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, 2016

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.

(formerly Discovery Laboratories, 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 ☒

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 7, 2016, there were outstanding 8,476,033 shares of the registrant's common stock, par value $0.001 per share.

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PART II - OTHER INFORMATION

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.), and its wholly owned, presently inactive subsidiary, Discovery Laboratories, Inc. (formerly Acute Therapeutics, Inc.).

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation our plans, statements concerning our financial plans, including future financial condition, and the period of time during which we expect our existing resources to fund our operations; our business strategy, outlook, objectives, future milestones, intentions, and goals; and plans regarding potential strategic alliances and collaborative arrangements to develop, manufacture and market our products and other potential strategic transactions. Forward-looking statements also include our product development plans, including development activities, anticipated timing of clinical trials and results and potential development milestones for our KL_4 surfactant and our Aerosol Delivery System (ADS) for production of aerosolized KL_4 surfactant; our expectations, timing and anticipated outcomes of submitting regulatory filings to secure marketing authorization for AEROSURF® and other KL_4 surfactant products that we may develop in the future; and our plans for the manufacture of drug products, active pharmaceutical ingredients (APIs), materials and medical devices, and future distribution plans for our products, if approved.

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, although we currently expect that our existing cash resources are sufficient to fund our operations through February 2017, our recent decisions (i) to delay the conclusion of the ongoing AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age by progressing to a third (60 minutes) and potentially a fourth (90 minutes) additional dose group, and (ii) to continue enrollment in the ongoing AEROSURF phase 2b clinical trial with only premature infants 29 to 32 week gestational age, with top line data for this trial now expected in mid-year 2017, will compel us to seek additional infusions of capital in order to complete these clinical trials, and that any further delay or other complication, including with respect to regulatory requirements, clinical site initiation and supply, patient enrollment, drug manufacture, and device development and performance, may further increase the amount of capital that we will require before we have generated top line results in the phase 2b clinical trial. Under such circumstances, we may find it difficult to raise the additional capital that we need to continue our development activities and support our ongoing operations after February 2017. As a result, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our ability to continue as a going concern;

- the risk, even if we are able to raise the funds required to complete the AEROSURF phase 2b clinical trial in accordance with our revised plan, that we will continue to require significant additional capital to support our continuing research and development activities, including a potential phase 3 clinical program, business operations and debt service obligations, and our activities to potentially identify and secure potential strategic transactions, and the risk that our ability to raise such capital may be adversely impacted by, among other things, if results from our clinical trial are not sufficient to support a strategic transaction or equity financing;

- the risk that our ability to raise additional capital is subject to certain risks, including (i) limitations on the amount that we can raise in primary offerings pursuant to our 2014 universal shelf registration statement on Form S-3 (2014 Universal Shelf), including under our "at-the-market" equity sales program (ATM Program); (ii) that our stockholders may not approve, as required under The NASDAQ Stock Market ("Nasdaq") listing rules, a financing transaction recommended by our Board that is priced at a discount and requires issuance of more than 20% of our outstanding common stock; and (iii) that unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution of stockholders' interests;

- the risk that we will be unable to regain compliance with Nasdaq listing requirements, in particular, (i) minimum stockholders' equity ($2.5 million) with respect to which we received a Nasdaq deficiency notification on May 19, 2016, or (ii) the alternative minimum market value of outstanding shares ($35 million); if we fail to regain compliance on or before November 15, 2016 (the grace period granted by the Listing Qualifications Department (the "Staff") of Nasdaq), our common stock may be delisted and the value of our common stock may decrease;

- 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

- the risk that our ongoing AEROSURF phase 2a and 2b clinical trials, which are part of our lead clinical development program, may be interrupted, delayed, or generate inconclusive or non-compelling data, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or safety profile, which would have a material adverse impact on our business and our ability to continue as a going concern;

- risks related to our AEROSURF development program, including with respect to the aerosol delivery system (ADS), lyophilized KL_4 surfactant and clinical development activities. Any issues identified in the course of our device and drug-related development activities could adversely affect or further delay our AEROSURF phase 2 clinical program and our ability to advance our AEROSURF development program in accordance with our revised plan, if at all;

- risks related to our efforts to gain regulatory approval in the U.S. and elsewhere for our drug products, medical device and combination drug/device product candidates, including AEROSURF and our lyophilized KL_4 surfactant, which is the drug component of AEROSURF and potentially could be developed as a separate surfactant drug product, including risks that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug products, medical device and combination drug/device product candidates;

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

- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers, and our CMOs' ability to manufacture our lyophilized KL_4 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; and risks related to ongoing manufacturing process development and our ability to comply with ultimate approval specifications for our active pharmaceutical ingredients and our drug product;

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

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

Risks related to Strategic and Other Transactions

- the risk that we may be unable to identify and enter into strategic alliances, collaboration agreements or other strategic transactions that would provide capital to support our AEROSURF development activities and resources and expertise to support the registration and commercialization of AEROSURF in markets outside the U.S. and potentially support the development and, if approved, commercialization, of our other potential KL4 surfactant pipeline products;

- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P., which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;

Other Risks Affecting 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 as detailed in “Risk Factors” in our most recent Annual Report on Form 10-K as amended, filed with the Securities and Exchange Commission (SEC) on March 29, 2016, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

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

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,383	$ 38,722
Prepaid interest, current portion	1,093	1,710
Prepaid expenses and other current assets	210	362
Total current assets	13,686	40,794
Property and equipment, net	1,022	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	1,501	2,319
Total assets	$ 16,434	$ 44,377
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,237	$ 3,263
Accrued expenses	8,892	7,582
Common stock warrant liability	–	223
Total current liabilities	14,129	11,068
Long-term debt	25,000	25,000
Other liabilities	155	43
Total liabilities	39,284	36,111
Stockholders' equity / (deficit):		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 60,000,000 shares authorized; 8,477,525 and 8,196,011 shares issued at September 30, 2016 and December 31, 2015, respectively; 8,476,033 and 8,194,519 shares outstanding at September 30, 2016 and December 31, 2015, respectively	8	8
Additional paid-in capital	592,262	590,490
Accumulated deficit	(612,066)	(579,178)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' (deficit) / equity	(22,850)	8,266
Total liabilities & stockholders' equity	$ 16,434	$ 44,377

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,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Product sales	$ –	$ –	$ –	$ 7
Grant revenue	961	66	1,142	325
Total revenues	961	66	1,142	332
Expenses:				
Cost of product sales	–	–	–	929
Research and development	7,081	6,452	25,757	20,663
Selling, general and administrative	1,613	2,057	7,053	8,793
Total expenses	8,694	8,509	32,810	30,385
Operating loss	(7,733)	(8,443)	(31,668)	(30,053)
Change in fair value of common stock warrant liability	–	139	223	577
Other income / (expense):				
Loss on debt extinguishment	–	(11,758)	–	(11,758)
Interest income	3	1	15	2
Interest expense	(648)	(1,495)	(1,907)	(3,962)
Other income	15	–	449	133
Other expense, net	(630)	(13,252)	(1,443)	(15,585)
Net loss	$ (8,363)	$ (21,556)	$ (32,888)	$ (45,061)
Net loss per common share – Basic and diluted	$ (1.00)	$ (2.80)	$ (3.98)	$ (6.86)
Weighted-average number of common shares outstanding – basic and diluted	8,355	7,550	8,262	6,601

