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

FORM 10-Q

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

For the quarterly period ended March 31, 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 May 10, 2016, there were outstanding 8,230,561 shares of the registrant's common stock, par value $0.001 per share.

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

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

- the risk that our 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;

- the risk that 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; our ability to raise such capital may be adversely impacted by any delay or inability to complete our AEROSURF phase 2b clinical trial as planned, or if we obtain results from our clinical trial that are not sufficient to support a strategic transaction or equity financing; limitations arising out of our status as a smaller reporting company on our ability to conduct primary offerings under our 2014 Universal Shelf, for our ATM Program or otherwise; the limited number of authorized shares available for issuance under our Amended and Restated Certificate of Incorporation, or failure to secure stockholder approval, if required, for a transaction involving greater than 20% of our outstanding common stock; any failure to comply with The Nasdaq Capital Market (Nasdaq) listing requirements, including with respect to the minimum bid price requirement, minimum market capitalization or minimum stockholders’ equity; and 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;

- 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;

- the risk that failure to maintain compliance with either of the minimum market value of outstanding shares ($35 million) or the minimum stockholders' equity ($2.5 million) Nasdaq listing requirements may result in receipt of a Nasdaq delisting notice; if upon receipt of a delisting notice, we fail to regain compliance within any allowed grace period or other process provided under the Nasdaq listing requirements, our common stock may be delisted and the value of our common stock may decrease;

- 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 KL4 surfactant, which is the drug component of AEROSURF and potentially could be developed as a separate surfactant drug product, including 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;

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

- risks 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, many 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 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;

- risks that reimbursement and health care reform may adversely affect our ability to secure appropriate funding and reimbursement; or that our products will not be accepted by physicians and others in the medical community; or that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;

- 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.

Trademark Notice
AEROSURF®, **SURFAXIN**®, and **WINDTREE THERAPEUTICS ™** are registered and common law trademarks of Windtree Therapeutics, Inc. (Warrington, PA).

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,400	$ 38,722
Prepaid interest, current portion	1,435	1,710
Prepaid expenses and other current assets	500	362
Total current assets	31,335	40,794
Property and equipment, net	1,100	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	2,050	2,319
Total assets	$ 34,710	$ 44,377
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 5,512	$ 3,263
Accrued expenses	9,135	7,582
Common stock warrant liability	–	223
Total current liabilities	14,647	11,068
Long-term debt	25,000	25,000
Other liabilities	40	43
Total liabilities	39,687	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; 36,000,000 shares authorized; 8,232,053 and 8,196,011 shares issued at March 31, 2016 and December 31, 2015, respectively; 8,230,561 and 8,194,519 shares outstanding at March 31, 2016 and December 31, 2015, respectively	8	8
Additional paid-in capital	591,148	590,490
Accumulated deficit	(593,079)	(579,178)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity/(deficit)	(4,977)	8,266
Total liabilities & stockholders' equity	$ 34,710	$ 44,377

See notes to consolidated financial statements.

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

(in thousands, except per share data)

	Three Months Ended March 31,	
	2016	**2015**
Revenues:		
Product sales	$ –	$ 7
Grant revenue	75	184
	75	191
Expenses:		
Cost of product sales	–	929
Research and development	10,360	7,082
Selling, general and administrative	3,657	3,353
	14,017	11,364
Operating loss	(13,942)	(11,173)
Change in fair value of common stock warrant liability	223	(31)
Other income / (expense):		
Interest and other income	440	233
Interest and other expense	(622)	(1,208)
Other income / (expense), net	(182)	(975)
Net loss	$ (13,901)	$ (12,179)
Net loss per common share –		
Basic and diluted	$ (1.70)	$ (1.96)
Weighted-average number of common shares outstanding – basic and diluted	8,191	6,114

See notes to consolidated financial statements.

