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

FORM 10-Q

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

For the quarterly period ended September 30, 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 or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 November 8, 2017, there were outstanding 63,213,973 shares of the registrant's common stock, par value $0.001 per share.

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Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc., and its wholly owned, 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, as a development company, with limited resources and no operating revenue, our ability to continue as a going concern depends upon our ability to secure additional capital when needed and in amounts sufficient to support our operations and continuing development activities. In October 2017, we entered into a Securities Purchase Agreement (SPA) with a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited (Lee's), pursuant to which Lee's acquired a controlling interest in our Company with an investment of $10 million. In connection therewith, we negotiated an Exchange and Termination Agreement with affiliates of Deerfield Management L.P. (Deerfield) to restructure and retire $25 million of long-term secured debt (Deerfield Loan). We also entered into a nonbinding memorandum of understanding with Battelle Memorial Institute (Battelle) outlining potential terms to restructure certain accounts payable related to our device development activities with Battelle (Battelle MOU), although there can be no assurance that our negotiations will be successful. (The transactions with LPH, Deerfield and Battelle are collectively referred to in this Quarterly Report on Form 10-Q as the November 2017 Restructuring). Although we believe that the November 2017 Restructuring has improved our financial position and better positions us to raise the capital needed to fund ongoing operations and development plans, we expect to incur continuing significant losses and will require significant additional capital to further advance our AEROSURF clinical development program, satisfy our current obligations and support our operations for the next several years. Moreover, we do not have sufficient existing cash and cash equivalents for at least the next year following the date that these 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;

- the risk that, since our transition to the OTC Markets Group Inc.'s OTCQB® Market (OTCQB) tier in early May 2017, lower trading volumes and waning analyst interest may make it more difficult to raise capital through equity-based market transactions; our stockholders may find it more difficult to trade our securities on the OTCQB; and the value and liquidity of our common stock may be adversely affected, which could have a material adverse effect on our ability to raise the additional capital that we require;

- risks related to our financing strategy, including that, since our transition to the OTCQB, we are no longer eligible to register shares using a registration statement on Form S-3 and will have to register equity securities that we may issue in connection with financings and strategic transactions on a Form S-1, which could be time-consuming and expensive, and since we are no longer eligible to use a Form S-3, we are no longer able to use our at-the-market equity sales program (ATM Program); our controlling stockholder may not approve a capital or strategic transaction recommended by management for which stockholder approval is required under Delaware law; our capital structure, which includes common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, may make it more difficult to conduct equity-based financings; and unfavorable credit and financial markets may adversely affect our ability to fund our activities. Moreover, even if we are successful in raising the required capital, any equity financings could result in substantial equity dilution of stockholders' interests;

- risks relating to our efforts to manage our cash resources and closely monitor cash outflows. In particular, during periods of limited cash resources, we work closely with our vendors, suppliers and service providers to assure that investment and spending decisions advance our corporate objectives at any time, which potentially could impair our relationships with important vendors, suppliers and servicers, which could have a material adverse effect on our business, operation and development programs;

- risks 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 planned 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 due to a range of potential factors, including without limitation, issues related to our ADS. For example, we are planning to conduct a confirmatory bridging clinical study (i) to gain experience with the next generation ADS (NextGen ADS), (ii) to confirm whether our device development objectives have been met, and (iii) to generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial. Failure to meet these clinical objectives potentially could have a material adverse effect on our development activities and our business and operations. We currently are assessing the potential design and requirements for this trial;

- risks related to development of our NextGen ADS, which is being designed for use going forward. The NextGen ADS combines the same aerosolization technology used during the phase 2 clinical program, with improved ergonomics, interface, controls, dose monitoring and in a modular design. We are also assessing the treatment interruptions that occurred during the phase 2b clinical trial at an unexpected rate and believe they were caused by specific lots of disposable cartridge filters with a higher tendency to clog. We are working to mitigate the chances of such events occurring with the NextGen ADS. However, our development efforts could be delayed or our NextGen ADS could fail to perform as expected, which if not identified during the design phase of device development, could negatively impact our clinical outcomes. Unforeseen device issues could arise at any time and could adversely impact the AEROSURF development program, as well as other potential future development activities, and potentially have a material adverse effect on our development activities and our business and operations;

- risks related to our development activities for lyophilized KL_4 surfactant, being developed as the drug product component of AEROSURF and potentially might be developed for use as a liquid instillate, which risks might arise and could delay or otherwise adversely affect the AEROSURF clinical development program and other potential development activities and which could have a material adverse effect on our development programs, 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

- risks relating to our License, Development and Commercialization Agreement dated as of June 12, 2017 with Lee's, as amended on August 14, 2017 (Lee's License), including the risks related to conducting development activities in the various markets in the licensed territory, risks associated with an international technology transfer of our KL_4 manufacturing processes and device manufacturing, risks related to regulatory filings and protection of intellectual property interests and risks related to the commercialization of our products in international markets;

- the risk that we may be unable to identify and enter into new 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; including potential regional product licensing arrangements;

Risks related to Manufacturing

- the risk that we, our contract manufacturing organizations (CMOs) or any of our third-party suppliers and related service providers, including without limitation contract laboratories engaged in release and stability testing activities, 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 or NextGen ADS and related components, and other materials on a timely basis at an acceptable cost or in an amount sufficient to support our needs and in providing the related services necessary to our manufacturing process and release of drug product for development work;

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

- risks relating to our ability and our design and development partner's ability to complete the development and design verification and validation of our NextGen ADS and related components, which we currently are developing with Battelle for use in our future clinical activities for AEROSURF. We recently entered into an MOU with Battelle to restructure our outstanding payables and amend our relationship. If we are unsuccessful in entering into a definitive agreement with Battelle, we may be delayed in our efforts to complete the design verification and validation of our NextGen ADS and related components, which could have a material adverse effect on our development programs, business and operations;

Other Risks Affecting our Business

- risks related to our ownership structure following the purchase by Lee's of a controlling interest in our Company, including that Lee's holds sufficient voting power to approve transactions that may not be in the interests of other stockholders, or to take control of the Board of Directors by nominating and electing its own directors; in addition as licensee under the License Agreement with Lee's (HK), Lee's does business with us and could compete with us at any time, which could give rise to potential or apparent conflicts of interest;

- 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 health care reform or market conditions, actions of our competitors, shifts in treatment paradigms and other factors may make it difficult to gain access to certain markets and patient populations and 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 2017 Quarterly Reports and 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)

	September 30, 2017	December 31, 2016
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,752	$ 5,588
Prepaid interest, current portion	1,094	1,094
Prepaid expenses and other current assets	248	512
Total current assets	3,094	7,194
Property and equipment, net	930	1,054
Restricted cash	225	225
Prepaid interest, non-current portion	408	1,226
Total assets	$ 4,657	$ 9,699
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,770	$ 1,813
Collaboration payable	4,183	3,967
Accrued expenses	5,365	7,611
Deferred revenue	1,070	-
Loan payable	2,600	-
Long-term debt, current portion	12,500	-
Total current liabilities	29,488	13,391
Long-term debt, non-current portion	12,500	25,000
Other liabilities	117	138
Total liabilities	42,105	38,529
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 3,203 and 0 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Common stock, $0.001 par value; 120,000,000 and 60,000,000 shares authorized at September 30, 2017 and December 31, 2016, respectively; 15,543,738 and 8,725,069 shares issued at September 30, 2017 and December 31, 2016, respectively; 15,542,246 and 8,723,577 shares outstanding at September 30, 2017 and December 31, 2016, respectively	16	9
Additional paid-in capital	605,177	592,883
Accumulated deficit	(639,587)	(618,668)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity	(37,448)	(28,830)
Total liabilities & stockholders' equity	$ 4,657	$ 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 September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Grant revenue	$ 17	$ 961	$ 1,383	$ 1,142
Expenses:				
Research and development	3,062	7,081	14,958	25,757
General and administrative	1,749	1,613	5,475	7,053
Total operating expense	4,811	8,694	20,433	32,810
Operating loss	(4,794)	(7,733)	(19,050)	(31,668)
Change in fair value of common stock warrant liability	-	-	-	223
Other income / (expense):				
Interest income	3	3	9	15
Interest expense	(652)	(648)	(1,878)	(1,907)
Other income	-	15	-	449
Other income / (expense), net	(649)	(630)	(1,869)	(1,443)
Net loss	$ (5,443)	$ (8,363)	$ (20,919)	$ (32,888)
Deemed dividend on Series A preferred stock	(1,915)	-	(6,051)	-
Net loss attributable to common shareholders	$ (7,358)	$ (8,363)	$ (26,970)	$ (32,888)
Net loss per common share				
Basic and diluted	$ (0.69)	$ (1.00)	$ (2.76)	$ (3.98)
Weighted average number of common shares outstanding				
Basic and diluted	10,647	8,355	9,766	8,262

