL4 surfactant with our novel aerosol delivery system (ADS). We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by a deficiency of natural lung surfactant in lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). By enabling administration of aerosolized KL4 surfactant, AEROSURF may reduce or eliminate the need for invasive endotracheal intubation and mechanical ventilation, which currently are required to administer life-saving surfactant therapy, but which are associated with serious respiratory conditions and other complications. To avoid the risks of surfactant administration, many neonatologists initially treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)), and then, if the infants do not do well, they are treated with delayed surfactant therapy using invasive procedures. We believe that AEROSURF, if approved, has the potential to address a serious unmet medical need by enabling earlier KL4 surfactant therapy for infants receiving nCPAP alone, reducing the number of premature infants who are subjected to invasive surfactant administration, and potentially providing transformative clinical and pharmacoeconomic benefits.

We are conducting an AEROSURF phase 2b clinical trial to evaluate aerosolized KL4 surfactant administered to premature infants 28 to 32 week gestational age receiving nCPAP, in two dose groups (25 and 50 minutes) with up to two potential repeat doses, compared to infants receiving nCPAP alone. This trial is being conducted in approximately 50 clinical sites in the U.S., Canada, the European Union (EU) and Latin America. Enrollment is ongoing and we remain on track to release top-line results in July 2017.

Note 2 – Liquidity Risks and Management's Plans

As of March 31, 2017, we had cash and cash equivalents of $8.0 million, current liabilities of $24.8 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion.

In February 2017, we completed a private placement offering for which we received net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration. In addition, from January 1, 2017 through March 31, 2017, we completed registered offerings under our at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) resulting in net proceeds to us of $1.0 million. Before any additional financings, including in connection with potential strategic transactions, we believe that we have sufficient cash resources available to support our development activities, business operations and debt service obligations through the planned completion of the AEROSURF® phase 2b clinical trial and announcement of results in July 2017.

We expect to continue to incur significant losses and require significant additional capital to further advance our AEROSURF clinical development program, if warranted by the results of our phase 2b clinical trial, support our operations and meet our debt service obligations beyond mid-year 2017, and we do not have sufficient existing 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 these financial statements are issued.

To potentially alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to seek additional capital through the following: (i) all or a combination of 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 public or private equity offerings. However, there can be no assurance that these alternatives will be available, or if available, that we will be able to raise sufficient capital through such transactions. If we are unable to raise the required capital, 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 these 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.

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other restrictions (discussed below) and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to consider transactions on less-than-favorable terms, or limit or cease our development activities, or consider other means of creating value for our stockholders. 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 believe that our ability to fund our activities in the near term will be highly dependent upon whether our AEROSURF phase 2b clinical trial is deemed a success and we achieve results that are sufficiently positive to support a strategic transaction and/or equity financing. Even if we are able to complete the phase 2b trial as planned, if the results of our clinical trial are inconclusive, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or safety 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.

Moreover, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) following the suspension of our common stock from The Nasdaq Capital Market® (Nasdaq) effective May 5, 2017, we transitioned trading of our common stock to OTCQB® Market ("OTCQB"), which is operated by OTC Market Groups Inc., under the symbol "WINT;" (ii) our 2014 Universal Shelf on Form S-3 will expire June 12, 2017 and, due to our suspension from Nasdaq, we will be unable to file a replacement shelf registration statement for use after the expiration date; (iii) since the market value of our common stock held by non-affiliated persons (public float) is less than $75 million, Form S-3 includes a "limited offering" rule that limits the size of primary securities offerings that we may conduct in any 12-month period to no more than one third of our public float calculated based on a closing price of our common stock within 60 days of a transaction. Since the suspension of our common stock from Nasdaq, we are no longer able to make use of our ATM Program, (iv) our stockholders may not approve a proposal to be presented for approval at our 2017 Annual Meeting of Stockholders to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, from 60 million to 120 million, which could impair our ability in the future to conduct equity financings or enter into certain strategic transactions; (v) our stockholders may not approve, to the extent required under Delaware law, strategic transactions (mergers and acquisitions) recommended by our Board, (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (vii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions on our ability to conduct primary offerings on Form S-3, to be in a position to raise more than one third the value of our public float, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL_4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. In August 2016, we announced that the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) had awarded to us a Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million to support the AEROSURF phase 2b clinical trial in premature infants 28 to 32 week gestational age. As of March 31, 2017, we have received and expended $1.0 million of this award. We also have received grants that support medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In June 2016, we announced the results of a study funded by the NIH that KL_4 surfactant could potentially be an effective medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (pneumonopathy) due to exposure from a nuclear accident or act of terrorism. In addition, in February 2017 we announced the results of a study funded by the NIH that KL_4 surfactant could be a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