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,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (32,888)	$ (45,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199	626
Change in provision for excess inventory	–	(174)
Stock-based compensation and 401(k) plan employer match	1,301	1,750
Fair value adjustment of common stock warrants	(223)	(577)
Amortization of discount of long-term debt	–	1,287
Loss on debt extinguishment	–	11,758
Debt discount write-off	–	707
Amortization of prepaid interest	1,435	420
Gain / (loss) on sale or disposal of equipment	(16)	84
Changes in:		
Inventory	–	201
Prepaid expenses and other current assets	152	388
Accounts payable	1,974	2,107
Accrued expenses	1,298	673
Other assets	–	66
Other liabilities	124	(113)
Net cash used in operating activities	(26,644)	(25,858)
Cash flows from investing activities:		
Purchase of property and equipment	(193)	(508)
Proceeds from sale of property and equipment	27	260
Net cash used in investing activities	(166)	(248)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	471	32,629
Proceeds from exercise of common stock warrants	–	136
Principal payments on long-term debt	–	(5,000)
Repayment of equipment loans	–	(62)
Net cash provided by / (used in) financing activities	471	27,703
Net decrease in cash and cash equivalents	(26,339)	1,597
Cash and cash equivalents – beginning of period	38,722	44,711
Cash and cash equivalents – end of period	$ 12,383	$ 46,308
Supplementary disclosure of cash flows information:		
Interest paid	$ 280	$ 1,453

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 KL_4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes both (i) a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and (ii) novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that combines our proprietary synthetic KL_4 surfactant with our novel aerosol delivery system (ADS). We are developing AEROSURF to enable administration of aerosolized KL_4 surfactant to premature infants receiving nCPAP without invasive intubation and mechanical ventilation. We believe that AEROSURF has the potential to transform the treatment of RDS and reduce the number of premature infants who are subjected to invasive administration procedures, whether within minutes of birth or following nCPAP failure (defined as the need for intubation and delayed surfactant therapy). By enabling noninvasive delivery of aerosolized KL_4 surfactant, we believe that AEROSURF will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

Note 2 – Liquidity Risks and Management's Plans

We expect that we will continue to incur significant losses and will require significant additional capital to advance our AEROSURF clinical development program and support our operations. As of September 30, 2016, we had cash and cash equivalents of $12.4 million, current accounts payable and accrued expenses of $14.1 million, including $4.0 million (including $0.3 million of accrued interest) due to Battelle Memorial Institute (Battelle) under our collaboration agreement, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). Before any additional financings or other transactions, we believe that we will have sufficient cash resources to support our development programs, business operations and debt service obligations through February 2017.

As a result of changes that we recently implemented in our AEROSURF phase 2 clinical program, the time required to complete our phase 2b clinical trial in premature infants 29 to 32 week gestational age has been extended, with results currently anticipated in mid-2017. Based on this revised time line, our current cash resources will not be sufficient to fund our development activities through completion of our phase 2b clinical trial and release of top-line results and we will require additional capital to be able to complete our AEROSURF phase 2b clinical trial.

Even if we are able to raise the capital required to complete our AEROSURF phase 2b clinical trial, our ability to fund our activities thereafter will be highly dependent upon whether our clinical trial is successful and we achieve results that are sufficiently positive to support a strategic transaction or equity financing. Our clinical trials are subject to other significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the phase 2b clinical trial within our planned time, if at all. If our clinical trial should be further delayed for any reason, our capital needs will likely increase. Moreover, if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require.

If we are unable to successfully complete enrollment and release top line data in accordance with our plan, or if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt, which could have a material adverse effect on our business and our ability to continue as a going concern.

To secure the additional capital that we will require, we plan to pursue all or a combination of potential strategic alliances, including potentially with respect to markets outside the U.S., collaboration agreements and other strategic transactions (including potential merger, acquisition or other corporate transaction). We also plan to seek additional capital through public or private equity offerings (including pursuant to the ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel)). If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we may be forced to limit our development activities, including potentially by reducing the size of our clinical trial or ending the trial earlier than planned, which could have an adverse impact on the results. Ultimately, without sufficient capital, we may be forced to cease our development activities.

Even if we are able to secure additional capital, such transactions and financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests, and the issuance or even potential issuance of shares could have a negative effect on the market price of our common stock. Moreover, our ability to secure additional capital at a time when we would like or require also may be affected by negative conditions in the broader financial and geopolitical markets or be constrained by the following factors: (i) our use of the 2014 Universal Shelf on Form S-3 is limited to no more than one third of our public float in any 12 month period (discussed below), (ii) in May 2016, we received a deficiency notice from The NASDAQ Stock Market ("Nasdaq") that we are no longer in compliance with the minimum stockholders' equity listing requirement (discussed below), and (iii) our stockholders may not approve, as required under Nasdaq listing rules, a strategic transaction recommended by our Board that is valued at a discount to the then-current market value of our common stock and involves greater than 20% of our outstanding common stock. Other potential risks and uncertainties affecting our ability to fund our business and development activities are described in our 2015 Form 10-K, as updated and supplemented in this Quarterly Report on Form 10-Q.

Our ability to secure needed capital using our 2014 Universal Shelf on Form S-3 is constrained by requirements affecting companies that have an aggregate market value of common stock held by nonaffiliated persons (public float) of less than $75 million. Form S-3 includes a “limited offering” rule that limits the size of primary securities offerings conducted by such smaller companies in any 12-month period to no more than one third of their public float (measured by reference to a closing price of our common stock within 60 days of a transaction). With respect to our ATM Program, on May 24, 2016, we filed a Prospectus Supplement to our 2014 Universal Shelf for approximately $10.5 million in securities, representing one third of our public float within 60 days of the date of the Prospectus Supplement. Accordingly, under the ATM Program, we could raise up to an aggregate of $10.5 million reduced by any other proceeds raised in the previous 12 months under the limited offering rule. For other public offerings that we may conduct under our 2014 Universal Shelf, we will be limited to one third of our public float (measured on a date within 60 days of the transaction) reduced by any amount raised in the previous 12 months under the limited offering rule. For example, based on the closing price per share of our common stock on October 24, 2016 ($3.24), our public float was approximately $27.2 million. As a result, we currently could raise up to an aggregate of $9.1 million under the limited offering rule, reduced by any amounts raised under the limited offering rule in the previous 12 months, including under the ATM Program and any other potential transaction. In addition, to raise additional capital, we may be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, or private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders’ interests.

Further, if we conduct an offering of our common stock at a price per share that represents a discount to the then-current market value of our common stock and that involves the issuance of more than 20% of the shares of common stock then outstanding, we may be required under Nasdaq listing rules to seek stockholder approval before we can proceed. There can be no assurance that we would be successful in obtaining such approvals. Failure to secure the additional capital that we will need, whether from non-dilutive sources or from equity offerings, would have a material adverse impact on our business and our ability to continue as a going concern.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL_4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program. We also have received grants that have supported 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.

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

Unless we are successful in securing the additional capital that we require to support our research and development activities, ongoing operations, and service and repay debt, management believes there is substantial doubt about our ability to continue as a going concern within one year after the filing date of this Form 10-Q. The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As of September 30, 2016, the financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

As of September 30, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was pre-paid upon issuance. Upon exercise of the pre-funded warrants, we would issue the shares to the holders and receive no additional proceeds. In addition, as of September 30, 2016, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation and approximately 40.8 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Nasdaq Deficiency Notice

On May 19, 2016, we received a notification letter from the Staff notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, we reported stockholders' deficit of $5.0 million. The Staff noted that, as of May 19, 2016, we also did not meet either of the alternative compliance standards under Nasdaq Listing Rule 5550(b) of (i) a market value of listed securities of at least $35 million, or (ii) net income of $500,000 from continuing operations. As of September 30, 2016, we had stockholders' deficit of $22.9 million and a market value of listed securities of $21.7 million and as of November 11, 2016, remained out of compliance with the Nasdaq Listing Rules.