See notes to condensed consolidated financial statements

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

(in thousands)

	Nine Months Ended September 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (20,919)	$ (32,888)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	199
Stock-based compensation and 401(k) plan employer match	839	1,301
Fair value adjustment of common stock warrants	-	(223)
Amortization of prepaid interest	818	1,435
Gain/(loss) on sale or disposal of equipment	-	(16)
Changes in:		
Prepaid expenses and other current assets	264	152
Accounts payable	3,155	1,702
Collaboration payable	216	601
Accrued expenses	(1,827)	969
Deferred revenue	1,070	-
Other liabilities	-	124
Net cash used in operating activities	(16,237)	(26,644)
Cash flows from investing activities:		
Purchase of property and equipment	(24)	(193)
Proceeds from sale of property and equipment	-	27
Net cash used in investing activities	(24)	(166)
Cash flows from financing activities:		
Proceeds from Private Placement issuance of securities, net of expenses	8,789	-
Proceeds from ATM Program, net of expenses	1,036	471
Proceeds from loan payable	2,600	-
Net cash provided by financing activities	12,425	471
Net increase/(decrease) in cash and cash equivalents	(3,836)	(26,339)
Cash, cash equivalents and restricted cash - beginning of year	5,813	38,947
Cash, cash equivalents and restricted cash - end of year	$ 1,977	$ 12,608
Supplementary disclosure of cash flows information:		
Interest paid	$ 514	$ 61

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. 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 delay surfactant therapy and treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)). 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.

In June 2017, we announced that we had completed an AEROSURF phase 2b clinical trial that was designed 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 was conducted in approximately 50 clinical sites in the U.S., Canada, the European Union and Latin America. Based on the planned top-line results, data show that AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours, which we believe was due in large part to an unexpected rate of treatment interruptions. Such interruptions occurred in about 24% of active enrollments, predominantly in the 50 minute dose group, and we believe were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. After excluding the patients whose dose was interrupted in the 50 minute dose group, the data show an nCPAP failure rate of 32% compared to 44% in the control group which is a 12% absolute reduction or a 27% relative reduction in nCPAP failure compared to control. These data suggest a meaningful treatment effect in line with our targeted outcome.

We are currently focused on our project with Battelle Memorial Institute (Battelle) to complete development of our next generation aerosol delivery device (NextGen ADS), which is intended to replace the prototype device used in our phase 2 clinical trials. The NextGen ADS combines the same aerosolization technology used during the phase 2 clinical program, but with improved ergonomics, interface, controls, and dose monitoring in a modular design. Design verification and validation are underway. Within this process, we are assessing whether the design of the NextGen ADS successfully mitigates the risk of clogging and related treatment interruptions that occurred during the Phase 2b clinical trial. To verify the design and confirm the performance of the NextGen ADS, including with respect to device-related treatment interruptions experienced with the phase 2 prototype ADS, we are planning to conduct a device bridging and confirmation clinical study (i) to gain experience with the next generation ADS (NextGen ADS), (ii) to confirm whether our development objectives have been met and (iii) to generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial, which was adversely affected by treatment interruptions. We currently are assessing the potential design and requirements for this trial.

In addition, in June 2017, we and a Hong Kong company, Lee's Pharmaceutical (HK), Ltd. (Lee's (HK)), entered into an exclusive license and collaboration agreement (License Agreement) for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets, with a future option to potentially add Japan. The agreement includes AEROSURF as well as the non-aerosol products, SURFAXIN® (approved in the U.S. in 2012) and SURFAXIN LS™ (an improved lyophilized formulation of SURFAXIN). We also granted Lee's (HK) an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory and a future option to manufacture the device in the licensed territory. In connection with the August 2017 Loan Agreement with Lee's (HK) (*see*, "– Note 7 – Loan Payable"), we amended the License Agreement to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. We are presently engaged in a technology transfer of our KL4 surfactant manufacturing process to Lee's (HK).

Note 2 – Liquidity Risks and Management's Plans

As of September 30, 2017, we had cash and cash equivalents of $1.8 million, current liabilities of $29.5 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion. Total long-term debt of $25 million was with affiliates of Deerfield Management, L.P. (Deerfield), who held a security interest in substantially all of our assets (Deerfield Loan).

On November 1, we announced that we had completed a series of transactions to generate short-term cash and potentially enable future capital transactions. Effective October 27, 2017, LPH Investments Limited (LPH), a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited (Lee's) acquired $10 million of newly issued shares of our common stock, representing a controlling interest in our Company. At the same time, we reached an agreement with Deerfield to restructure and retire the outstanding $25 million long-term debt, and entered into a nonbinding memorandum of understanding with Battelle (Battelle MOU) outlining potential terms to restructure certain accounts payable related to our device development activities with Battelle. In connection with the Battelle MOU, Battelle executed and delivered a waiver of its rights to receive payments under a liquidation preference pursuant to Series A Convertible Preferred Stock held by Battelle and the related Certificate of Designation of Preferences, Rights and Limitations effective February 15, 2017 (the foregoing transactions with LPH, Deerfield and Battelle are collectively referred to in this Quarterly Report on Form 10-Q as the November 2017 Restructuring). *See*, "– Note 10 – Subsequent Events."

Although we believe that the November 2017 Restructuring has improved our financial position and better positions us to raise the capital needed to fund on-going operations and development plans, we expect to incur continuing significant losses and will require significant additional capital to further advance our AEROSURF clinical development program, satisfy our current obligations and support our operations for the next several years. Moreover, we do not have sufficient existing cash and cash equivalents for at least the next year following the date that these 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, and other 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. There can be no assurance that these alternatives will be available, or if available, that we will have sufficient cash resources and liquidity to fund our development activities and business operations for at least the next year following the date that these 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.

As of November 1, 2017, after closing the November 2017 Restructuring, we had cash and cash equivalents of $5.4 million. While we seek the additional capital that we require, we are working with our vendors and service providers to extend payment terms of certain obligations and our available cash. We believe that, before any additional financings, we will have sufficient cash resources to partially satisfy our existing obligations and fund our operations into January 2018.

These 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 capital that we will require through equity financings and other similar transactions is subject to regulatory and other constraints, including: (i) our common stock is currently quoted on the OTCQB® Market (OTCQB), which is operated by OTC Markets Group Inc., under the symbol WINT and may experience periods of illiquidity; (ii) our common stock is currently considered a "penny stock," such that brokers are required to adhere to more stringent market rules, which could result in reduced trading activity and trading levels in our common stock and limited or no analyst coverage; (iii) because we are no longer listed on a national securities exchange, we are not eligible to file a Form S-3 registration statement and our recent Form S-3 has expired; (iv) without a Form S-3, we are not able to use our ATM Program; (v) our controlling stockholder may not approve management proposals to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, which could impair our ability to conduct equity financings or enter into certain strategic transactions (mergers and acquisitions) that require stockholder approval under Delaware law; (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock 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, we expect that we will more likely conduct securities offerings as private placements with registration rights, which we would register under a registration statement on Form S-1, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

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. 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 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 late May 2017, we announced that we have been awarded $0.9 million under a previously announced Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF phase 2b clinical trial. We currently are determining whether, as a subsidiary of Lee's, we continue to be eligible for SBIR grants. We also have received from time to time 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. 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.