If we fail in the future to make any required payment under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield) or if we fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare a default under the loan agreement, which could result in the acceleration of the payment obligations under all or a portion of our indebtedness. Since we have pledged substantially all of our assets to secure our obligations under the Deerfield Loan, a debt default would enable the lenders to foreclose on our assets securing the debt and could significantly diminish the market value and marketability of our common stock.

As of March 31, 2017, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance and 7,049 convertible preferred stock units issued in the February 2017 private placement offering, of which each unit is convertible into 1,000 shares. Upon exercise of the pre-funded warrants and the convertible preferred stock units, we would issue common shares to the holders and receive no additional proceeds. In addition, as of March 31, 2017, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 25.7 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

There can be no assurance that our phase 2b clinical trial or other development program will be successful, that any products we develop will obtain necessary regulatory approval, that any approved product will be commercially viable, or that we will be able to secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

Nasdaq Suspension of Listing

On May 3, 2017, we received written notification from The Nasdaq Stock Market LLC (“Nasdaq”) that the Nasdaq Qualifications Hearings Panel (the “Panel”) had determined to delist our common stock from The Nasdaq Capital Market and that trading in our common stock would be suspended on The Nasdaq Capital Market effective at the open of business on Friday, May 5, 2017. Our shares were being delisted due to our continuing failure to comply with the minimum stockholders’ equity requirement set forth in Nasdaq Listing Rule 5550(b)(1). We filed an application to have our shares quoted on the OTCQB and our shares began trading there effective Friday, May 5, 2017.

The transition to the OTCQB does not have an immediate effect on our business operations, including our plans to complete and release top-line results from the AEROSURF phase 2b clinical trial by mid-2017. We also will continue to be registered with the SEC under the Exchange Act and will continue to file periodic financial reports that will be available on the SEC’s website, www.SEC.gov. However, delisting our common stock from Nasdaq and transitioning to the OTCQB may adversely affect our ability to raise the additional capital that we will require, through public or private sales of equity securities, and may impair the ability of our stockholders to trade our securities, which could negatively impact the value and liquidity of our common stock. If our common stock falls within the definition of a “penny stock,” brokers trading in our common stock will be required to adhere to more stringent market rules, which could result in reduced trading activity in our common stock, which could result in reduced trading levels and limited or no analyst coverage. Moreover, reduced trading activity in our common stock could adversely affect liquidity and make it more difficult for stockholders to sell their common stock.

Note 3 – Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. 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 accounting principles generally accepted in the U.S. for complete condensed 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 months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. There have been no changes to our critical accounting policies since December 31, 2016. For a discussion of our accounting policies, *see*, "– Note 4 – Accounting Policies and Recent Accounting Pronouncements,” in the Notes to Condensed Consolidated Financial Statements in our 2016 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Note 4 – Stockholders’ Equity

February 2017 Private Placement

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units at a price per Unit of $1,495, for an aggregate purchase price of approximately $10.5 million, including $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each Unit consists of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share ("Preferred Shares"); and (ii) 1,000 Series A-1 Warrants ("Warrants") to purchase one share of common stock at an exercise price equal to $1.37 per share. Each Preferred Share may be converted at the holder's option at any time into 1,000 shares of common stock at a conversion price of $1.37 per share. The Warrants may be exercised beginning six months after the date of issuance and through the seventh anniversary of the date of issuance. The Preferred Shares and the Warrants may not be converted or exercised to the extent that the holder would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of our outstanding shares of common stock. In addition to the offering, the securities purchase agreement also provides that, until February 13, 2018, the investors are entitled to participate in subsequent bona fide capital raising transactions that we may conduct.