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

(in thousands)

	Three Months Ended March 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (13,901)	$ (12,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	76	425
Change in provision for excess inventory	–	(174)
Stock-based compensation and 401(k) plan employer match	658	792
Fair value adjustment of common stock warrants	(223)	31
Amortization of discount of long-term debt	–	555
Amortization of prepaid interest	544	–
Changes in:		
Inventory	–	201
Prepaid expenses and other current assets	(138)	245
Accounts payable	2,249	352
Accrued expenses	1,550	1,108
Deferred revenue	–	(43)
Other liabilities	–	27
Net cash used in operating activities	(9,185)	(8,660)
Cash flows from investing activities:		
Purchase of property and equipment	(137)	(448)
Net cash used in investing activities	(137)	(448)
Cash flows from financing activities:		
Repayment of equipment loans	–	(20)
Net cash (used in) provided by financing activities	–	(20)
Net decrease in cash and cash equivalents	(9,322)	(9,128)
Cash and cash equivalents – beginning of period	38,722	44,711
Cash and cash equivalents – end of period	$ 29,400	$ 35,583
Supplementary disclosure of cash flows information:		
Interest paid	$ 22	$ 649

See notes to consolidated financial statements.

Notes to 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 a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants, a serious respiratory condition that can result in long-term respiratory problems, developmental delay and death. Premature infants born prior to 37 weeks gestational age may not have fully developed natural lung surfactant and therefore may develop RDS and need surfactant therapy to sustain life. Higher incidence and severity of RDS are correlated with younger gestational ages; however, RDS can occur at any premature gestational age. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system such as increased intracranial pressure and risk for brain injury. Mechanical ventilation is associated with ventilator-associated lung injury, chronic lung disease and increased risk of infection. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, since nCPAP does not address the underlying surfactant deficiency associated with RDS, many premature infants respond poorly to nCPAP (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). In addition, many premature infants with RDS who receive surfactant therapy as initial therapy are capable of breathing without mechanical ventilation, but require surfactant therapy for RDS. Because administration of surfactant therapy requires intubation, these infants generally are supported with mechanical ventilation for either a limited or extended period of time. If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to these premature infants without exposing them to the risks associated with intubation and mechanical ventilation.

AEROSURF is an investigational combination drug/device product that combines our proprietary KL_4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. 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, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure. By enabling delivery of our aerosolized KL_4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL_4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our potential aerosolized KL_4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL_4 surfactant product candidates, beginning with AEROSURF.

Effective February 1, 2016, we announced the appointment of Craig Fraser to serve as our President and Chief Executive Officer. Upon recommendation of the Nomination and Governance Committee of our Board of Directors Mr. Fraser was also appointed to serve as a member of the Board, effective immediately. As part of this transition, we initiated a plan to reassess, refocus and rebrand our Company. Effective April 19, 2016, we changed our name to Windtree Therapeutics, Inc. Our common stock now trades under the symbol WINT and our new website is windtreetx.com.

Note 2 – Basis of Presentation

The accompanying interim unaudited 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 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 that was approved by our Board of Directors and stockholders and 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 months ended March 31, 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, 2016. For a discussion of our accounting policies, *see*, Note 3, "Accounting Policies and Recent Accounting Pronouncements," in the Notes to 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 3 – Liquidity Risks and Management's Plans

As of March 31, 2016, we had cash and cash equivalents of approximately $29.4 million, current accounts payable and accrued expenses of $14.6 million, including $4.1 million (of which $0.1 million is interest accrued at a rate of 12% per annum) 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). The principal portion of the Deerfield Loan is payable in two equal installments in February 2018 (subject to potential deferral in certain circumstances) and February 2019. In addition, as of March 31, 2016, we had negative stockholders' equity of $5.0 million. We have incurred substantial losses since inception, due to investments in research and development, manufacturing, the commercialization of SURFAXIN, and we expect to continue to incur substantial losses over the next four to five years. Before any additional financings or other transactions, we anticipate that we will have sufficient cash available to support our development programs, business operations and debt service obligations through the first quarter of 2017.

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. In the future, our ability to continue as a going concern is dependent on our ability to raise additional capital to fund our research and development programs and meet our obligations on a timely basis. To be able to raise additional capital, however, we believe that we will need to successfully complete our ongoing phase 2b clinical trial and release positive top line data in the first quarter of 2017, in accordance with our plan. If we are unable to complete the trial as planned, 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 required capital, which could significantly limit our ability to continue as a going concern. As of March 31, 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 in existence.