The deficiency notice had, and continues to have, no immediate effect on our listing status with the Nasdaq Capital Market. In July 2016, we submitted a plan to regain compliance and the Staff granted us an extension until November 15, 2016 to evidence our compliance with the minimum stockholders' equity rule. The elements of the plan that we submitted included potential debt modifications, strategic alliances and collaboration agreements, and transactions to secure additional capital through public or private equity offerings (including our ATM Program). Under the terms of the extension, we must regain compliance with the minimum stockholders' equity rule no later than November 15, 2016, provide to the Staff a publicly available report that evidences such compliance and otherwise complies with conditions included in the extension notice. If after publicly reporting that we have regained compliance on or before November 15, 2016, should we fail to evidence compliance in the filing with the SEC of our periodic report on Form 10-K for the year ending December 31, 2016, we may be subject to delisting. If we fail to satisfy the terms of the extension on or before November 15, 2016 and we also are not in compliance with an alternative listing requirement (minimum value of listed securities of at least $35 million) under Nasdaq Listing Rule 5550(b), the Staff will provide a written delisting notification that our common stock will be delisted. There can be no assurance that we will be able to regain compliance with either the minimum stockholders' equity rule or the minimum value of listed securities rule within the extension period, or at all. If the Staff issues a delisting notice, we will be entitled to request that the Staff's determination be reviewed by a Nasdaq Hearings Panel. In that event, the Staff's delisting determination would be stayed pending issuance of a written Hearings Panel decision and our common stock would continue to trade on Nasdaq at least until the Hearings Panel has issued its determination. A hearing would generally be scheduled within 45 days of our request for a hearing. Among other things, a Hearings Panel may affirm the Staff's determination and delist our common stock or grant an exception to the listing standards for a limited time (up to 180 days from the Staff delisting determination), as permitted by Nasdaq Listing Rule 5815(c)(1)(A). If we were to request a review of a Staff delisting determination, there can be no assurance that a Hearings Panel would grant us a further exception for an additional period of time. If our common stock were delisted, the liquidity and trading price of our common stock may be adversely affected. Moreover, if our common stock is delisted, broker dealers may become subject to certain regulatory burdens that could discourage them from effecting transactions in our common stock, further limiting the liquidity of our common stock in the market.

Note 3 – Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete condensed consolidated financial statements. All share and per share information in this Quarterly Report related to our common stock has been retroactively restated to reflect the reverse stock split and reduction in authorized shares made effective on January 22, 2016. 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, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. There have been no changes to our critical accounting policies since December 31, 2015. For a discussion of our accounting policies, *see*, Note 4, "Accounting Policies and Recent Accounting Pronouncements," in the Notes to Condensed Consolidated Financial Statements in our 2015 Form 10-K, as amended (2015 Form 10-K). Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Note 4 – Stockholders' Equity

At-the-Market (ATM) Program

We have an ATM Program with Stifel pursuant to which Stifel, as our exclusive agent, may sell through the ATM Program, at such times that we may elect through February 11, 2019, up to a maximum of $25 million of shares of our common stock. For a detailed description of our ATM Program, *see*, Note 10, "Stockholders' Equity – At-the-Market Program," in the 2015 Form 10-K, and our Current Report on Form 8-K dated February 11, 2016. Shares of our common stock sold under the ATM Program are issued pursuant to our 2014 Universal Shelf, which currently is subject to limitations under the Form S-3 registration statement (*see*, Note 2 – "Liquidity Risks and Management's Plans").

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.

As of September 30, 2016, approximately $22.5 million remained available under the ATM Program, subject to certain limitations under our 2014 Universal Shelf, which are described in Note 2, “Liquidity Risk and Management’s Plans.”

Note 5 – Summary of Significant Accounting Policies

Use of Estimates

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

Severance

Effective February 1, 2016, we terminated the Employment Agreement between ourselves and our then President and Chief Executive Officer (Former CEO). During the first quarter of 2016, we incurred a severance charge of $1.2 million in selling, general and administrative expense under the terms of the Former CEO’s employment agreement, including $0.2 million related to stock option expense for certain options that will continue to vest through August 1, 2017. Of the $1.0 million in severance not related to stock-based compensation, $0.5 million was paid during the nine months ended September 30, 2016. The remaining $0.5 million will be paid through the third quarter of 2017.

2016 Restructuring Plan

In May 2016, we implemented a restructuring plan to conserve our resources and focus on execution of the AEROSURF phase 2 clinical program. The total severance cost of $0.4 million for all impacted employees was charged to expense during the second quarter of 2016 ($0.3 million to research and development expenses and $0.1 million to selling, general and administrative expenses). We paid $0.1 million and $0.2 million of the severance during the second and third quarters of 2016, respectively. The remaining $0.1 million will be paid during the fourth quarter of 2016.

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, 2016 and 2015, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 9.4 million and 9.2 million shares, respectively. For the three and nine months ended September 30, 2016 and 2015, 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, 2016 and 2015, 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).

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements – Going Concern*, which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization's management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. While we currently intend to adopt the standard as of December 31, 2016, if this standard had been adopted as of September 30, 2016, management believes that it would have concluded that there is substantial doubt about the Company's ability to continue as a going concern one year from the date of filing this Form 10-Q. *See*, Note 2 for additional information on our liquidity risks and management's plans.

In February 2016, the FASB issued ASU No. 2016-02, amending the accounting for leases in *Leases* (ASU Topic 482). This ASU requires lessees to put most leases on their balance sheets but recognize expenses in the income statement in a manner similar to current accounting standards. The ASU is effective for the annual period ending December 31, 2019 and interim periods thereafter. Early adoption is permitted. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. We are currently evaluating the effect that ASU 2016-02 may have on our condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation- Stock Compensation* (ASU 2016-09). ASU 2016-09 was issued as part of the FASB Simplification Initiative. 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. The standard is effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. We are currently evaluating the effect that ASU 2016-09 may have on our condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*. This update amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the more timely recognition of losses. The standard is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted beginning in 2019, with a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. We are currently evaluating the effect that ASU 2016-13 may have on our condensed consolidated financial statements and related disclosures.

Note 6 – Fair Value of Financial Instruments

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

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

- Level 1 – Quoted prices in active markets for identical assets and liabilities.

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

Fair Value on a Recurring Basis

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

	Fair Value September 30, 2016	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 12,383	$ 12,383	$ –	$ –
Certificate of deposit	225	225	–	–
Total assets	$ 12,608	$ 12,608	$ –	$ –

	Fair Value December 31, 2015	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 38,722	$ 38,722	$ –	$ –
Certificate of deposit	225	225	–	–
Total assets	$ 38,947	$ 38,947	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 223	$ –	$ –	$ 223

The tables below summarize the activity of Level 3 inputs measured on a recurring basis for the nine months ended September 30, 2016 and 2015:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2015	$ 223
Change in fair value of common stock warrant liability	(223)
Balance at September 30, 2016	$ –

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2014	$ 1,258
Exercise of warrants	(184)
Change in fair value of common stock warrant liability	(577)
Balance at September 30, 2015	$ 497

The significant unobservable inputs for a trinomial model used in the fair value measurement of the common stock warrants measured on a recurring basis are the historical volatility of our common stock market price, expected term of the applicable warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. In addition to the significant unobservable inputs noted above, certain fair value measurements also take into account an assumption of the likelihood and timing of the occurrence of an event that would result in an adjustment to the exercise price in accordance with the anti-dilutive pricing provisions in certain of the warrants. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, may result in significantly higher or lower fair value measurements. The change for the nine months ended September 30, 2016 represents the write-off of the derivative liability upon expiration of the underlying warrants in February 2016.