At-the-Market (ATM) Program

During the three months ended March 31, 2017, we completed offerings of our common stock under our ATM Program of 805,916 shares resulting in an aggregate purchase price of approximately $1,034,000 ($990,000 net). As of March 31, 2017, approximately $21.3 million remained unutilized under the ATM Program. During the three months ended March 31, 2016, there were no offerings under our ATM Program.

Effective on May 5, 2017, since the suspension of our common stock from Nasdaq, we are no longer able to make use of our ATM Program (*see*, " –Note 2 – Liquidity Risks and Management's Plans")

Note 5 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements, in conformity with accounting principles generally accepted in the U.S., 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.

Severance

Effective February 1, 2016, we terminated the Employment Agreement between ourselves and our then President and Chief Executive Officer (Former CEO). During the first quarter of 2016, we incurred a severance charge of $1.2 million in selling, general and administrative expense under the terms of the Former CEO's employment agreement, including $0.2 million related to stock option expense for certain options that will continue to vest through August 1, 2017. Of the $1.0 million in severance not related to stock-based compensation, $0.8 million was paid as of March 31, 2017. The remaining $0.2 million will be paid through the third quarter of 2017.

Research and Development Expense

We account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical 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.

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 March 31, 2017 and 2016, the number of shares of common stock potentially issuable upon the conversion of preferred stock or the exercise of stock options and warrants was 24.3 million and 9.2 million shares, respectively. For the three months ended March 31, 2017 and 2016, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

In accordance with Accounting Standards Codification Topic 260, *Earnings per Share*, when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of these warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of warrants classified as derivative liabilities. For the three months ended March 31, 2017 and 2016, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive.

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

Beneficial Conversion Feature

The issuance of our Series A Convertible Preferred Stock (*see*, "– Note 4 – 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 Series A Convertible Preferred Stock. As the Series A Convertible Preferred Stock is immediately convertible by the holders, the discount allocated to the beneficial conversion factor was immediately accreted and recognized as a $3.6 million one-time, non-cash deemed dividend to the preferred shareholders.

Recently Adopted Accounting Standards

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. We adopted ASU 2014-15 effective December 31, 2016. 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. *See*, "– Note 2 – Liquidity Risks and Management's Plans."

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This update addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. We adopted ASU 2016-09 during the three months ended March 31, 2017 and will continue to recognize stock compensation expense with estimated forfeitures. 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 2017 financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The new standard requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. We adopted ASU 2016-18 on March 31, 2017 on a retrospective basis. As a result, beginning-of-period cash, cash equivalents and restricted cash in the statement of cash flows increased by $0.2 million for each of the three month periods ended March 31, 2017 and 2016.

Recent Accounting Pronouncements

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. Early adoption is permitted. We are currently evaluating the effect that ASU 2017-09 may have on our consolidated financial statements and related disclosures.

Note 6 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
(in thousands)	March 31, 2017	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 8,022	$ 8,022	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 8,247	$ 8,247	$ -	$ -

	Fair Value	Fair value measurement using		
(in thousands)	December 31, 2016	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 5,588	$ 5,588	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 5,813	$ 5,813	$ -	$ -

The following table summarizes changes in the fair value of common stock warrant liability measured on a recurring basis using Level 3 inputs for the three months ended March 31, 2016 representing the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

(in thousands)	
Balance at January 1, 2016	**$ 223**
Change in fair value of common stock warrant liability	(223)
Balance at March 31, 2016	**$ -**

Fair Value of Long-Term Debt

At March 31, 2017, the estimated fair value of the Deerfield Loan (*see*, "– Note 7 – Deerfield Loan") was $21.4 million, compared to a carrying value for current and non-current portions of $25.0 million. The estimated fair value of the Deerfield Loan is based on discounting the future contractual cash flows to the present value at the valuation date. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts we could realize in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 7 – Long-term Debt