To potentially mitigate the risk that we may be unable to continue as a going concern, we plan to pursue all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions (including potentially a merger, acquisition or other corporate transaction). We also may seek additional capital through public or private equity offerings (including our ATM Program), which could have a dilutive impact on our stockholders and 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 in addition to the timing and outcomes of our clinical activities, including whether we will be able to maintain compliance with the Nasdaq listing requirements, limitations on our ability to use our 2014 Universal Shelf and conditions in the broader financial markets, may present significant challenges to accessing the capital markets at a time when we would like or require. Even if we are able to secure additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. If none of the foregoing alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we may be forced to limit or cease our development activities.

We have in the past 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 and 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 continue to pursue such funding opportunities 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 our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, 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.

Our ability to secure capital under our ATM Program or pursuant to public offerings under our 2014 Universal Shelf is constrained by the value of our equity securities held by nonaffiliated persons and entities (public float), which as of May 10, 2016 is approximately $17.5 million. Our 2014 Universal Shelf was filed on Form S-3, which limits the size of primary securities offerings conducted by companies that have a public float of less than $75 million to no more than one-third of their public float in any 12-month period. Accordingly, we are presently able to raise no more than approximately $5.8 million in a primary offering under our 2014 Universal Shelf. To raise capital, we may be required to seek other forms of transactions, 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. In addition, although we have regained compliance with the Minimum Bid Price Requirement of the Nasdaq Listing Rules, we anticipate that we may receive a delisting notice from the Nasdaq Capital Market based on our failure to maintain at least one of the requirements contained in Nasdaq Listing Rule 5550(b), specifically maintaining a minimum market capitalization of at least $35 million or stockholders' equity of at least $2.5 million. Failure to regain compliance with at least one these requirements could lead to delisting of our Common Stock and would likely further depress the value of our stock.

In addition, to be able to raise sufficient capital to support our activities in the near term through strategic alliances or other strategic transactions involving the issuance of our capital stock, or through public or private equity offerings, given our current per share market price, we expect to seek approval from our stockholders to increase the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation. In addition, if any such offering were to involve the issuance of common stock in excess of 20% of our outstanding common stock, 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.

As of March 31, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire purchase 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 March 31, 2016, there were 36 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation and approximately 17.0 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Note 4 – 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, the Employment Agreement between ourselves and John G. Cooper, our then President and Chief Executive Officer (the Former CEO) was terminated. In connection therewith, upon execution by the Former CEO of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to the following severance and other benefits, in addition to any vested benefits under our company plans or policies: (i) a pro rata bonus equal to a percentage of his Annual Bonus Amount (as defined in the Employment Agreement) determined by dividing the aggregate bonuses paid to other contract executives for the year 2016 by the aggregate target bonuses of such other contract executives for 2016, and further prorated for the number of days the Former CEO was employed during 2016, payable at the time that other contract executives are paid bonuses with respect to 2016; (ii) a severance amount equal to the sum of the Former CEO's base salary then in effect and his Annual Bonus Amount, payable in equal installments through August 1, 2017 (the Severance Period); and (iii) all stock options held by the Former CEO will continue to vest during the Severance Period, and continue to be exercisable for up to 36 months after the date of termination. From and after the end of the Severance Period, the Former CEO will forfeit all of his unvested stock options in accordance with the terms of the 2011 Plan. The Former CEO also is subject to non-competition and non-solicitation restrictions for 12 months and 18 months, respectively, after the date of termination under a separate confidentiality agreement. All of our obligations under the Employment Agreement will cease if at any time during the Severance Period the Former CEO engages in a material breach of the Employment Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach.

For the three months ended March 31, 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 those options that will continue to vest through the Severance Period. Of the $1.0 million in severance not related to stock-based compensation, $0.1 million was paid during the first quarter of 2016. The remaining $0.9 million will be paid through August 1, 2017.