Significant Unobservable Input Assumptions of Level 3 Valuations	September 30, 2016	September 30, 2015
Historical volatility	–	99%
Expected term (in years)	–	0.4
Risk-free interest rate	–	0.05%

Fair Value of Long-Term Debt

At September 30, 2016 and December 31, 2015, the estimated fair value of the Deerfield Loan (*see*, Note 7, "Deerfield Loan") approximated the carrying value of $25.0 million. The estimated fair value of the Deerfield Loan is based on discounting the future contractual cash flows to the present value at the valuation date. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts we could realize in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 7 – Deerfield Loan

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

(in thousands)	September 30, 2016	December 31, 2015
Note payable	$ 25,000	$ 25,000

The principal amount of the loan is payable in two equal annual installments of $12.5 million, payable in each of February 2018 and 2019. Under the Deerfield Loan agreement, the February 2018 installment is subject to a potential one-year deferral until February 2019 if we have achieved a market capitalization of $250 million as set forth in the Deerfield Loan agreement. *See*, Note 9, "Deerfield Loan," in the Notes to Condensed Consolidated Financial Statements in our 2015 Form 10-K.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Amortization of prepaid interest expense	$ 347	$ 420	$ 1,435	$ 420
Cash interest expense	191	150	191	1,451
Non-cash amortization of debt discount	–	138	–	1,287
Debt discount write-off	–	707	–	707
Amortization of debt costs	–	2	–	12
Write-off of debt costs	–	66	–	66
Total interest expense	$ 538	$ 1,483	$ 1,626	$ 3,943

Amortization of prepaid interest expense represents non-cash amortization of $5 million of units that Deerfield agreed to purchase in our July 2015 public offering and accept in satisfaction of $5 million of future interest payments due under the Deerfield Notes at an interest rate of 8.75%.

For 2016, cash interest expense represents interest at an annual rate of 8.75% on the outstanding principal amount for the period, paid in cash on a quarterly basis that exceeds the non-cash amortization of the prepaid interest expense. For 2015, cash interest expense represents interest at an annual rate of 8.75% on the outstanding principal amount for the period, paid in cash on a quarterly basis, up to the date of second amendment to the Deerfield Loan agreement dated July 22, 2015.

Non-cash amortization of debt discount represents the amortization of previously capitalized transaction fees and the amortization of the reduction of the carrying value of the debt due to the fair value of the Deerfield Warrants issued.

Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan in July 2015.

Note 8 – Stock Options and Stock-Based Employee Compensation

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

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at December 31, 2015	517	$ 51.35	
Granted	763	2.09	
Forfeited or expired	(138)	69.15	
Outstanding at September 30, 2016	1,142	$ 16.30	8.2
Vested and exercisable at September 30, 2016	303	$ 49.97	5.2

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,	
	2016	2015
Weighted average expected volatility	78%	83%
Weighted average expected term (years)	5.7	5.6
Weighted average risk-free interest rate	1.4%	1.5%
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,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 140	$ 192	$ 462	$ 551
Selling, general and administrative	133	226	664	801
Total	$ 273	$ 418	$ 1,126	$ 1,352

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, 2015 that we filed with the Securities and Exchange Commission (SEC) on March 29, 2016, as amended (2015 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 studies supported in part from funds from the National Institutes of Health (NIH). Such information is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

This MD&A is provided as a supplement to the accompanying interim unaudited condensed consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited condensed consolidated financial statements (including the notes thereto). Unless otherwise specified, references to Notes in this MD&A shall refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company focused on developing novel KL_4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes both (i) a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and (ii) novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that combines our proprietary synthetic KL_4 surfactant with our novel aerosol delivery system (ADS). We believe that AEROSURF has the potential to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS, a serious respiratory condition caused by a deficiency of natural lung surfactant in lungs of premature infants, is the most prevalent respiratory disease in the neonatal intensive care unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Surfactant therapy is the primary life-saving therapy for addressing the underlying surfactant deficiency associated with RDS. In the U.S., surfactants are animal-derived and usually administered using invasive endotracheal intubation and mechanical ventilation, procedures that may result in serious respiratory conditions and other complications. To avoid the risks of these procedures, many premature infants are treated initially with noninvasive respiratory support such as nasal continuous positive airway pressure (nCPAP). Since nCPAP alone does not address surfactant deficiency, many premature infants on nCPAP respond poorly and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy without exposing premature infants to the risks associated with intubation and mechanical ventilation.

We are developing AEROSURF to enable administration of aerosolized KL_4 surfactant to premature infants receiving nCPAP without invasive intubation and mechanical ventilation. We believe that AEROSURF has the potential to transform the treatment of RDS and reduce the number of premature infants who are subjected to invasive administration procedures, whether within minutes of birth or following nCPAP failure. By enabling noninvasive delivery of aerosolized KL_4 surfactant, we believe that AEROSURF will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

Business and Pipeline Program Updates

The reader is referred to, and encouraged to read in its entirety (i) "Item 1 – Business," in our Annual Report on Form 10-K for the year ended December 31, 2015 that we filed with the SEC on March 29, 2016, as amended, (2015 Form 10-K), which contains a discussion of our Business and Business Strategy and information concerning our proprietary technologies and KL_4 pipeline programs, and (ii) our other filings with the SEC, including without limitation our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016, and Current Reports on Form 8-K.

Effective April 19, 2016, we changed our name from Discovery Laboratories, Inc. to Windtree Therapeutics, Inc. Our common stock now trades under the symbol WINT and our new website is windtreetx.com.

Following are updates related to our development programs:

AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age

- We are conducting an AEROSURF phase 2a multicenter, randomized, open-label, controlled clinical study in premature infants 26 to 28 week gestational age receiving nCPAP for RDS. This trial is designed to evaluate safety and tolerability of aerosolized KL_4 surfactant administered initially in two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to infants receiving nCPAP alone. The trial protocol also provides for two additional doses (60 and 90 minutes), if required. In addition to the primary objective of assessing safety and tolerability, we are also assessing performance of the ADS and available physiological and clinical outcome data for information indicating that aerosolized KL_4 surfactant is being delivered to the lungs and potentially reducing or delaying the time to invasive surfactant therapy due to nCPAP failure. We initially anticipated completing enrollment in this trial in the second quarter of 2016; however, the trial required additional time, due in part to a longer initiation process than expected at a number of clinical sites. In addition, while these younger infants 26 to 28 week gestational age are known to have greater surfactant deficiency, a higher incidence and severity of RDS and other non-respiratory complications of prematurity, we have observed that a greater proportion than anticipated is very quickly intubated, even in the delivery room, resulting in fewer infants being eligible for enrollment.

- Based on our earlier assessment of data from the initial phase 2a clinical trial in premature infants 29 to 34 week gestational age, we expected that we would be able to enroll infants 26 to 28 week gestational age in the ongoing phase 2b trial if (i) the safety and tolerability profile from the first two dose groups of this phase 2a trial was adequate and (ii) we had defined an appropriate dose range for this patient population. We completed the second dose group (45 minutes) in September 2016. The Safety Review Committee, which meets after each dose group in our program is completed, assessed the available data and the appropriateness of proceeding to the next dose escalation. The emerging safety profile for premature infants 26-28 week gestational age included the following preliminary observations:
    - the safety and tolerability profile of the AEROSURF groups was generally comparable to the control group;
    - the adverse events and serious adverse events (SAE) seen were expected for this population and generally comparable between AEROSURF and the control groups; and
    - there was no pattern of increased adverse events or SAE with increasing doses of AEROSURF.

  Based on this assessment of the first two dose groups, the younger infants met the safety criteria necessary to include the younger infants in the phase 2b clinical trial.

- One of the key goals in a safety and tolerability clinical trial is to identify the appropriate tolerable dose range for the patient population and potentially doses that impact relevant outcomes. Through the first two dose groups, we observed an early effect of AEROSURF on prolonging time to nCPAP failure. However, we have not yet observed a durable effect over time that is sufficient to achieve the desired reduction of nCPAP failure rates through 72 hours. The data suggests that younger gestational age infants may potentially require higher doses of surfactant due to a greater surfactant deficiency and more variable inhalation characteristics. Accordingly, to further understand the dose range needed for this patient population, we determined to continue this phase 2a clinical trial by progressing to a third dose group (60 minutes), after which we plan to further assess and determine whether it is appropriate to continue to a fourth dose group (90 minutes). Since this decision will delay completion of this trial, we currently expect to exclude this patient population from the phase 2b clinical trial at this time. We plan to assess these younger infants 26 to 28 week gestational age in a blinded clinical trial after completing the extended phase 2a clinical trial and after obtaining additional data in the phase 2b clinical trial in older 29-32 week gestational age infants.