Long-term debt consists solely of amounts due under the Deerfield Loan for the periods presented:

(in thousands)	**March 31, 2017**	**December 31, 2016**
Current portion	$ 12,500	$ -
Non-current portion	12,500	25,000
Total Deerfield Loan	$ 25,000	$ 25,000

The principal amount of the loan is payable in two equal annual installments of $12.5 million, payable in each of February 2018 and 2019. Under the Deerfield Loan agreement, the February 2018 installment is subject to a potential one-year deferral until February 2019 if we have achieved a market capitalization of $250 million as set forth in the Deerfield Loan agreement. *See*, "– Note 9 – Long-term Debt," in the Notes to Consolidated Financial Statements in our 2016 Form 10-K.

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

	Three Months Ended March 31,	
(in thousands)	**2017**	**2016**
Amortization of prepaid interest expense	$ 270	$ 544
Cash interest expense	254	-
Total interest expense	$ 524	$ 544

Amortization of prepaid interest expense represents non-cash amortization of $5 million of units purchased by Deerfield in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Loan. Cash interest expense represents interest at an annual rate of 8.25% on the outstanding principal amount in 2017, paid in cash on a quarterly basis.

Note 8 – 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, 2017	1,142	$ 14.66	
Granted	822	1.23	
Forfeited or expired	(1)	112.42	
Outstanding at March 31, 2017	1,963	$ 8.96	8.7
Vested and exercisable at March 31, 2017	486	$ 29.89	6.2
Vested and expected to vest at March 31, 2017	1,798	$ 9.07	8.6

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:

	Three Months Ended March 31, 2017	2016
Weighted average expected volatility	79%	79%
Weighted average expected term (in years)	6.6	5.7
Weighted average risk-free interest rate	2.22%	1.40%
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 March 31, 2017	2016
Research and development	$ 159	$ 182
Selling, general and administrative	141	421
Total	$ 300	$ 603

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 elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2016 that we filed with the Securities and Exchange Commission (SEC) on March 31, 2017 (2016 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. The disclosure in this Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) of this Quarterly Report on Form 10-Q includes information on preclinical studies supported in part from funds from the National Institutes of Health (NIH). Such information is solely our responsibility and does not necessarily represent the official views of the National Institutes of Health.

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). 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 KL_4 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 (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. We believe that our proprietary technology platform 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 combines our KL_4 surfactant with our novel aerosol delivery system (ADS). We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by a deficiency of natural lung surfactant in lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). By enabling administration of aerosolized KL_4 surfactant, AEROSURF may reduce or eliminate the need for invasive endotracheal intubation and mechanical ventilation, which currently are required to administer life-saving surfactant therapy, but which are associated with serious respiratory conditions and other complications. To avoid the risks of surfactant administration, many neonatologists initially treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)), and then, if the infants do not do well, they are treated with delayed surfactant therapy using invasive procedures. We believe that AEROSURF, if approved, has the potential to address a serious unmet medical need by enabling earlier KL_4 surfactant therapy for infants receiving nCPAP alone, reducing the number of premature infants who are subjected to invasive surfactant administration, and potentially providing transformative clinical and pharmacoeconomic benefits.

We are conducting an AEROSURF phase 2b clinical trial to evaluate aerosolized KL_4 surfactant administered to premature infants 28 to 32 week gestational age receiving nCPAP, in two dose groups (25 and 50 minutes) with up to two potential repeat doses, compared to infants receiving nCPAP alone. This trial is being conducted in approximately 50 clinical sites in the U.S., Canada, the European Union (EU) and Latin America. Enrollment is ongoing and we remain on track to release top-line results in July 2017.