Restructuring Plan

In April 2015, we implemented a restructuring plan to voluntarily cease the commercialization of SURFAXIN and focus our resources on the development of our aerosolized KL4 surfactant pipeline for respiratory diseases, beginning with AEROSURF. As part of the restructuring plan, we ceased manufacturing activities at our manufacturing facility in Totowa, New Jersey (Totowa Facility), which we closed upon the expiration of our lease on June 30, 2015.

The total severance cost for all impacted employees is $2.9 million, of which $1.0 million was accrued as of December 31, 2014 for Totowa employees. The remaining $1.9 million was charged to expense through the second quarter of 2015 ($1.0 million to research and development expenses and $0.9 million to selling, general and administrative expenses). We paid $2.6 million and $0.1 million of the severance and retention benefits during 2015 and the first quarter of 2016, respectively. The remaining $0.2 million will be paid during the second 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.

For the quarters ended March 31, 2016 and 2015, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 9.2 million and 1.7 million shares, respectively. As of March 31, 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 (ASC 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 quarters ended March 31, 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 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 March 31, 2016, management of the Company believes that it would have concluded there is substantial doubt about the Company's ability to continue as a going concern one year from the date of filing of this Form 10-Q. See Note 3 for additional information on our liquidity risks and management's plans.

In February 2016, the FASB issued Accounting Standards Update (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 will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update 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 will have on our consolidated financial statements and related disclosures.

Note 5 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
	March 31, 2016	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 29,400	$ 29,400	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 29,625	$ 29,625	$ –	$ –

	Fair Value	Fair value measurement using		
	December 31, 2015	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 three months ended March 31, 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 March 31, 2016	$ –

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2014	$ 1,258
Change in fair value of common stock warrant liability	31
Balance at March 31, 2015	$ 1,289

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.

Significant Unobservable Input Assumptions of Level 3 Valuations	March 31, 2016	March 31, 2015
Historical volatility	–	61 %
Expected term (in years)	–	0.9
Risk-free interest rate	–	0.25 %

Fair Value of Long-Term Debt

At March 31, 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 6 – Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging – Contracts in Entity's Own Equity* (ASC 815), either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

On February 22, 2011, we issued registered warrants (2011 Warrants) that expired on February 22, 2016 and had a fair value at issuance of $8.0 million. These warrants contained anti-dilution provisions that in certain circumstances would adjust the exercise price if we issued any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. Although by their express terms, these warrants were not subject to potential cash settlement, due to the nature of the anti-dilution provisions, they were classified as derivative liabilities and reported, at each balance sheet date until their expiration, at estimated fair value determined using a trinomial pricing model. The exercise price of these warrants was adjusted downward to $2.66 per share at the time of the July 2015 public offering.

No warrants were exercised during the three months ended March 31, 2016 and 2015.

Changes in the estimated fair value of warrants classified as derivative liabilities are reported in the accompanying Consolidated Statement of Operations as the "Change in fair value of common stock warrants." The change for the quarter ended March 31, 2016 represents the write-off of the derivative liability upon expiration of the underlying warrants in February 2016.

Note 7 – Deerfield Loan

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

(in thousands)	**March 31, 2016**	**December 31, 2015**
Note Payable	$ 25,000	$ 25,000

The principal amount of the loan is payable in two $12.5 million annual installments due in each of February 2018 and 2019. Under the Deerfield Loan agreement, the February 2018 installment is subject to potential deferral of one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement. *See*, Note 9, "Deerfield Loan," in the Notes to 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 March 31,**	
	2016	**2015**
Cash interest expense	$ –	$ 647
Amortization of prepaid interest expense	544	–
Non-cash amortization of debt discount	–	554
Amortization of debt costs	–	5
Total interest expense	$ 544	$ 1,206

For the three months ended March 31, 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. For the three months ended March 31, 2016, amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes at an interest rate of 8.75%. For the three months ended March 31, 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. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan.

Note 8 – Stock Options and Stock-Based Employee Compensation

We recognize in our 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.