AEROSURF phase 2b clinical trial in premature infants 26 to 32 week gestational age

- The ongoing AEROSURF phase 2b clinical trial is a multicenter, randomized, controlled study with masked treatment assignment in up to approximately 240 premature infants and is designed to evaluate the safety and tolerability of aerosolized KL_4 surfactant (including with up to two potential repeat doses) administered in two dose groups (25 and 50 minutes) compared to infants receiving nCPAP alone. The key objectives of this trial are:
    - to identify an acceptable endpoint by evaluating the following endpoints to find evidence of efficacy:
        - 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;
    - to identify the dose regimen for the planned phase 3 clinical program; and
    - to provide an estimation of the expected efficacy margin of AEROSURF treatment.

- This trial is being conducting in approximately 50 clinical sites in the U.S., Canada, Europe and Latin America. We had expected to release top-line data in the first quarter of 2017, however, with the continuation of the phase 2a clinical trial in premature infants 26 to 28 week gestational age (discussed above), we no longer plan to enroll the younger infants in this phase 2b clinical trial. Instead, we are planning to implement the following adjustments to our phase 2b clinical plan:
    - we will enroll only premature infants 29 to 32 week gestational age,
    - to maintain a similar current statistical power and provide an opportunity for a stronger data set, we will continue to study a total of up to approximately 240 premature infants,
    - we expect that the trial will take approximately 90 additional days longer to complete, and
    - we now expect to release top-line data in mid-year 2017.

  We believe that these adjustments, including the investment of additional time to complete both ongoing clinical trials, potentially will provide an opportunity for a statistically better phase 2b result to support future regulatory activity and potential business development and financing opportunities.

- Battelle Memorial Institute (“Battelle”) has completed the manufacture of a sufficient number of ADSs to support our expanded development activities for the AEROSURF phase 2 clinical program. We continue to benefit from the opportunity to assess the ADS in different settings in the field, and modify and refine the operating procedures and design elements as needed. The information obtained from these activities is being incorporated into our development of the next generation ADS.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2015. For a discussion of our accounting policies, *see*, Note 4, “Accounting Policies and Recent Accounting Pronouncements,” in the Notes to Condensed Consolidated Financial Statements (Notes) in our 2015 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended September 30, 2016 and 2015 was $8.4 million (or $1.00 basic net loss per share) and $21.6 million (or $2.80 basic net loss per share), respectively. Included in the net loss is interest expense of $0.6 million and $1.5 million for 2016 and 2015, respectively.

The net loss for the nine months ended September 30, 2016 and 2015 was $32.9 million (or $3.98 basic net loss per share) and $45.1 million (or $6.86 basic net loss per share), respectively. Included in the net loss is (i) for 2016, a total severance charge of $1.6 million (*see*, Note 5, "Summary of Significant Accounting Policies"); (ii) interest expense of $1.9 million and $4.0 million for 2016 and 2015, respectively; and (iii) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million and $0.6 million for 2016 and 2015, respectively.

The operating loss for the three months ended September 30, 2016 and 2015 was $7.7 million and $8.4 million, respectively. The decrease in operating loss from 2015 to 2016 was due to a $0.9 million increase in grant revenues offset by a $0.2 million increase in operating expenses.

The operating loss for the nine months ended September 30, 2016 and 2015 was $31.7 million and $30.1 million, respectively. The increase in operating loss from 2015 to 2016 was due to a $2.4 million increase in operating expenses offset by a $0.8 million increase in grant revenues.

Grant Revenue

We recognized grant revenue of $1.0 million and $0.1 million for the three months ended September 30, 2016 and 2015, respectively, and $1.1 million and $0.3 million for the nine months ended September 30, 2016 and 2015, respectively.

Grant revenue for 2016 represents funds received and expended under three NIH grants: (i) an initial award of $1.0 million under a Phase II SBIR from the NHLBI valued at up to $2.6 million over three years to support the AEROSURF phase 2b clinical trial; (ii) the third and final $1.0 million tranche of a previously announced $3.0 million 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); and (iii) a $0.2 million fixed-price contract to support development of our aerosolized KL_4 surfactant to mitigate influenza-related lung injury. As of September 30, 2016, all funding under the second $1.0 million tranche of the Radiation Grant awarded in 2015 had been received and $0.2 million is currently recorded as deferred grant revenue and will be recognized as grant revenue when the funds are expended, which is expected to be during the fourth quarter of 2016.

Grant revenue for 2015 represents funds received and expended under (i) a $2.4 million Fast Track SBIR grant from the NHLBI of the NIH to provide support for the initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS; and (ii) the second $1.0 million tranche under the Radiation Grant.

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 programs.

Research and development expenses by category for the three and nine months ended September 30, 2016 and 2015 are as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Product development and manufacturing	$ 2,081	$ 2,872	$ 8,215	$ 11,071
Medical and regulatory operations	1,715	1,711	5,778	5,137
Direct preclinical and clinical programs	3,285	1,869	11,764	4,455
Total research and development expenses	$ 7,081	$ 6,452	$ 25,757	$ 20,663

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.2 million and $0.3 million for the three months ended September 30, 2016 and 2015, respectively, and of $0.6 million and $0.9 million for the nine months ended September 30, 2016 and 2015, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with CMOs, validation activities, quality assurance and analytical chemistry capabilities that support the manufacture of our KL4 surfactant used in research and development activities, and our medical devices, including our ADS, (ii) design and development activities related to our ADS for use in our AEROSURF clinical program; and (iii) pharmaceutical and manufacturing development activities, including development of our lyophilized 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 for the three months ended September 30, 2016 decreased $0.8 million compared to the same period in 2015 due to the May 2016 restructuring and other cost reduction initiatives initiated in the second quarter of 2016.

Product development and manufacturing expenses for the nine months ended September 30, 2016 decreased $2.9 million compared to the same period in 2015, due to (i) a decrease of $3.3 million in manufacturing and analytical testing costs following the closure of our Totowa Facility in June 2015 and (ii) the May 2016 restructuring and other cost reduction initiatives initiated in the second quarter of 2016, partially offset by increased investments of (i) $0.3 million for development activities under our collaboration agreement with Battelle, and (ii) $0.4 million for the technology transfer of our lyophilized surfactant manufacturing process to a new facility at our CMO.

Medical and Regulatory Operations

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.

Medical and regulatory operations expenses for the nine months ended September 30, 2016 increased $0.6 million, compared to the same period in 2015 due to an increase in preclinical and clinical capabilities to support our AEROSURF development program.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical 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 programs expenses for the three and nine months ended September 30, 2016 increased $1.4 million and $7.3 million, respectively, compared to the same periods in 2015 due to an increase in AEROSURF phase 2 clinical program costs, including the initiation of additional clinical trial sites and the manufacture of additional clinic-ready ADS units.

If we are successful with our ongoing clinical trials, we anticipate that direct clinical program costs for AEROSURF will increase significantly over the next few years as we complete our phase 2 clinical program, assess the results, prepare for and execute the later stages of the planned AEROSURF clinical development program including a potential phase 3 clinical program.

Research and Development Projects – Updates

For our lead clinical program, we are focused on the AEROSURF phase 2 clinical program and are presently enrolling an AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age and an AEROSURF phase 2b clinical trial in premature infants 29 to 32 week gestational age. These projects, including the potential timing, are discussed in this Quarterly Report on Form 10-Q (*see*, "– Overview," and "– Overview – Business and Pipeline Program Updates"), and in our 2015 Form 10-K, "Item 1 – Business – Business Strategy." If successful, we plan in the future to make increased investments in preparation for a potential phase 3 clinical program and in our development capabilities, including for manufacturing development of our lyophilized KL_4 surfactant, further development of our ADS under our Collaboration Agreement with Battelle, and the conduct of the ongoing and planned clinical trials.