As a development company, with limited resources and no operating revenues, we believe that our ability to continue as a going concern in the near term is highly dependent upon our successfully completing the AEROSURF phase 2b clinical trial in mid-2017, as planned, and obtaining results that are sufficiently positive to support a strategic transaction and/or equity financing immediately thereafter. If the results are suboptimal or present an unacceptable benefit/risk profile, we may be unable to secure the additional required capital and ultimately could be forced to curtail our development activities and cease operations.

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 2016 Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

The following are updates to our business and development programs since filing the 2016 Form 10-K on March 31, 2017:

- On May 3, 2017, we received written notification from The Nasdaq Stock Market LLC ("Nasdaq") that the Nasdaq Qualifications Hearings Panel (the "Panel") had determined to delist our common stock from The Nasdaq Capital Market® and that trading in our common stock would be suspended on The Nasdaq Capital Market effective at the open of business on Friday, May 5, 2017. Our shares are being delisted due to our continuing failure to comply with the minimum stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1). We filed an application to have our shares quoted on the OTCQB® Market ("OTCQB"), which is operated by OTC Market Group Inc. under the symbol "WINT," and our shares began trading there effective Friday, May 5, 2017.

  The transition to the OTCQB does not have an immediate effect on our business operations, including our plans to complete and release top-line results from the AEROSURF phase 2b clinical trial by mid-2017. We also will continue to be registered with the SEC under the Exchange Act and will continue to file periodic financial reports that will be available on the SEC's website, www.SEC.gov. However, delisting our common stock from Nasdaq and transitioning to the OTCQB may adversely affect our ability to raise the additional capital that we will require, through public or private sales of equity securities, and may impair the ability of our stockholders to trade our securities, which could negatively impact the value and liquidity of our common stock.

- We announced in April 2017 that the AEROSURF phase 2b independent Data Safety Monitoring Board (DSMB) completed its second and final interim safety review and recommended continuing the trial without modification. This final DSMB interim review was convened following achievement in mid-March 2017 of a pre-specified patient enrollment milestone. In addition, we reaffirmed our plan to announce top-line results from the AEROSURF phase 2b clinical trial in July 2017.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2016. For a discussion of our accounting policies, *see*, "Note 4 – Accounting Policies and Recent Accounting Pronouncements," in the Notes to Consolidated Financial Statements (Notes) in our 2016 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The operating loss for the three months ended March 31, 2017 and 2016 was $8.1 million and $13.9 million, respectively. The decrease in operating loss from 2016 to 2017 was due to both a $0.1 million increase in grant revenues and a $5.7 million decrease in operating expenses.

The net loss for the three months ended March 31, 2017 and 2016 was $8.7 million and $13.9 million, respectively. Included in the net loss is (i) interest expense of $0.5 million for both 2017 and 2016 associated with the Deerfield Loan (*see*, "Note 7 – Deerfield Loan"); and (ii) for 2016, $1.2 million for a severance charge related to the termination of our former CEO and the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million.

The net loss attributable to common shareholders for the three months ended March 31, 2017 and 2016 was $12.3 million (or $1.37 basic net loss per common share) and $13.9 million (or $1.70 basic net loss per common share), respectively. Included in the net loss attributable to common shareholders in 2017 is a $3.6 million one-time, non-cash deemed dividend on preferred stock (*see*, "Note 5 – Summary of Significant Accounting Policies").

Grant Revenue

We recognize grant revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured.

For the three months ended March 31, 2017 and 2016 we recognized grant revenue of $0.2 million and $0.1 million, respectively.

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) medical and regulatory operations, and (c) direct preclinical and clinical development programs. We also account for research and development and report 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 months ended March 31, 2017 and 2016 are as follows:

	Three Months Ended March 31,	
(in thousands)	**2017**	**2016**
Product development and manufacturing	$ 1,877	$ 3,781
Clinical, medical and regulatory operations	1,808	2,065
Direct preclinical and clinical programs	2,728	4,514
Total Research and Development Expenses	$ 6,413	$ 10,360

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.2 million and $0.3 million for the three months ended March 31, 2017 and 2016, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with 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 $1.9 million for the three months ended March 31, 2017 compared to the same period in 2016 due to our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures.