As of September 30, 2017, and November 8, 2017, we had outstanding 0.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance, and 3,203 convertible preferred shares issued in the February 2017 private placement offering. Each preferred share is convertible into 1,000 shares of common stock. Upon exercise of the pre-funded warrants and conversion of the convertible preferred shares, we would issue common shares to the holders and receive no additional proceeds.

In addition, as of September 30, 2017, there were 120 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 85.0 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

Note 3 – Basis of Presentation

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine months ended September 30, 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 5 – Summary of Significant Accounting Policies" in this Quarterly Report on Form 10-Q, and "– Note 4 – Accounting Policies and Recent Accounting Pronouncements" in the Notes to 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 August 15, 2017 and through February 15, 2024. 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 the event of a liquidation, including without limitation, the sale of substantially all of our assets and certain mergers and other corporate transactions (as defined in the Certificate of Designation of Preferences, Rights and Limitations relating to the Preferred Shares), the holder of Preferred Shares will have a liquidation preference that could result in the holder receiving a return of its initial investment before any payments are made to holders of common stock, and then participating with other equity holders until it has received in the aggregate up to three times its original investment. 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.

As of November 8, 2017, 3,846 Preferred Shares have been converted into 3,846,000 shares of common stock and 3,203 Preferred Shares remain outstanding.

At-the-Market (ATM) Program

During the nine months ended September 30, 2017, we completed offerings of our common stock under our ATM Program of 847,147 shares. This resulted in an aggregate purchase price of approximately $1,082,000 ($1,036,000 net) for the nine month period ended September 30, 2017. During the three and nine months ended September 30, 2016, we completed offerings of our common stock under our ATM Program of 159,051 shares and 187,022 shares, respectively. This resulted in an aggregate purchase price of approximately $432,000 ($402,000 net) and $503,000 ($471,000 net), respectively, for the three and nine month periods ended September 30, 2016.

Effective May 5, 2017, we were 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 U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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 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 continued to vest through August 1, 2017. Of the $1.0 million in severance not related to stock-based compensation, $0.9 million was paid as of September 30, 2017.

During the second quarter of 2016, we incurred a severance charge of $0.4 million related to a May 2016 workforce reduction that was a component of a broader effort to initiate cash conservation and other cost reduction measures.

On July 13, 2017, we implemented a reduction in workforce by 20 employees, representing approximately 42% of our total workforce, from 48 to 28 employees. The reduction was across all functions of the Company and affected employees were eligible for certain severance and other benefits resulting in a severance charge of $0.2 million in the third quarter of 2017.

Deferred Revenue

Deferred revenue represents amounts collected but not yet earned and includes $1.0 million received in July 2017 for an upfront license fee in connection with the License Agreement with Lee's. The License Agreement constitutes a multiple-element arrangement and revenue will be recognized as deliverables are completed and all revenue recognition criteria have been met.

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 September 30, 2017 and 2016, the number of shares of common stock potentially issuable upon the conversion of preferred stock or exercise of stock options and warrants was 18.2 million and 9.4 million shares, respectively. For the three and nine months ended September 30, 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 and nine months ended September 30, 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 Preferred Shares in the first quarter of 2017 (*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 Preferred Shares. As the Preferred Shares are immediately convertible by the holders, the discount allocated to the beneficial conversion feature was immediately accreted and recognized as a $3.6 million one-time, non-cash deemed dividend to the preferred shareholders during the first quarter of 2017.

An additional discount to the Preferred Shares of $4.5 million was created due to the allocation of proceeds to the Warrants which were issued with the Preferred Shares. This discount is amortized proportionately as the Preferred Shares are converted. For the three and nine month periods ended September 30, 2017, we recognized a non-cash deemed dividend to the preferred shareholders of $1.9 million and $2.4 million, respectively, related to the Preferred Shares converted during the periods.

Recently Adopted Accounting Standards

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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). 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 these 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 an 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 nine-month periods ended September 30, 2017 and 2016.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the annual period ending December 31, 2018 and interim periods within that annual period. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company has not yet completed its final review of the impact of this guidance including the new disclosure requirements, as it is continuing to evaluate the impacts of adoption and the implementation approach to be used. The Company plans to adopt the new standard effective January 1, 2018 using the modified retrospective method. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current conclusions.

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:

(in thousands)	Fair Value September 30, 2017	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 1,752	$ 1,752	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 1,977	$ 1,977	$ -	$ -

(in thousands)	Fair Value December 31, 2016	Fair value measurement using 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 nine months ended September 30, 2016 representing the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

Balance at January 1, 2016	**$ 223**
Change in fair value of common stock warrant liability	(223)
Balance at September 30, 2016	**$ -**

Fair Value of Long-Term Debt

At September 30, 2017, the estimated fair value of the Deerfield Loan (*see*, "– Note 8 – Long-term Debt") was $23.0 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 that could be realized 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. The methodology and assumptions do not take into consideration the restructuring and retirement of the Deerfield Loan effective November 1, 2017 (*see*, "– Note 10 – Subsequent Events").

Note 7 – Loan Payable

Loan Payable consists solely of amounts due under a loan agreement with Lee's (HK).

On August 14, 2017, we entered into a loan agreement (Loan Agreement) with Lee's (HK). Under the Loan Agreement, Lee's (HK) agreed to lend us up to $3.9 million (Loan), to be funded at Lee's (HK)'s sole discretion in three equal installments on August 15, September 10 and October 10, 2017. The Loan was to be used to support AEROSURF development activities and sustain our operations through October 31, 2017, while we and Lee's (HK) negotiated the SPA and related agreements. The Loan accrued interest at a rate of 12% per annum. We received the three installments of $1.3 million from Lee's (HK) in accordance with the schedule. As partial consideration for the SPA, the outstanding principal balance of the Loan was applied in full satisfaction of a like amount of cash consideration payable by Lee's (HK) at the closing of the SPA, and the Loan was discharged in full (*see*, "– Note 10 – Subsequent Events").

As of September 30, 2017, accrued interest on the Loan was $28,000.

As partial consideration for the Loan, the Company and Lee's (HK) also agreed to amend the License, Development and Commercialization Agreement dated as of June 12, 2017 between the parties (License Agreement) and have entered into Amendment No. 1 to the License Agreement (the Amendment). Under the terms of the Amendment, reductions have been made to certain of the milestone and royalty payments. As a result, the Company may receive up to $35.8 million (previously, $37.5 million) in potential clinical, regulatory and commercial milestone payments. The options to add Japan to the Licensed Territory (as defined in the License Agreement) and to manufacture the Company's aerosol delivery device in and for the Licensed Territory are made effective immediately. In addition, Zhaoke Pharmaceutical (Hefei) Co. Ltd. an affiliate of Lee's (HK), has been made a party to the License Agreement. Except as set forth in the Amendment, all other terms and conditions of the License Agreement remain in full force and effect.

Note 8 – Long-term Debt

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

(in thousands)	September 30, 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. *See*, "Note 10 – Subsequent Events".

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

(in thousands)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Amortization of prepaid interest expense	$ 276	$ 347	$ 819	$ 1,435
Cash interest expense	260	191	771	191
Total interest expense	$ 536	$ 538	$ 1,590	$ 1,626

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, paid in cash on a quarterly basis.