Nonclinical Updates

With respect to our AEROSURF development activities, in September 2016, we announced that the FDA has granted Fast Track designation for AEROSURF (lucinactant for inhalation) for the treatment of premature infants with RDS. The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track Designation may qualify for priority review to expedite the FDA review process, if relevant criteria are met.

In addition, in October 2016, we released data from a lung deposition study conducted in non-human primates (NHPs) that demonstrates that the ADS is capable of delivering aerosolized KL_4 surfactant throughout all regions of the lung. The study consisted of a series of experiments in NHPs designed to assess the distribution and deposition of aerosolized KL_4 surfactant in the lung when administered using the ADS. Data from this study were generated from an *in vivo* distribution study using three NHPs, cynomolgus macaques, which received three-to-ten minute exposures of technetium-labeled KL_4 surfactant that was aerosolized using the same model ADS being used in the AEROSURF phase 2b clinical program. After administration, researchers assessed overall pulmonary distribution of aerosolized KL_4 surfactant. Additionally, lung data of the NHPs were analyzed using a quantitative methodology whereby regional distribution was assessed across ten equally sized shells (or layers) of the lung, from the innermost shell through the outermost shell. Results from analysis of the images show that aerosolized KL_4 surfactant, delivered using the ADS via nCPAP, was generally uniformly deposited in all regions of the NHP lungs and that there was generally uniform distribution in all regions of the lung, with an average total lung distribution of 52 percent in the five inner shells and 48 percent in the five outer shells. We believe that this study serves as yet another validation of the potentially transformational capabilities of our ADS device.

From time to time, we have 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 AEROSURF. In August 2016, we announced that we have been awarded a Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million over three years from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF® phase 2b clinical trial in premature infants 26 to 32 week gestational age (GA) receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS). Under the terms of the grant, the Company has initially been awarded $1.0 million and, over the next two years, may be awarded up to an additional $1.6 million through the completion of the phase 2b clinical trial and one-year patient follow-up. The Company had previously been awarded a $2.4 million SBIR from the NHLBI in support of the AEROSURF phase 2a clinical trial in premature infants 29 to 34 week GA which was completed in late 2015.

We also have received grants in support of medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In addition, in July 2016, we announced that we have received the third and final $1.0 million award under a previous Phase II SBIR from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH valued at up to $3.0 million over three years to support continued development of aerosolized KL4 surfactant as a potential medical countermeasure to mitigate radiation-induced lung injury. We previously were awarded $2.0 million under this Phase II grant, and an earlier $0.6 million SBIR Phase I award. In November 2016, we presented data from an initial grant-funded study at the 62nd Radiation Research Society Annual Meeting. In the initial study, KL4 surfactant was administered via an intranasal route into the lungs of C57/BL6 mice 24-hours following exposure to a single fraction of high-dose (13.5 Gy) thoracic-targeted X-ray irradiation (XRT). Mice were evaluated for evidence of reduced blood oxygenation and lung inflammation between two to four weeks post-XRT, and lung fibrosis, chronic pneumonitis, oxidative stress and local and systemic inflammation at 18-weeks post-XRT, by assessing lung function, and analyzing bronchoalveolar fluid (BALF), serum and lung tissue. The data from this study indicate that KL4 surfactant treatment significantly preserved blood oxygenation in irradiated mice two and four weeks post-XRT suggesting reduced acute lung injury, coupled with significantly reduced lung inflammation in irradiated mice three and 18 weeks post-XRT. KL4 surfactant-treated irradiated mice also showed a decrease in lung fibrosis and pneumonitis at 18 weeks post-XRT, and evidence of reduced chronic/late-phase radiation-induced lung injury. In addition, although there can be no assurance, based on our assessment of this data, we also believe that further study is warranted to assess whether KL4 surfactant may be effective in mitigating radiation pneumonopathy associated with cancer radiation therapy. Although there can be no assurance, we expect to pursue additional funding opportunities that may be announced and expect that we may qualify for similar programs in the future. Ultimately, if we are not successful in our development activities, we will not be able to commercialize, or generate any revenues from the sale of, our products and our prospects, financial condition and results of operations will be substantially harmed.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Selling, general and administrative Expenses	$ 1,613	$ 2,057	$ 7,053	$ 8,793

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

Selling, general and administrative expenses for the three months ended September 30, 2016 decreased $0.4 million compared to the same period in 2015 due to cost reduction initiatives initiated in the second quarter of 2016.

Selling, general and administrative expenses for the nine months ended September 30, 2016 decreased $1.7 million compared to the same period in 2015 due to the cessation of sales and marketing activities associated with our decision in April 2015 to cease commercial and manufacturing activities for SURFAXIN®, the liquid dosage form of our KL4 surfactant, and focus our limited resources on the development of AEROSURF. This decrease was partially offset by $1.2 million of severance charges during the first quarter of 2016 (*see*, Note 5, “Summary of Significant Accounting Policies”).

Other Income and (Expense)

(in thousands)	Three Months Ended September 30		Nine Months Ended September 30	
	2016	2015	2016	2015
Loss on debt extinguishment	$ –	$ (11,758)	$ –	$ (11,758)
Interest income	3	1	15	2
Interest expense	(648)	(1,495)	(1,907)	(3,962)
Other income/(expense)	15	–	449	133
Other income/(expense), net	$ (630)	$ (13,252)	$ (1,443)	$ (15,585)

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

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

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Amortization of prepaid interest expense	$ 347	$ 420	$ 1,435	$ 420
Cash interest expense	191	150	191	1,451
Non-cash amortization of debt discount	–	138	–	1,287
Debt discount write-off	–	707	–	707
Amortization of debt costs	–	2	–	12
Write-off of debt costs	–	66	–	66
Total interest expense	$ 538	$ 1,483	$ 1,626	$ 3,943

Amortization of prepaid interest expense represents non-cash amortization of $5 million of Series A and Series B units that Deerfield agreed to purchase in our July 2015 public offering and accept in satisfaction of $5 million of future interest payments due under the Deerfield Notes at an interest rate of 8.75%. Cash interest expense represents interest at an annual rate of 8.75% on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan, and the write-off of debt costs represents the write-off of the remaining costs at the time of the debt restructuring.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We expect that we will continue to incur significant losses and will require significant additional capital to advance our AEROSURF clinical development program and support our operations. As of September 30, 2016, we had cash and cash equivalents of $12.4 million, current accounts payable and accrued expenses of $14.1 million, including $4.0 million (including $0.3 million of accrued interest) due to Battelle Memorial Institute (Battelle) under our collaboration agreement, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). Before any additional financings or other transactions, we believe that we will have sufficient cash resources to support our development programs, business operations and debt service obligations through February 2017.

As a result of changes that we recently implemented in our AEROSURF phase 2 clinical program, the time required to complete our phase 2b clinical trial in premature infants 29 to 32 week gestational age has been extended, with results currently anticipated in mid-2017. Based on this revised time line, our current cash resources will not be sufficient to fund our development activities through completion of our phase 2b clinical trial and release of top-line results and we will require additional capital to be able to complete our AEROSURF phase 2b clinical trial.

Even if we are able to raise the capital required to complete our AEROSURF phase 2b clinical trial, our ability to fund our activities thereafter will be highly dependent upon whether our clinical trial is successful and we achieve results that are sufficiently positive to support a strategic transaction or equity financing. Our clinical trials are subject to other significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the phase 2b clinical trial within our planned time, if at all. If our clinical trial should be further delayed for any reason, our capital needs will likely increase. Moreover, if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require.

If we are unable to successfully complete enrollment and release top line data in accordance with our plan, or if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt, which could have a material adverse effect on our business and our ability to continue as a going concern.