Clinical, Medical and Regulatory Operations

Clinical, medical and regulatory operations includes (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 $0.3 million for the three months ended March 31, 2017 compared to the same period in 2016 due to our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures.

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 $1.8 million for the three months ended March 31, 2017 compared to the same period in 2016 due to a decrease in AEROSURF phase 2 clinical development program costs, including the initiation of fewer clinical trial sites and a decrease in the manufacture of clinic-ready ADSs, as many of these upfront site initiations and manufacture of ADSs were completed during the three months ended March 31, 2016 and are not ongoing clinical trial costs.

General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2017	2016
General and Administrative Expenses	$ 1,922	$ 3,657

General and administrative expenses consist of costs for executive management, business development, intellectual property, finance and accounting, legal, human resources, information technology, facility, other administrative costs and, for 2015, sales and marketing activities.

General and administrative expenses decreased $1.7 million for the three months ended March 31, 2017 compared to the same period in 2016 due to (i) cost reduction initiatives beginning in the second quarter of 2016 and (ii) $1.2 million of severance charges during the three months ended March 31, 2016 (*see*, "Note 5 –
Summary of Significant Accounting Policies").

Other Income and (Expense)

(in thousands)	Three Months Ended March 31, 2017	2016
Interest income	$ 3	$ 7
Interest expense	(611)	(622)
Other income	-	433
Other income / (expense), net	$ (608)	$ (182)

Interest expense primarily consists of interest expense associated with the Deerfield Loan (*see*, "Note 7 – Deerfield Loan").

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

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

(in thousands)	Three Months Ended March 31, 2017	2016
Amortization of prepaid interest expense	$ 270	$ 544
Cash interest expense	254	-
Total interest expense	$ 524	$ 544

Amortization of prepaid interest expense represents non-cash amortization of $5 million of units that Deerfield purchased in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Loan. Cash interest expense represents interest at an annual rate of 8.25% on the outstanding principal amount in 2017, paid in cash on a quarterly basis.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2017, we had cash and cash equivalents of $8.0 million, current liabilities of $24.8 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion.

In February 2017, we completed a private placement offering for which we received net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration. In addition, from January 1, 2017 through March 31, 2017, we completed registered offerings under our at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) resulting in net proceeds to us of $1.0 million. Before any additional financings, including in connection with potential strategic transactions, we believe that we have sufficient cash resources available to support our development activities, business operations and debt service obligations through the planned completion of the AEROSURF phase 2b clinical trial and announcement of results in July 2017.

We expect to continue to incur significant losses and require significant additional capital to further advance our AEROSURF clinical development program, if warranted by the results of our phase 2b clinical trial, support our operations and meet our debt service obligations beyond mid-year 2017, and we do not have sufficient existing 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 these financial statements are issued.

To potentially alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to seek additional capital through the following: (i) all or a combination of 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 public or private equity offerings. However, there can be no assurance that these alternatives will be available, or if available, that we will be able to raise sufficient capital through such transactions. If we are unable to raise the required capital, 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.

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other restrictions (discussed below) and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to consider transactions on less-than-favorable terms, or limit or cease our development activities, or consider other means of creating value for our stockholders. 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 believe that our ability to fund our activities in the near term will be highly dependent upon whether our AEROSURF phase 2b clinical trial is deemed a success and we achieve results that are sufficiently positive to support a strategic transaction and/or equity financing. Even if we are able to complete the phase 2b trial as planned, if the results of our clinical trial are inconclusive, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or safety 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.