Note 9 – Stock Options and Stock-Based Employee Compensation

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

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	(258)	9.43	
Outstanding at September 30, 2017	1,706	$ 8.98	8.0
Vested and exercisable at September 30, 2017	612	$ 21.55	6.0
Vested and expected to vest at September 30, 2017	1,597	$ 9.13	7.9

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

	Nine Months Ended September 30, 2017	2016
Weighted average expected volatility	79%	78%
Weighted average expected term (in years)	6.6	5.7
Weighted average risk-free interest rate	2.22%	1.4%
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 September 30, 2017	2016	Nine Months Ended September 30, 2017	2016
Research and development	$ 77	$ 140	$ 360	$ 462
General and administrative	101	133	372	664
Total	$ 178	$ 273	$ 732	$ 1,126

Note 10 – Subsequent Events

Effective October 27, 2017, we entered into the SPA with LPH Investments Limited (LPH), a company incorporated in the Cayman Islands with limited liability. LPH is a wholly-owned subsidiary of Lee's. Under the SPA, LPH invested $10 million (the Investment) in our Company and acquired 46,232,085 shares of our common stock (the Shares), at a price of $0.2163 per share, which represents a 15% premium over the average of the daily volume-weighted average price per share (VWAP) over the 10-day trading period ending on and including the date of the SPA. Following the transactions described in the SPA, LPH beneficially owned 73% of our issued and outstanding shares of common stock. The Investment includes cancellation of $3.9 million in outstanding loans ($2.6 million of which was recorded as loan payable as of September 30, 2017) that we borrowed from Lee's (HK) under the Loan Agreement, effective August 14, 2017, between ourselves and Lee's (HK). Pursuant to the SPA, we granted LPH the right to appoint up to two individuals to serve on our Board of Directors, and LPH may designate such individuals on or prior to the 30th day following the closing of the transactions contemplated by the SPA (the Closing). In addition, the SPA also amends the executive employment agreement of each of our President and Chief Executive Officer (Craig Fraser), Senior Vice President and Chief Financial Officer (John A. Tattory) and Senior Vice President and Chief Medical Officer (Steven G. Simonson, M.D.), such that in lieu of the Annual Bonuses (as defined in each executive's employment agreement) that would have been payable to the executives during the 24-month period following the Closing, the executives are entitled to an award of equity under our 2011 Long-Term Incentive Plan, as amended, having a value when issued equal to the combined total value of the 2017 and 2018 Target Bonus Amounts (as defined in each executive's employment agreement) and vesting in two equal installments on March 15, 2018 and March 15, 2019. Under the terms of the SPA, we also granted to LPH a preemptive right to purchase in future offerings of equity securities up to that number of shares of the Company's equity securities needed to maintain LPH's percentage of beneficial ownership of the Company's outstanding voting stock immediately prior to each such offering, subject to certain limitations and exclusions.

Contemporaneously with the execution of the SPA, we and LPH entered into a registration rights agreement pursuant to which we agreed to provide certain registration rights with respect to the Shares under the SPA, which rights are limited to registration of up to 25% of the Shares during the initial 18-month period following the closing of the SPA. We issued the Shares to LPH pursuant to Rule 506(b) of Regulation D and Regulation S under, and Section 4(a)(2) of, the Securities Act of 1933.

Contemporaneously with the execution of the SPA, we and Deerfield entered into an Exchange and Termination Agreement (the Exchange and Termination Agreement). Under the Exchange and Termination Agreement, (i) promissory notes evidencing an aggregate principal amount of $25 million that we owed to Deerfield under a Facility Agreement dated as of February 13, 2013 (Facility Agreement), as amended from time to time, and (ii) warrants to purchase up to 500,000 shares of our common stock at an exercise price of $39.34 per share held by Deerfield (the Deerfield Warrants) were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) an aggregate of 1,422,250 shares of common stock and (iii) the right to receive certain milestone payments (Milestone Payments) based on achievement of specified development and commercial milestones related to the Company's AEROSURF® development program, which, if achieved, could potentially total up to $15 million.

Contemporaneously with the execution of the Exchange and Termination Agreement, we and Deerfield entered into a registration rights agreement pursuant to which we agreed to provide certain registration rights with respect to the shares of common stock issued to Deerfield under the Exchange and Termination Agreement. We issued the shares of common stock to Deerfield pursuant to Rule 506(b) of Regulation D under, and Section 4(a)(2) of, the Securities Act of 1933.

On November 1, 2017 (the Closing Date), we, Lee's and Deerfield consummated the transactions contemplated by the SPA and the Exchange and Termination Agreement. Effective upon the Closing Date, (i) the Facility Agreement, including the outstanding promissory notes thereunder, and (ii) that certain Security Agreement, dated as of February 13, 2013, among Deerfield and us were cancelled and terminated.

To facilitate consummation of the SPA, effective upon the Closing, Battelle, holder of an aggregate of 1,095 shares of Series A Convertible Preferred Stock, par value $0.001 per share, of the Company (Preferred Shares), executed a waiver wherein Battelle waived its right to the Liquidity Preference (as defined in the Designation of Preferences, Rights and Limitations for the Preferred Shares) with respect to their Preferred Shares. In addition, we and Battelle entered into a non-binding memorandum of understanding outlining the key terms for a potential restructuring of the amounts due to Battelle under development and collaboration agreements between ourselves and Battelle.

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 NIH.

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 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. 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 delay surfactant therapy and treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)). 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.

In June 2017, we announced that we had completed an AEROSURF phase 2b clinical trial that was designed 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 was conducted in approximately 50 clinical sites in the U.S., Canada, the European Union and Latin America. Based on the planned top-line results, data show that AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours, which we believe was due in large part to an unexpected rate of treatment interruptions. Such interruptions occurred in about 24% of active enrollments, predominantly in the 50 minute dose group, and we believe were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. After excluding the patients whose dose was interrupted in the 50 minute dose group, the data show an nCPAP failure rate of 32% compared to 44% in the control group which is a 12% absolute reduction or a 27% relative reduction in nCPAP failure compared to control. These data suggest a meaningful treatment effect in line with our targeted outcome.

We are currently focused on our project with Battelle Memorial Institute (Battelle) to complete development of our next generation aerosol delivery device (NextGen ADS), which is intended to replace the prototype device used in our phase 2 clinical trials. The NextGen ADS combines the same aerosolization technology used during the phase 2 clinical program, but with improved ergonomics, interface, controls, and dose monitoring in a modular design. Design verification and validation are underway. Within this process, we are assessing whether the design of the NextGen ADS successfully mitigates the risk of clogging and related treatment interruptions that occurred during the Phase 2b clinical trial. To verify the design and confirm the performance of the NextGen ADS, including with respect to device-related treatment interruptions experienced with the phase 2 prototype ADS, we are planning to conduct a device bridging and confirmation clinical study (i) to gain experience with the next generation ADS (NextGen ADS), (ii) to confirm whether our development objectives have been met and (iii) to generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial, which was adversely affected by treatment interruptions. We currently are assessing the potential design elements and requirements for this trial.

In addition, in June 2017, we and a Hong Kong company, Lee's Pharmaceutical (HK), Ltd. (Lee's (HK)), entered into an exclusive license and collaboration agreement (License Agreement) for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets, with a future option to potentially add Japan. The agreement includes AEROSURF as well as the non-aerosol products, SURFAXIN® (approved in the U.S. in 2012) and SURFAXIN LS™ (an improved lyophilized formulation of SURFAXIN). We also granted Lee's (HK) an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory and a future option to manufacture the device in the licensed territory. In connection with the August 2017 Loan Agreement with Lee's (HK) (*see*, "– Business and Pipeline Program Updates"), we amended the License Agreement to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. We are presently engaged in a technology transfer of our KL4 surfactant manufacturing process to Lee's (HK).

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. In addition, our Quarterly Reports on Form 10-Q for the first and second quarters of 2017 contain business and development program updates for the applicable quarter.