To secure the additional capital that we will require, we plan to pursue all or a combination of potential strategic alliances, including potentially with respect to markets outside the U.S., collaboration agreements and other strategic transactions (including potential merger, acquisition or other corporate transaction). We also plan to seek additional capital through public or private equity offerings (including pursuant to the ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel)). If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we may be forced to limit our development activities, including potentially by reducing the size of our clinical trial or ending the trial earlier than planned, which could have an adverse impact on the results. Ultimately, without sufficient capital, we may be forced to cease our development activities.

Even if we are able to secure additional capital, such transactions and financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests, and the issuance or even potential issuance of shares could have a negative effect on the market price of our common stock. Moreover, our ability to secure additional capital at a time when we would like or require also may be affected by negative conditions in the broader financial and geopolitical markets or be constrained by the following factors: (i) our use of the 2014 Universal Shelf on Form S-3 is limited to no more than one third of our public float in any 12 month period (discussed below), (ii) in May 2016, we received a deficiency notice from The NASDAQ Stock Market ("Nasdaq") that we are no longer in compliance with the minimum stockholders' equity listing requirement (discussed below), and (iii) our stockholders may not approve, as required under Nasdaq listing rules, a strategic transaction recommended by our Board that is valued at a discount to the then-current market value of our common stock and involves greater than 20% of our outstanding common stock. Other potential risks and uncertainties affecting our ability to fund our business and development activities are described in our 2015 Form 10-K, as updated and supplemented in this Quarterly Report on Form 10-Q.

Our ability to secure needed capital using our 2014 Universal Shelf on Form S-3 is constrained by requirements affecting companies that have an aggregate market value of common stock held by nonaffiliated persons (public float) of less than $75 million. Form S-3 includes a "limited offering" rule that limits the size of primary securities offerings conducted by such smaller companies in any 12-month period to no more than one third of their public float (measured by reference to a closing price of our common stock within 60 days of a transaction). With respect to our ATM Program, on May 24, 2016, we filed a Prospectus Supplement to our 2014 Universal Shelf for approximately $10.5 million in securities, representing one third of our public float within 60 days of the date of the Prospectus Supplement. Accordingly, under the ATM Program, we could raise up to an aggregate of $10.5 million reduced by any other proceeds raised in

the previous 12 months under the limited offering rule. For other public offerings that we may conduct under our 2014 Universal Shelf, we will be limited to one third of our public float (measured on a date within 60 days of the transaction) reduced by any amount raised in the previous 12 months under the limited offering rule. For example, based on the closing price per share of our common stock on October 24, 2016 ($3.24), our public float was approximately $27.2 million. As a result, we currently could raise up to an aggregate of $9.1 million under the limited offering rule, reduced by any amounts raised under the limited offering rule in the previous 12 months, including under the ATM Program and any other potential transaction. In addition, to raise additional capital, we may be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, or private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

Further, if we conduct an offering of our common stock at a price per share that represents a discount to the then-current market value of our common stock and that involves the issuance of more than 20% of the shares of common stock then outstanding, we may be required under Nasdaq listing rules to seek stockholder approval before we can proceed. There can be no assurance that we would be successful in obtaining such approvals. Failure to secure the additional capital that we will need, whether from non-dilutive sources or from equity offerings, would have a material adverse impact on our business and our ability to continue as a going concern.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program. We also have received grants that have supported 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.

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

Unless we are successful in securing the additional capital that we require to support our research and development activities, ongoing operations, and service and repay debt, management believes there is substantial doubt about our ability to continue as a going concern within one year after the filing date of this Form 10-Q. The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As of September 30, 2016, the financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

As of September 30, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was pre-paid upon issuance. Upon exercise of the pre-funded warrants, we would issue the shares to the holders and receive no additional proceeds. In addition, as of September 30, 2016, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation and approximately 40.8 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Nasdaq Deficiency Notice

On May 19, 2016, we received a notification letter from the Staff notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, we reported stockholders' deficit of $5.0 million. The Staff noted that, as of May 19, 2016, we also did not meet either of the alternative compliance standards under Nasdaq Listing Rule 5550(b) of (i) a market value of listed securities of at least $35 million, or (ii) net income of $500,000 from continuing operations. As of September 30, 2016, we had stockholders' deficit of $22.9 million and a market value of listed securities of $21.7 million and as of November 11, 2016, remained out of compliance with the Nasdaq Listing Rules.

The deficiency notice had, and continues to have, no immediate effect on our listing status with the Nasdaq Capital Market. In July 2016, we submitted a plan to regain compliance and the Staff granted us an extension until November 15, 2016 to evidence our compliance with the minimum stockholders' equity rule. The elements of the plan that we submitted included potential debt modifications, strategic alliances and collaboration agreements, and transactions to secure additional capital through public or private equity offerings (including our ATM Program). Under the terms of the extension, we must regain compliance with the minimum stockholders' equity rule no later than November 15, 2016, provide to the Staff a publicly available report that evidences such compliance and otherwise complies with conditions included in the extension notice. If after publicly reporting that we have regained compliance on or before November 15, 2016, should we fail to evidence compliance in the filing with the SEC of our periodic report on Form 10-K for the year ending December 31, 2016, we may be subject to delisting. If we fail to satisfy the terms of the extension on or before November 15, 2016 and we also are not in compliance with an alternative listing requirement (minimum value of listed securities of at least $35 million) under Nasdaq Listing Rule 5550(b), the Staff will provide a written delisting notification that our common stock will be delisted. There can be no assurance that we will be able to regain compliance with either the minimum stockholders' equity rule or the minimum value of listed securities rule within the extension period, or at all. If the Staff issues a delisting notice, we will be entitled to request that the Staff's determination be reviewed by a Nasdaq Hearings Panel. In that event, the Staff's delisting determination would be stayed pending issuance of a written Hearings Panel decision and our common stock would continue to trade on Nasdaq at least until the Hearings Panel has issued its determination. A hearing would generally be scheduled within 45 days of our request for a hearing. Among other things, a Hearings Panel may affirm the Staff's determination and delist our common stock or grant an exception to the listing standards for a limited time (up to 180 days from the Staff delisting determination), as permitted by Nasdaq Listing Rule 5815(c)(1)(A). If we were to request a review of a Staff delisting determination, there can be no assurance that a Hearings Panel would grant us a further exception for an additional period of time. If our common stock were delisted, the liquidity and trading price of our common stock may be adversely affected. Moreover, if our common stock is delisted, broker dealers may become subject to certain regulatory burdens that could discourage them from effecting transactions in our common stock, further limiting the liquidity of our common stock in the market.

Cash Flows

As of September 30, 2016, we had cash and cash equivalents of $12.4 million compared to $38.7 million as of December 31, 2015. Cash outflows for the nine months ended September 30, 2016 consisted of $26.6 million used for ongoing operating activities and $0.2 million for investing activities offset by cash inflows for the nine months ended September 30, 2016 of $0.5 million for financing activities.

Operating Activities

Net cash used in operating activities for both the nine months ended September 30, 2016 and 2015 was $26.6 million and $25.9 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for both the nine months ended September 30, 2016 and 2015 represents capital expenditures of $0.2 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016 was $471,000 and represents net proceeds from the use of the ATM Program. Net cash provided by financing activities for the nine months ended September 30, 2015 was $27.7 million and represents $32.6 million of proceeds from the July 2015 registered public offering and $0.1 million of proceeds from the exercise of warrants, partially offset by $5.0 million in principal payment on the Deerfield Loan and $0.1 million in repayment of equipment loans.

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

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings. In May 2014, we filed with the SEC a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of September 30, 2016, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately $139.8 million remained available under the 2014 Universal Shelf. However, until such time as our public float (as defined in the Form S-3) equals or exceeds $75 million, our ability to use the 2014 Universal Shelf is limited to no more than one third of our public float in any 12-month period. *See*, "–Overview." The 2014 Universal Shelf will expire in June 2017.