Moreover, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) following the suspension of our common stock from The Nasdaq Capital Market® (Nasdaq) effective May 5, 2017, we transitioned trading of our common stock to OTCQB® Market ("OTCQB"), which is operated by OTC Market Groups Inc., under the symbol "WINT;" (ii) our 2014 Universal Shelf on Form S-3 will expire June 12, 2017 and, due to our suspension from Nasdaq, we will be unable to file a replacement shelf registration statement for use after the expiration date; (iii) since the market value of our common stock held by non-affiliated persons (public float) is less than $75 million, Form S-3 includes a "limited offering" rule that limits the size of primary securities offerings that we may conduct in any 12-month period to no more than one third of our public float calculated based on a closing price of our common stock within 60 days of a transaction. Since the suspension of our common stock from Nasdaq, we are no longer able to make use of our ATM Program, (iv) our stockholders may not approve a proposal to be presented for approval at our 2017 Annual Meeting of Stockholders to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, from 60 million to 120 million, which could impair our ability in the future to conduct equity financings or enter into certain strategic transactions; (v) our stockholders may not approve, to the extent required under Delaware law, strategic transactions (mergers and acquisitions) recommended by our Board, (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (vii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions on our ability to conduct primary offerings on Form S-3, to be in a position to raise more than one third the value of our public float, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. In August 2016, we announced that the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) had awarded to us a Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million to support the AEROSURF® phase 2b clinical trial in premature infants 28 to 32 week gestational age. As of March 31, 2017, we have received and expended $1.0 million of this award. We also have received grants that support medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In June 2016, we announced the results of a study funded by the NIH that KL4 surfactant could potentially be an effective medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (pneumonopathy) due to exposure from a nuclear accident or act of terrorism. In addition, in February 2017 we announced the results of a study funded by the NIH that KL4 surfactant could be a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

If we fail in the future to make any required payment under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield) or if we fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare a default under the loan agreement, which could result in the acceleration of the payment obligations under all or a portion of our indebtedness. Since we have pledged substantially all of our assets to secure our obligations under the Deerfield Loan, a debt default would enable the lenders to foreclose on our assets securing the debt and could significantly diminish the market value and marketability of our common stock.

As of March 31, 2017, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance and 7,049 convertible preferred stock units issued in the February 2017 private placement offering, of which each unit is convertible into 1,000 shares. Upon exercise of the pre-funded warrants and the convertible preferred stock units, we would issue common shares to the holders and receive no additional proceeds. In addition, as of March 31, 2017, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 25.7 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

There can be no assurance that our phase 2b clinical trial or other development program will be successful, that any products we develop will obtain necessary regulatory approval, that any approved product will be commercially viable, or that we will be able to secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

Nasdaq Suspension of Listing

On May 3, 2017, we received written notification from The Nasdaq Stock Market LLC (“Nasdaq”) that the Nasdaq Qualifications Hearings Panel (the “Panel”) had determined to delist our common stock from The Nasdaq Capital Market® and that trading in our common stock would be suspended on The Nasdaq Capital Market effective at the open of business on Friday, May 5, 2017. Our shares were being delisted due to our continuing failure to comply with the minimum stockholders’ equity requirement set forth in Nasdaq Listing Rule 5550(b)(1). We filed an application to have our shares quoted on the OTCQB and our shares began trading there effective Friday, May 5, 2017.

The transition to the OTCQB does not have an immediate effect on our business operations, including our plans to complete and release top-line results from the AEROSURF phase 2b clinical trial by mid-2017. We also will continue to be registered with the SEC under the Securities Exchange Act of 1934 (Exchange Act) and will continue to file periodic financial reports that will be available on the SEC’s website, www.SEC.gov. However, delisting our common stock from Nasdaq and transitioning to the OTCQB may adversely affect our ability to raise the additional capital that we will require, through public or private sales of equity securities, and may impair the ability of our stockholders to trade our securities, which could negatively impact the value and liquidity of our common stock. If our common stock falls within the definition of a “penny stock,” brokers trading in our common stock will be required to adhere to more stringent market rules, which could result in reduced trading activity in our common stock, which could result in reduced trading levels and limited or no analyst coverage. Moreover, reduced trading activity in our common stock could adversely affect liquidity and make it more difficult for stockholders to sell their common stock.