The following are updates to our business and development programs for the third quarter ending September 30, 2017:

- On August 14, 2017, we announced that we entered into a Loan Agreement with Lee's Pharmaceutical (HK), Ltd. (Lee's (HK)) under which Lee's agreed to lend us up to $3.9 million (Lee's Loan) to be paid in Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017. We received all three installments as scheduled. The loan was used to support our activities through October 31, 2017, while we and Lee's negotiated a $10 million securities purchase agreement (SPA) pursuant to which Lee's acquired a controlling interest in our Company. In addition, we negotiated with affiliates of Deerfield Management Company L.P. (Deerfield) to restructure (Loan Restructuring) the outstanding $25 million long-term loan (Deerfield Loan) effective as of the closing of the SPA. Under the Loan Restructuring the notes and the warrants issued in connection with the Deerfield Loan were retired in exchange for $2.5 million in cash, common stock equal to 2% of our outstanding shares, plus potential future milestones payments of up to $15 million. (*See*, "Note 10 – Subsequent Events").

- During this period, we continued implementing cost-cutting measures and further evaluated the needs of our Company going forward. On July 13, 2017, following completion of our AEROSURF phase 2b clinical trial, we implemented a reduction in our workforce from 48 to 28 employees affecting all functions of our Company. Affected employees were eligible for certain severance and other benefits. As a result, we recorded a one-time charge of approximately $0.2 million in the third quarter of 2017.

- During this period, we completed the analysis of results from the AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age receiving nCPAP for RDS. The FDA requested that we conduct a separate safety study in smaller premature infants before including them in a phase 2b study. The clinical trial was a multicenter, randomized, open-label, controlled study in premature infants 26 to 28 weeks gestational age receiving nCPAP for RDS, and designed to evaluate the safety and tolerability of aerosolized KL4 surfactant administered in three escalating doses (30, 45, and 60 minute), with potential repeat doses, compared to infants receiving nCPAP alone. A total of 48 premature infants, including 24 in three AEROSURF dose groups, and 24 on nCPAP alone (control), were enrolled in this clinical trial. Key observations include:

    - Overall, the safety and tolerability profile of AEROSURF was generally comparable to the control group. All reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS. Based on an interim safety committee review after the first two dose groups (30 and 45 minutes), 28 week gestational age premature infants were enrolled in the phase 2b clinical trial.
    - The overall nCPAP failure rate observed in the previous phase 2a clinical trial in 29 – 34 week gestational age premature infants was 53% and in the recently completed phase 2b clinical trial in 28 – 32 week gestational age premature infants, 44%, compared to 67% in the control group.
    - Early nCPAP failures within 6 hours after randomization were less frequently observed in the AEROSURF treated groups compared to control group. Similar to the phase 2a study in 29 – 34 week gestational age premature infants and phase 2b study in 28 – 32 week gestational age premature infants, the data suggest that AEROSURF may have an early effect and may be prolonging the time to nCPAP failure compared to control; however, the overall rate of nCPAP failure was comparable at 72 hours between control and treatment groups. At 72 hours, nCPAP failure rates were 63%, 88% and 63% in the 30, 45 and 60 minute AEROSURF dose groups, respectively, compared to 67% in the control group.
    - As was observed in the AEROSURF phase 2b clinical trial, some treatments were interrupted. Such interruptions occurred in one-third of active enrollments, and we believe were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. Although complicated by small numbers, analysis of data of patients whose dose was not impacted by device-related treatment interruptions (n=16) resulted in nCPAP failure rates of 57%, 100% and 50% in the 30 (n=7), 45 (n=3) and 60 (n=6) minute AEROSURF dose groups, respectively compared to 67% in the control group.
    - An important observation that has emerged from this trial is a significantly lower rate of neonatal bronchopulmonary dysplasia (BPD) or chronic lung disease of the newborn in AEROSURF treated patients compared to control. BPD rates were 0% (0 of 24) in the AEROSURF treated patients compared to 25% (6 of 24) in the control group.

The results observed in this trial met the objective of demonstrating an acceptable safety and risk profile to allow inclusion of 26 – 28 week gestational age premature infants in any future studies in the AEROSURF development program.

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 5 – Summary of Significant Accounting Policies" and "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

Operating Loss and Net Loss

The operating loss for the three months ended September 30, 2017 and 2016 was $4.8 million and $7.7 million, respectively. The decrease in operating loss from 2016 to 2017 was due to a $3.9 million decrease in operating expenses, partially offset by a $0.9 million decrease in grant revenue.

The operating loss for the nine months ended September 30, 2017 and 2016 was $19.1 million and $31.7 million, respectively. The decrease in operating loss from 2016 to 2017 was due to a $12.4 million decrease in operating expenses.

The net loss for the three months ended September 30, 2017 and 2016 was $5.4 million and $8.4 million, respectively. Included in the net loss is (i) interest expense of $0.6 million in both 2017 and 2016; and (ii) for 2017, $0.2 million for a severance charge related to July 2017 workforce reduction (*see*, "Note 5 – Summary of Significant Accounting Policies").

The net loss for the nine months ended September 30, 2017 and 2016 was $20.9 million and $32.9 million, respectively. Included in the net loss is (i) interest expense of $1.9 million in both 2017 and 2016; (ii) a severance charge of $0.2 million and $1.6 million, respectively, for 2017 and 2016 (*see*, "Note 5 – Summary of Significant Accounting Policies"); and (iii) for 2016, $0.4 million in proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits and $0.2 million in non-cash income related to the change in fair value of certain common stock warrants classified as derivative liabilities.

The net loss attributable to common stockholders for the three and nine months ended September 30, 2017 was $7.3 million (or $0.69 basic net loss per common share) and $26.9 million (or $2.76 basic net loss per common share), respectively. The net loss attributable to common stockholders for the three and nine months ended September 30, 2016 was $8.4 million (or $1.00 basic net loss per common share) and $32.9 million (or $3.98 basic net loss per common share), respectively. Included in the net loss attributable to common stockholders for the three and nine months ended September 30, 2017 is a $1.9 million and a $6.1 million non-cash deemed dividend on preferred stock, respectively (*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 September 30, 2016, we recognized grant revenue of $1.0 million. For the nine months ended September 30, 2017 and 2016, we recognized grant revenue of $1.4 million and $1.1 million, respectively.

Grant revenue for the nine months ended September 30, 2017 includes $1.1 million of funds received and expended under a Phase II Small Business Innovation Research Grant (SBIR) from the National Heart, Lung, and Blood Institute (NHLBI) of the NIH to support the AEROSURF phase 2b clinical trial (AEROSURF Grant), and $0.3 million of funds under a Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) to support continued development of our aerosolized KL_4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (Radiation Grant).

Grant revenue for the three and nine months ended September 30, 2016 includes $0.7 million of funds received and expended under the AEROSURF Grant, $0.1 million under the Radiation Grant, and $0.1 million under a fixed-price contract to support development of our aerosolized KL_4 surfactant to mitigate influenza-related lung injury (Influenza Grant).

As of September 30, 2017, all funding under the AEROSURF Grant, the Radiation Grant, and the Influenza Grant has been received and $0.1 million related to the Radiation Grant is currently recorded as deferred revenue and will be recognized as grant revenue when the funds are expended.

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 KL_4 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 and nine months ended September 30, 2017 and 2016 are as follows:

(in thousands)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Product development and manufacturing	$ 1,306	$ 2,081	$ 5,013	$ 8,215
Clinical, medical and regulatory operations	1,277	1,715	4,654	5,778
Direct preclinical and clinical programs	479	3,285	5,291	11,764
Total Research and Development Expenses	$ 3,062	$ 7,081	$ 14,958	$ 25,757

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.1 and $0.2 million for the three months ended September 30, 2017 and 2016, respectively, and of $0.5 million and $0.6 million for the nine months ended September 30, 2017 and 2016, respectively.