At-the-Market Program (ATM Program)

We have an ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel as our exclusive agent, at such times that we may determine, may sell a maximum of $25 million of our common stock through February 11, 2019. The ATM Program Agreement (ATM Agreement), which was amended effective February 11, 2016, will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2019 or (3) the termination of the ATM Agreement in accordance with its terms. Either party may terminate the ATM Agreement at any time upon written notification to the other party in accordance with the ATM Agreement, and upon such termination, the offering will terminate. We are not required to sell any shares at any time during the term of the ATM Program. We agreed to pay Stifel a commission equal to 3.0% of the gross proceeds of any sales of shares. See "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – At-the-Market Program (ATM Program) – Stifel ATM Program," in our 2015 Form 10-K, and our Current Report on Form 8-K dated February 11, 2016. Shares of our common stock sold under the ATM Program are issued pursuant to our 2014 Universal Shelf, which currently is subject to limitations under the Form S-3 registration statement (*see*, "– Overview").

During the three and nine months ended September 30, 2016, we completed offerings of our common stock under our ATM Program of 159,051 and 187,022 shares, respectively. This resulted in an aggregate gross proceeds to us 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.

As of September 30, 2016, approximately $22.5 million remained available under the ATM Program, subject to certain current limitations under our 2014 Universal Shelf as described in Note 2 – Liquidity Risk and Management's Plans.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended September 30, 2016 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 2015 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. The risks and uncertainties set forth below and discussed elsewhere in this Quarterly Report on Form 10-Q and described in our 2015 Form 10-K are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. If any of the risks and uncertainties set forth below or in our 2015 Form 10-K actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. 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."

We will require significant additional capital to support our research and development activities and operations and have sufficient cash resources to service and repay debt, but our ability to raise such capital may be adversely impacted by a number of factors may represent significant challenges to accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Moreover, any financings could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

As of September 30, 2016, we had cash and cash equivalents of $12.4 million, current accounts payable and accrued expenses of $14.1 million, including $4.0 million (including $0.3 million of accrued interest) due to Battelle Memorial Institute (Battelle) under our collaboration agreement, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). Before any additional financings or other transactions, we believe that we will have sufficient cash resources to support our development programs, business operations and debt service obligations through February 2017 and will require additional capital to be able to complete our AEROSURF phase 2b clinical trial and release top-line results in mid-2017.

Since April 2015, we have focused our capital and resources primarily on the AEROSURF clinical development program and further development of our lyophilized KL4 surfactant drug product and our aerosol delivery system (ADS). 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, if approved, and from potential strategic alliance and collaboration arrangements, and 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, operations and debt service are likely to far outpace the rate at which we may generate revenues and other cash inflows from all available sources.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development programs, or, if approved, commercialization of our products.

We also could be required to:

- seek collaborators for one or more of our development programs for territories that we had planned to retain or on terms that are less favorable than might otherwise be available; and/or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

We plan to seek the additional capital that we require from potential strategic alliances, collaboration arrangements and other similar transactions, and through potential public and private offerings in the equity markets, which could have a dilutive impact on our stockholders. In such event, the issuance, or even potential issuance, of shares could have a negative effect on the market price of our common stock. However, a number of factors, including our status as a smaller reporting company under the SEC regulations, conditions in the global financial markets, and the timing and outcomes of our clinical activities, may present significant challenges to accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for our at-the-market equity program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel), which can be cancelled at any time, we do not have in place arrangements to obtain additional capital. Any financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

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

We are currently conducting a phase 2a clinical program evaluating the safety and tolerability of aerosolized KL4 surfactant drug product administered using our proprietary aerosol delivery system (ADS) to premature infants 26 to 28 week gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. We are also conducting a phase 2b clinical trial in premature infants 29 to 32 weeks gestational age receiving nCPAP for RDS, which is designed to evaluate the safety and tolerability of aerosolized KL4 surfactant compared to infants receiving nCPAP alone and evaluate certain 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. These clinical trials are two of a series of clinical trials, including a pivotal phase 3 clinical program, that will be needed to gain marketing authorization for AEROSURF, if at all. Such development programs generally take two 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 (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 single clinical program. Conditions imposed by the FDA and foreign regulators on our clinical program could significantly increase the time required to complete and the costs of conducting clinical trials. For example, we may not be successful in achieving a study design that is acceptable to both the FDA and regulators in other countries, which would cause us to limit the scope of our activities or greatly increase our investment. Even if we obtain promising preliminary findings or results in earlier preclinical studies and clinical trials, we may suffer significant setbacks in any stage of our clinical trials. Clinical data is susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. If any of the risks outlined in this risk factor and elsewhere in this Quarterly Report on Form 10-Q or in our 2015 Form 10-K, including with respect to regulatory requirements, clinical site initiation and supply, patient enrollment, drug manufacture, device development and performance, should delay the results, we would likely need, but may be unable to secure, additional capital to complete the trial. Moreover, even if we are able to complete the clinical trial within our

anticipated time, if our results are inconclusive or non-compelling or otherwise insufficient to support a strategic or financing transaction, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business.

The timing and completion of current and planned clinical trials of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both. Patient enrollment is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the severity of the disease under investigation;
- the eligibility and enrollment criteria for the study;
- the willingness of patients' parents or guardians to participate in the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

We have initiated a number of clinical sites outside the U.S. where our experience is more limited. We use the services of third party clinical trial consultants and third party contract research organizations (CROs) to carry out most of our clinical trial related activities and accurately report their results, which may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for substantially all of our clinical trial related activities and reporting. If our CROs do not successfully carry out their activities or meet expected deadlines, our trials may be delayed. We may also need to replace our CROs. Although we believe that there are a number of other third-party CROs we could engage to continue these activities, the replacement of an existing CRO may result in delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our drug candidates. If we fail to adequately manage the design, execution and regulatory aspects of our complex and diverse clinical trials, our studies and any potential regulatory approvals may be delayed, or we may fail to gain approvals for our product candidates.

We have engaged a third-party clinical supply organization (CSO) to assist us in storing, shipping and tracking the drug product, medical devices and other materials that are required for us to conduct our clinical trial in the U.S. and international sites in Canada, EU, and Latin America. If our CSO fails to timely perform its obligations under our agreement or if we are unable to manufacture an adequate supply of drug, medical devices and other materials to stock inventories with our CSO and provide for delivery to our clinical sites, we may experience delays in the initiation and enrollment activities of our clinical sites, which could delay or otherwise impair our ability to execute our clinical trials on a timely basis, if at all.

Moreover, because AEROSURF is a combination drug-device product, the success of our clinical trial is highly dependent upon our ability to successfully develop and manufacture our synthetic lyophilized KL_4 surfactant and our ADS and related components. We continue our work with our CMO to be in a position to manufacture sufficient drug supply for our clinical program when needed. We also continue our development efforts with Battelle, which also manufactured the phase 2 ADS and related components to support our phase 2 clinical program. We are conducting ongoing assessments of our medical device performance and have responded, and plan to respond, to events that may occur during the course of the clinical trial. If our ADS should fail to perform as designed, such failures potentially could adversely affect the execution and results of our clinical program. If we are unsuccessful in our development activities or if for any reason we are unable to manufacture our drug, medical device and related components, our clinical trials could be delayed or otherwise adversely affected.

If patients are enrolled in our clinical trials, they could suffer adverse medical events or side effects that are known to be associated with surfactant administration or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial (ACT) Steering Committee, the Independent Safety Review Committee (ISRC), or the FDA could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. If our ACT Steering Committee, the ISRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, ACT Steering Committee and/or ISRC recommendation, or business reasons.

In addition to our planned clinical program to support AEROSURF, in the future, we also may initiate or support clinical trials evaluating other KL_4 surfactant pipeline products. All of these clinical trials are expected to be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

See also, related risk factors discussed in our 2015 Form 10-K.

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, 2016

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

Date: November 14, 2016

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101.1	The following condensed consolidated financial statements from the Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2016 and September 30, 2015 (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2016 and September 30, 2015, and (v) Notes to Condensed consolidated financial statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2016

/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, 2016

/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, 2016 (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, 2016

/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.