Cash Flows

As of March 31, 2017, we had cash and cash equivalents of $8.0 million compared to $5.6 million as of December 31, 2016. Cash outflows for the three months ended March 31, 2017 consisted of $7.4 million used for ongoing operating and investing activities offset by cash inflows for the three months ended March 31, 2017 of $9.8 million for financing activities.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2017 and 2016 was $7.3 million and $9.2 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.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2017 and 2016 represents capital expenditures of $20,000 and $137,000, respectively.

Financing Activities

Net cash provided by financing activities for three months ended March 31, 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.

Financings Pursuant to Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of equity offerings. In May 2014, we filed a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) with the SEC that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of March 31, 2017, after reserves for outstanding unexercised warrants and amounts remaining available under our ATM Program, approximately $139.8 million remained available under the 2014 Universal Shelf. Given the limited offering restrictions that apply to smaller company transactions under the 2014 Universal Shelf (*see*, "– Liquidity and Capital Resources"), we expect that the 2014 Universal Shelf will expire in June 2017 with the remaining capacity largely unutilized.

Private Placement Offering

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units for net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration in the form of a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of (i) one share (Preferred Share) of Series A Convertible Preferred Stock; which may be converted at any time into 1,000 shares of common stock at a conversion price of $1.37 per share, and (ii) 1,000 Series A-1 Warrants to purchase one share of common stock at an exercise price equal to $1.37 per share which may be exercised beginning six months after the date of issuance and through the seventh anniversary of the date of issuance. The Preferred Shares and the Warrants may not be converted or exercised if, following such conversion or exercise, the holder would beneficially own more than 9.99% (or other lesser percent as designated by each holder) of our outstanding shares of common stock.

At-the-Market Program (ATM Program)

ATM Program

During the quarter ended March 31, 2017, we completed offerings of our common stock under our ATM Program of 805,916 shares, resulting in aggregate gross and net proceeds to us of approximately $1.0 million. During the three months ended March 31, 2016, there were no offerings under the ATM Program. As of March 31, 2017, approximately $21.3 million remained unutilized under the ATM Program.

Effective on May 5, 2017, since the suspension of our common stock from Nasdaq, we are no longer able to make use of our ATM Program (*see*, "Note 2 – Liquidity Risks and Management's Plans")

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 March 31, 2017 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 the other information in this Quarterly Report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in the section "Item 1A. Risk Factors" in our 2016 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. The risks and uncertainties set forth below and discussed elsewhere in this Quarterly Report on Form 10-Q and described in our 2016 Form 10-K 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. If any of the risks and uncertainties set forth below or in our 2016 Form 10-K 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 – Overview." In addition, risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations.

At times, our shares of common stock, which since May 5, 2017 are quoted on the OTCQB, may be thinly traded, which may make it difficult to sell shares of our common stock or our stockholders may be unable to sell their shares at or near ask prices or even at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Since May 5, 2017, when our common stock was suspended from Nasdaq, our common stock has been quoted on the OTCQB. Companies quoted on the OTCQB may experience periods of illiquidity when the trading volumes of their stocks decline. A number of factors could cause this circumstance and could affect the trading in our common stock. Since we are now a smaller reporting company that is not listed on an exchange, stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume may stop covering our common stock, and even if we are followed by such persons, they may abide by investment policies that avoid trading in unlisted securities or that exclude from their portfolios securities that trade at less than $5.00 per share ("penny stocks"). As a consequence, there is a risk that we may experience periods of several days or more when trading activity in shares of our common stock is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. There can be no any assurance that a broader or more active public trading market for our common stock will be sustained, or that current trading levels will be sustained or not diminish.

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: May 15, 2017

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

Date: May 15, 2017

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

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 March 31, 2017, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of March 31, 2017 (unaudited) and December 31, 2016, (ii) Statements of Operations (unaudited) for the three and nine months ended March 31, 2017 and March 31, 2016 (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2017 and March 31, 2016, 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: May 15, 2017

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

Exhibit 31.2

CERTIFICATIONS

I, John A. 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: May 15, 2017

By: /s/ John A. Tattory
John A. 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 March 31, 2017 (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: May 15, 2017

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

/s/ John A. Tattory
John A. 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.