Product Development and Manufacturing

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

Product development and manufacturing expenses decreased $0.8 million for the three months ended September 30, 2017 compared to the same period in 2016 due to (i) a $0.5 million decrease in costs related to development activities under our collaboration agreement with Battelle, and (ii) our ongoing efforts, initiated in the second quarter of 2016, to conserve cash and reduce costs.

Product development and manufacturing expenses decreased $3.2 million for the nine months ended September 30, 2017 compared to the same period in 2016 due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures, (ii) a $1.3 million decrease in costs related to development activities under our collaboration agreement with Battelle, (iii) a $0.6 million decrease in costs associated with the technology transfer of our lyophilized surfactant manufacturing facility process to a new facility at our CMO, and (iv) the July 2017 workforce reduction.

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 $0.4 million and $1.1 million, respectively, for the three and nine months ended September 30, 2017 compared to the same periods in 2016 due to (i) our ongoing efforts, initiated in the second quarter of 2016, to conserve cash and reduce costs; and (ii) the July 2017 workforce reduction.

Direct Preclinical and Clinical Development Programs

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

Direct preclinical and clinical development programs expenses decreased $2.8 million for the three months ended September 30, 2017 compared to the same period in 2016 due to a decrease in AEROSURF phase 2 clinical development program costs during the second quarter of 2017.
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Direct preclinical and clinical development programs expenses decreased $6.5 million for the nine months ended September 30, 2017 compared to the same period in 2016 due to a decrease in AEROSURF phase 2 clinical development program costs as many upfront site initiation costs and manufacturing costs related to ADS delivery, site set-up and training were completed during the three and nine months ended September 30, 2016 and are not ongoing clinical trial costs.

General and Administrative Expenses

(in thousands)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
General and Administrative Expenses	$ 1,749	$ 1,613	$ 5,475	$ 7,053

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

General and administrative expenses decreased $1.6 million for the nine months ended September 30, 2017 compared to the same period in 2016 due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures and (ii) $1.6 million of severance charges during the nine months ended September 30, 2016 compared to severance charges of $0.2 million for the nine months ended September 30, 2017 (*see*, "Note 5 – Summary of Significant Accounting Policies").

Other Income and (Expense)

(in thousands)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Interest income	$ 3	$ 3	$ 9	$ 15
Interest expense	(652)	(648)	(1,878)	(1,907)
Other income	-	15	-	449
Other income / (expense), net	$ (649)	$ (630)	$ (1,869)	$ (1,443)

Interest expense consists of interest expense associated with the Deerfield Loan (*see*, "Note 8 – Long-term Debt") and under our collaboration agreement with Battelle (*see*, "Note 7 – Collaboration Payable and Accrued Expenses" in the Notes to Consolidated Financial Statements in our 2016 Form 10-K).

Other income / (expense) primarily consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits. The decrease in tax credits for the nine months ended September 30, 2017 to the same period in 2016 is due to the timing of the sale of the tax credits. The 2015 tax credits were sold in the first quarter of 2016 while the 2016 tax credits were sold in the fourth quarter of 2016.

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

(in thousands)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Amortization of prepaid interest expense	$ 276	$ 347	$ 819	$ 1,435
Cash interest expense	260	191	771	191
Total interest expense	$ 536	$ 538	$ 1,590	$ 1,626

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, paid in cash on a quarterly basis.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2017, we had cash and cash equivalents of $1.8 million, current liabilities of $29.5 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion. Total long-term debt of $25 million was with affiliates of Deerfield Management, L.P. (Deerfield), who held a security interest in substantially all of our assets (Deerfield Loan).

On November 1, we announced that we had completed a series of transactions to generate short-term cash and potentially enable future capital transactions. Effective October 27, 2017, LPH Investments Limited (LPH), a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited (Lee's) acquired $10 million of newly issued shares of our common stock, representing a controlling interest in our Company. At the same time, we reached an agreement with Deerfield to restructure and retire the outstanding $25 million long-term debt, and entered into a nonbinding memorandum of understanding with Battelle (Battelle MOU) outlining potential terms to restructure certain accounts payable related to our device development activities with Battelle. In connection with the Battelle MOU, Battelle executed and delivered a waiver of its rights to receive payments under a liquidation preference pursuant to Series A Convertible Preferred Stock held by Battelle and the related Certificate of Designation of Preferences, Rights and Limitations effective February 15, 2017 (the foregoing transactions with LPH, Deerfield and Battelle are collectively referred to in this Quarterly Report on Form 10-Q as the November 2017 Restructuring). *See*, "Note 10 – Subsequent Events".

Although we believe that the November 2017 Restructuring has improved our financial position and better positions us to raise the capital needed to fund on-going operations and development plans, we expect to incur continuing significant losses and will require significant additional capital to further advance our AEROSURF clinical development program, satisfy our current obligations and support our operations for the next several years. Moreover, we do not have sufficient existing cash and cash equivalents for at least the next year following the date that these 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, and other 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. There can be no assurance that these alternatives will be available, or if available, that we will have sufficient cash resources and liquidity to fund our development activities and business operations for at least the next year following the date that these 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.

As of November 1, 2017, after closing the November 2017 Restructuring, we had cash and cash equivalents of $5.4 million. While we seek the additional capital that we require, we are working with our vendors and service providers to extend payment terms of certain obligations and our available cash. We believe that, before any additional financings, we will have sufficient cash resources to partially satisfy our existing obligations and fund our operations into January 2018.

These 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 capital that we will require through equity financings and other similar transactions is subject to regulatory and other constraints, including: (i) our common stock is currently quoted on the OTCQB® Market (OTCQB), which is operated by OTC Markets Group Inc., under the symbol WINT and may experience periods of illiquidity; (ii) our common stock is currently considered a "penny stock," such that brokers are required to adhere to more stringent market rules, which could result in reduced trading activity and trading levels in our common stock and limited or no analyst coverage; (iii) because we are no longer listed on a national securities exchange, we are noteligible to file a Form S-3 registration statement and our recent Form S-3 has expired; (iv) without a Form S-3, we are not able to use our ATM Program; (v) our controlling stockholder may not approve management proposals to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, which could impair our ability to conduct equity financings or enter into certain strategic transactions (mergers and acquisitions) that require stockholder approval under Delaware law; (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock 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, we expect that we will more likely conduct securities offerings as private placements with registration rights, which we would register under a registration statement on Form S-1, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

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. 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 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 late May 2017, we announced that we have been awarded $0.9 million under a previously announced Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF phase 2b clinical trial. We currently are determining whether, as a subsidiary of Lee's, we continue to be eligible for SBIR grants. We also have received from time to time 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. 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.

As of September 30, 2017, and November 8, 2017, we had outstanding 0.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance, and 3,203 convertible preferred shares issued in the February 2017 private placement offering. Each preferred share is convertible into 1,000 shares of common stock. Upon exercise of the pre-funded warrants and conversion of the convertible preferred shares, we would issue common shares to the holders and receive no additional proceeds.

In addition, as of September 30, 2017, there were 120 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 85.0 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

Cash Flows

As of September 30, 2017, we had cash and cash equivalents of $1.8 million compared to $5.6 million as of December 31, 2016. Cash outflows for the nine months ended September 30, 2017 consist of $16.2 million used for ongoing operating and investing activities offset by cash inflows for the nine months ended September 30, 2017 of $12.4 million for financing activities.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2017 and 2016 was $16.2 million and $26.6 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The decrease in net cash used in operating activities is due to our ongoing efforts, initiated in the second quarter of 2016, to conserve cash as well as a decrease in AEROSURF phase 2 clinical development program costs.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2017 and 2016 represents capital expenditures of $24,000 and $193,000, respectively, partially offset in 2016 by $27,000 in proceeds from sale of property and equipment.

Financing Activities

Net cash provided by financing activities for nine months ended September 30, 2017 was $12.4 million and represents net cash proceeds from (i) the February 2017 private placement of $8.8, (ii) the use of the ATM Program of $1.0 million, and (iii) $2.6 million in proceeds from a loan payable in connection with our loan agreement with Lee's (HK).

Net cash provided by financing activities for the nine months ended September 30, 2016 was $0.5 million and represents proceeds from the use of the ATM Program.

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

Private Placement Offering

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 August 15, 2017 and through February 15, 2024. 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 the event of a liquidation, including without limitation, the sale of substantially all of our assets and certain mergers and other corporate transactions (as defined in the Certificate of Designation of Preferences, Rights and Limitations relating to the Preferred Shares), the holder of Preferred Shares will have a liquidation preference that could result in the holder receiving a return of its initial investment before any payments are made to holders of common stock, and then participating with other equity holders until it has received in the aggregate up to three times its original investment. 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.

As of November 8, 2017, 3,846 Preferred Shares have been converted into 3,846,000 shares of common stock and 3,203 Preferred Shares remain outstanding.

At-the-Market Program (ATM Program)

ATM Program

During the nine months ended September 30, 2017, we completed offerings of our common stock under our ATM Program of 847,147 shares. This resulted in an aggregate purchase price of approximately $1,082,000 ($1,036,000 net) for the nine month period ended September 30, 2017. During the three and nine months ended September 30, 2016, we completed offerings of our common stock under our ATM Program of 159,051 shares and 187,022 shares, respectively. This resulted in an aggregate purchase price of approximately $432,000 ($402,000 net) and $503,000 ($471,000 net), respectively, for the three and nine month periods ended September 30, 2016.

Effective May 5, 2017, we were no longer able to make use of our ATM Program (*see*, “Liquidity and Capital Resources”).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended September 30, 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 and in our Quarterly Reports for the previous quarters in 2017. 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 and in our Quarterly Reports for the previous quarters in 2017, 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 or discussed in our Quarterly Reports for the previous quarters in 2017 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.

We currently have sufficient capital to fund our development programs, support our business operations and pay our obligations on a timely basis into January 2018. If we do not secure additional capital to support our future activities before our existing cash resources are exhausted, we likely will be unable to continue as a going concern.

As of November 1, 2017, after closing the November 2017 Restructuring, we had cash and cash equivalents of $5.4 million. While we seek the additional capital that we require, we are working with our vendors and service providers to extend payment terms of certain obligations and our available cash. We believe that, before any additional financings, we will have sufficient cash resources to partially satisfy our existing obligations and fund our operations into January 2018.

We expect to continue to require significant additional infusions of capital to execute our business strategy until such time as revenues from the commercialization of AEROSURF® and our other KL4 surfactant product candidates, if approved, from potential strategic alliance and collaboration arrangements and from other sources, are sufficient to offset our cash flow requirements. For the next several years, we do not expect to receive revenues from the sale of approved products, and our cash outflows for development programs and business operations are likely to far outpace the rate at which we may generate revenues and other cash inflows from all available sources.

Our ability to continue as a going concern is dependent upon our ability to raise additional capital, to fund our development programs, support our business operations and pay our current obligations on a timely basis. In the near term, we plan to seek the additional capital that we require through one or a combination of the following: (i) strategic transactions and other 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. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we likely will not have sufficient cash resources and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders’ interests and, in such event, the market price of our common stock may decline.

Our clinical development program for AEROSURF involves significant risks and uncertainties that are inherent in the clinical development. Our clinical trials may be delayed, or fail, which will harm our business prospects.

In June 2017, we announced the results of our AEROSURF phase 2b clinical trial in premature infants 28 to 32 weeks gestational age receiving nCPAP for RDS, which was designed to evaluate (i) the safety and tolerability of aerosolized KL_4 surfactant compared to infants receiving nCPAP alone and (ii) certain potential endpoints, including time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. This clinical trial was one of a series of clinical trials, including a planned phase 3 clinical development program, that we expect will be needed to gain marketing authorization for AEROSURF. Development programs generally take up to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the U.S. Food and Drug Administration (the FDA) or a foreign regulator on the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a phase 3 clinical program in the U.S. and EU and potentially other markets. Conditions imposed by the FDA and foreign regulators on our clinical development program could significantly increase the time required to complete our clinical programs, and the costs of conducting, and the risks associated with clinical trials. For example, we may not be able to design a study that is acceptable to the FDA and EMA regulators, which could potentially cause us to limit the scope of our geographical activities or greatly increase our investment. Or, in conducting multinational trials in various regions of the world, we may fail to correctly anticipate variability in clinical trial results due to differences in clinical practices and treatment modalities. Even if we obtain promising preliminary findings or results in earlier preclinical studies and clinical trials, including in our device bridging and confirmation clinical trial, we may suffer significant delays or setbacks in any stage of our clinical trials. We may be unable to enroll patients quickly enough to complete any or all of our planned clinical trials within an acceptable time frame. Any of the risks described in this risk factor and elsewhere in this and our other Quarterly Reports on Form 10-Q, in risk factors described in our Annual Report on Form 10-K and in our other public filings, including without limitation with respect to regulatory requirements, institutional review board approval, clinical site initiation and supply, patient enrollment, drug manufacture, device development and performance, lack of compatibility with complementary technologies, or treatment time requirements, could potentially delay a clinical trial and, in any such event, we may be forced to end our clinical trial earlier than planned, which could adversely affect the results and potentially impair our ability to secure, additional capital to fund our development program. Moreover, even if we are able to complete the planned clinical program within our anticipated time, if our results are inconclusive or non-compelling or otherwise insufficient to support a strategic or financing transaction, we may be unable to secure the additional capital needed to further develop AEROSURF and may be forced to limit or cease our development activities, which would have a material adverse effect on our business.

Failure to complete the development of our NextGen ADS intended for future development activities and, if approved, initial commercial activities, in a timely manner, if at all, would have a material adverse effect on our efforts to develop AEROSURF as well as our other aerosolized KL_4 surfactant products, and our business strategy.

We have developed a clinic-ready aerosol delivery system (ADS) that was suitable for use in our phase 2 clinical development program and are working with Battelle Memorial Institute (Battelle) to further develop a next generation (NextGen) ADS for use in our remaining AEROSURF development activities and, if approved, early commercial use. Our device development activities are generally directed to controlling risks of mechanical and other failures, assuring timely availability and consistency of performance, low variability machine to machine, and rigorous testing and verification processes to avoid design defects. Among other things we are assessing the dose interruptions that occurred with the prototype phase 2 ADS and taking steps to assure that we have mitigated the chances of such failures occurring in the NextGen ADS.

Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not succeed in developing on a timely basis, if at all, a NextGen ADS that is acceptable for use in our remaining AEROSURF development activities, including our planned device bridging and confirmation clinical trial and our planned phase 3 clinical trial and, if approved, has levels of efficiency, consistent performance, reliability and cost appropriate for commercial activities.
- We will require access to sophisticated engineering capabilities. We have our own medical device engineering staff and we are currently working with Battelle, which is assisting us in our development program and has expertise in medical device development and medical device design. If for any reason we are unable to retain our engineering staff or if the agreement with Battelle expires or is terminated, we will require design engineers and medical device experts to support our development efforts, including for a clinic-ready NextGen ADS for use in our planned phase 3 clinical development program and, potentially, for commercial use and later enhanced versions of the ADS. Any failure to identify such talent would have a material adverse effect on our business strategy and impair our ability to develop or commercialize AEROSURF or other aerosolized KL_4 surfactant products.
- We also depend on having access to certain system components used in our clinical program that are currently available commercially, such as nasal continuous positive airway pressure (nCPAP) equipment and are working to improve certain other components for use in our future clinical development activities. If for any reason, we are unable to secure access to reliable and reasonably priced system componentry and equipment and other materials, our development activities could be delayed, the costs of necessary components could be unacceptably high and the performance of AEROSURF could suffer.
- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and medical device development and commercialization expertise. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop AEROSURF or other aerosolized KL_4 surfactant products.

Risks related to ownerships structure

We are a subsidiary of Lee's, and accordingly our business may be substantially controlled by Lee's.

Lee's, through its wholly-owned subsidiary, LPH, owns approximately 73% of our issued and outstanding voting shares of common stock. Under the terms of the SPA, within 30 days from November 1, 2017, Lee's has the right to designate two individuals to serve on our Board of Directors. As a majority stockholder, Lee's could cause corporate actions to be taken even if the interests of Lee's conflict with the interests of our other stockholders. This concentration of voting power could have the effect of deterring or preventing a change in control that might be beneficial to our other stockholders.

As the majority stockholder, Lee's will have the voting power to approve or disapprove any matter or corporate transaction presented to our stockholders for approval, including but not limited to:

- election of the entire Board of Directors
- any amendment of our certificate of incorporation or bylaws;
- any merger or consolidation of us with another company;
- any recapitalization or reorganization of our capital stock;
- any sale of assets or purchase of assets; or
- a corporate dissolution or a plan of liquidation of our business.

Conflicts of interest may arise from our relationship with Lee's

Our relationship with Lee's could give rise to certain conflicts of interest that could have an impact on our development programs, business opportunities, and operations generally.

- An affiliate of Lee's, Lee's (HK), is a licensee under a June 2017 license agreement, as amended, providing for rights in and to our intellectual property to develop, manufacture and commercialize our KL_4 surfactant products in a territory in Asia that includes China, Hong Kong, Japan and approximately a dozen other countries. Lee's may determine that some of our other patents or technology would be useful in its business or that of another Lee's affiliate, and Lee's or another Lee's affiliate may hold patents or technology that we may determine would be useful in our business. In such cases, we may enter into license or sublicense agreements with Lee's or another Lee's affiliate for the use of such patents or technology. Conflicts of interest will arise in determining the scope and financial terms of any such licenses or sublicenses, including the fields of use permitted, licensing fees, and royalties, if any, and other matters.
- We and Lee's or any of its other subsidiaries may determine to engage in research and development of the same or similar products or technologies, or products that would otherwise compete in the market place. Even if we utilize different technologies than Lee's or its other subsidiaries, we could find ourselves in competition with them for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements, and for customers if we and Lee's or another Lee's subsidiary both bring products to market.
- Lee's, as a majority stockholder, could prevent us from engaging in development programs, investments, business ventures, or agreements to develop, license, or acquire products or technologies that would or might compete with those owned, licensed, or under development by Lee's or any of its other subsidiaries.

Each conflict of interest will be resolved by our respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time. However, no assurance can be given that the actions taken by the respective boards of directors will be satisfactory to all of our stockholders.

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: November 14, 2017

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

Date: November 14, 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
10.1+	Amendment No. 1 dated as of August 14, 2017 to the License Development and Commercialization Agreement by and between the Company and Lee's Pharmaceutical (HK) Ltd. dated as of June 12, 2017	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.1	The following condensed consolidated financial statements from the Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of September 30, 2017 (unaudited) and December 31, 2016, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2017 and September 30, 2016 (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2017 and September 30, 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.

+Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the Commission

EXECUTION COPY

AMENDMENT N°. 1 TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT ("AMENDMENT N°. 1") by and between WINDTREE THERAPEUTICS, INC. and LEE'S PHARMACEUTICAL (HK) LTD.

Effective as of August 14, 2017, Windtree Therapeutics, Inc. ("***Licensor***") and Lee's Pharmaceutical (HK) Ltd. ("***Licensee***") hereby agree to amend the License, Development and Commercialization Agreement between them dated as of June 12, 2017 (the "***Agreement***") in consideration of Licensee lending to Licensor the amount of Three Million, Nine Hundred Thousand Dollars ($3,900,000) in cash ("***Bridge Loan***"), which loan shall be subject to and payable in accordance with the terms of the Loan Agreement between the Parties dated of even date herewith. Capitalized terms used herein not otherwise defined shall have the meanings ascribed to them in the Agreement.

The Parties hereby agree to amend the Agreement as follows:

1. Zhaoke Pharmaceutical (Hefei) Co. Ltd. an Affiliate of Licensee, is hereby made a party to the Agreement for the purpose of manufacturing, distributing, Commercializing and supporting Development activities for Aerosolized Products and Non-Aerosolized Products, subject in each case, to the terms and conditions of the Agreement.

2. Section 2.3 is hereby deleted in its entirety and the country of Japan is hereby added to the definition of "Licensed Territory."

3. The definition of "Licensed Territory" is deleted in its entirety and replaced with the following:

   "***Licensed Territory***" means PRC, Japan, Hong Kong, [***], Taiwan, [***], South Korea, Thailand, and [***]."

4. Section 7.3.(a) is hereby deleted in its entirety and replaced with the following:

   "**(a) Regulatory/Commercial Milestones**. In addition to the payment set forth in Section 7.1, Licensee shall pay the following one-time non-refundable regulatory/commercial milestone payments to Licensor, each within [***] after the first achievement of each regulatory/commercial milestone event indicated below:

Regulatory/Commercial Milestone Event	Milestone Payment, US$
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5. Notwithstanding anything in Section 7.4(a)(i) to the contrary, no royalty shall be payable with respect to [***] of Net Sales [***].

6. Notwithstanding anything in Section 2.1(a) and subject to the requirements of Section 15.5, as modified according to paragraph 7 of this AMENDMENT N°. 1, Licensor hereby grants to Licensee the right to manufacture and assemble the Device. Licensee's right to manufacture the Device is not sublicensable other than to its Affiliates in accordance with Section 2.1(c).

7. Section 15.5 is hereby deleted in its entirely and replaced with the following:

"**15.5. Device Manufacturing & Technology Transfer**.
Upon completion of a design verification procedure for the Device by or on behalf of Licensor, the Parties will enter into good faith discussions and use Commercially Reasonable Efforts to reach agreement on a Device manufacturing plan and any amendments to this Agreement as may be necessary or appropriate to provide for the rights granted to Licensee pursuant to paragraph 6 of AMENDMENT N°. 1 to this Agreement. After completion of a design verification process for the Device and agreement on a Device manufacturing plan and related amendments to this Agreement, Licensor shall use Commercially Reasonable Efforts to provide promptly to Licensee such technology transfer of the Device, as necessary for Licensee to manufacture and assemble the Device in and for the Licensed Territory with all related costs to be borne by Licensee. The Parties agree that the above mentioned manufacturing plan shall be submitted to the JSC for its review and approval, which approval shall not be unreasonably withheld or delayed.

Except as amended herein through this AMENDMENT N°. 1, the remaining terms and conditions of the Agreement shall remain in full force and effect. This AMENDMENT N°. 1 to the Agreement confirms an agreement among Windtree Therapeutics, Inc. and Lee's Pharmaceutical (HK) Ltd. and Zhaoke Pharmaceutical (Hefei) Co. Ltd. with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. The Parties reserve the right to further amend the Agreement to conform it to the changes made pursuant to this AMENDMENT N°. 1. The Parties have executed this AMENDMENT N°. 1 to the Agreement as of the day and date first set forth above.

Windtree Therapeutics, Inc.

By: /s/ Craig E. Fraser
Name: Craig E. Fraser
Title: Chief Executive Officer

Lee's Pharmaceutical (HK) Ltd.

By: /s/ Benjamin Li, Ph.D
Name: Benjamin Li, Ph.D
Title: Chief Executive Officer

Zhaoke Pharmaceutical (Hefei) Co. Ltd.

By: /s/ Benjamin Li, Ph.D
Name: Benjamin Li, Ph.D
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

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

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

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

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

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

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

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

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

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: November 14, 2017

/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: November 14, 2017

/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 September 30, 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: November 14, 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.