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

	Three Months Ended March 31,	
	2016	**2015**
Weighted average expected volatility	79%	83%
Weighted average expected term	5.7 years	5.6 years
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 March 31,	
	2016	**2015**
Research & Development	$ 182	$ 213
Selling, General & Administrative	421	386
Total	$ 603	$ 599

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. You should review the "Forward-Looking Statements" section, and the risk factors discussed elsewhere in this Quarterly Report on Form 10-Q, as well as 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is provided as a supplement to the accompanying interim unaudited 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 consolidated financial statements (including the notes thereto). Unless otherwise specified, references to Notes in this MD&A shall refer to the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants, a serious respiratory condition that can result in long-term respiratory problems, developmental delay and death. Premature infants born prior to 37 weeks gestational age may not have fully developed natural lung surfactant and therefore may develop RDS and need surfactant therapy to sustain life. Higher incidence and severity of RDS are correlated with younger gestational ages; however, RDS can occur at any premature gestational age. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system such as increased intracranial pressure and risk for brain injury. Mechanical ventilation is associated with ventilator-associated lung injury, chronic lung disease and increased risk of infection. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, since nCPAP does not address the underlying surfactant deficiency associated with RDS, many premature infants respond poorly to nCPAP (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). In addition, many premature infants with RDS who receive surfactant therapy as initial therapy are capable of breathing without mechanical ventilation, but require surfactant therapy for RDS. Because administration of surfactant therapy requires intubation, these infants generally are supported with mechanical ventilation for either a limited or extended period of time. If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to these premature infants without exposing them to the risks associated with intubation and mechanical ventilation.

AEROSURF is an investigational combination drug/device product that combines our proprietary KL4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We are developing AEROSURF to enable administration of aerosolized KL4 surfactant to premature infants receiving nCPAP without invasive intubation and mechanical ventilation. We believe that, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure. By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our potential aerosolized KL4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL4 surfactant product candidates, beginning with AEROSURF. *See*, "–Business and Pipeline Program Updates."

Business and Pipeline Program Updates

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our Annual Report on Form 10-K for the year ended December 31, 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, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

Effective February 1, 2016, we announced the appointment of Craig Fraser to serve as our President and Chief Executive Officer. Upon recommendation of the Nomination and Governance Committee of our Board of Directors Mr. Fraser was also appointed to serve as a member of the Board, effective immediately. In addition, effective February 1, 2016, the Employment Agreement between ourselves and John G. Cooper, our then President and Chief Executive Officer was terminated. As part of this transition, we initiated a plan to reassess, refocus and rebrand our Company. Effective April 19, 2016, we changed our name to Windtree Therapeutics, Inc. Our common stock now trades under the symbol WINT and our new website is windtreetx.com.

Following are updates to our products and pipeline programs since the filing of our 2015 Form 10-K:

- Enrollment is underway for an AEROSURF phase 2a multicenter, randomized, open-label, controlled clinical study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS that is designed to evaluate safety and tolerability of aerosolized KL_4 surfactant administered in two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to infants receiving nCPAP alone. We anticipate releasing top-line results in the third quarter of 2016. As with the previous phase 2a clinical trials, the primary objective of this phase 2a clinical trial is to evaluate safety and tolerability; we are also assessing performance of the ADS in the NICU and available physiological data for information that indicates 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.
- In late 2015, we initiated our AEROSURF phase 2b clinical trial in premature infants 26 to 32 weeks gestational age receiving nCPAP for RDS. The trial is a multicenter, randomized, controlled study with masked treatment assignment in approximately 240 premature infants and is designed to evaluate the safety and efficacy of aerosolized KL_4 surfactant (including with potential repeat doses) administered in two dose groups (25 and 50 minutes), compared to infants receiving nCPAP alone. We plan to evaluate the following endpoints: 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. We expect to conduct this trial in up to 60 clinical sites in the U.S., Canada, Europe and Latin America. Enrollment is beginning with premature infants 29 to 32 week gestational age, and will include premature infants 26 to 28 weeks gestational age after we complete the ongoing phase 2a clinical trial in this age group. We anticipate releasing top-line results in the first quarter of 2017.
- We are also planning to manufacture a sufficient number of ADSs to support the AEROSURF phase 2b clinical trial. We are working with Battelle Memorial Institute ("Battelle"), which assisted us in the development and manufacture of our phase 2a clinic-ready ADS to manufacture a sufficient number of ADSs to support our continuing development activities and our phase 2b clinical trial.
- On March 31, 2016, we entered into a second amendment ("Amendment") to our Collaboration Agreement with Battelle dated October 10, 2014, as previously amended (the "Collaboration Agreement"). Under the Amendment, we and Battelle agreed to (i) undertake certain additional activities, (ii) optimize the development schedule provided in the Project Plan (as defined in the Collaboration Agreement), among other things, to reallocate resources and re-align the Project Plan schedule with the anticipated completion date for our AEROSURF phase 2b clinical trial, and (iii) change the definition of "Milestone Date," or the anticipated date for completion of Stage 3 activities under the Project Plan, from July 15, 2016 to November 15, 2016, and (iv) increase the Project Plan Fixed Cost (as defined in the Collaboration Agreement) by approximately $230,000, to an amount between $11,181,000 and up to $12,261,100. As of the Amendment date, our fixed fee for Stages 2 and 3 under the Project Plan (50% of the Project Plan Fixed Cost) is adjusted to an amount between $5,590,500 and $6,130,550.

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 3, "Accounting Policies and Recent Accounting Pronouncements," in the Notes to 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 March 31, 2016 and 2015 was $13.9 million (or $1.70 basic net loss per share) and $12.2 million (or $1.96 basic net loss per share), respectively. Included in the net loss is (i) for 2016, $1.2 million for a severance charge related to the termination of our former CEO; (ii) interest expense of $0.5 million and $1.2 million for 2016 and 2015, respectively, associated with the Deerfield Loan; and (iii) for 2016, the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million.

The operating loss for the three months ended March 31, 2016 and 2015 was $13.9 million and $11.2 million, respectively. The increase in operating loss from 2015 to 2016 was due to a $2.7 million increase in operating expenses and a $0.1 million decrease in grant revenues.

Grant Revenue

We recognized grant revenue of $0.1 million and $0.2 million for the three months ended March 31, 2016 and 2015, respectively.

Grant revenue for 2016 represents funds received and expended under a $1.0 million Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) 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. As of March 31, 2016, $0.3 million remained available under this grant and is expected to be received in the second and third quarters of 2016.

Grant revenue for 2015 represents funds received and expended under (i) a $1.9 million Fast Track Small Business Innovation Research (SBIR) grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (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) a $1.0 million Phase II SBIR grant from 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.

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 months ended March 31, 2016 and 2015 are as follows:

(in thousands)	Three Months Ended March 31, 2016	2015
Product development and manufacturing	$ 3,781	$ 4,086
Medical and regulatory operations	2,065	1,774
Direct preclinical and clinical programs	4,514	1,222
Total Research and Development Expenses	$ 10,360	$ 7,082

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.4 million for the three months ended March 31, 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 KL_4 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 a lyophilized dosage form of our KL_4 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 March 31, 2016 decreased $0.3 million compared to the same period in 2015, due to a decrease of $1.6 million in manufacturing costs due to the closure of our Totowa Facility in June 2015, partially offset by increased investments of (i) $0.5 million for development activities under our collaboration agreement with Battelle for the further development of our ADS for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercial activities, and (ii) $0.8 million for a second 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, 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 three months ended March 31, 2016 increased $0.3 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 months ended March 31, 2016 increased $3.3 million compared to the same period in 2015 due to an increase in AEROSURF phase 2 clinical program costs, including ongoing clinical trial site initiations and the manufacture of additional clinic-ready ADS units.

If we receive encouraging clinical results from our ongoing clinical trials, we anticipate that our direct clinical program costs will increase significantly over the next two years as we execute the remainder of the AEROSURF phase 2 clinical development program and prepare for a potential phase 3 clinical program. If successful, we estimate that direct clinical program costs for 2016 for the AEROSURF Phase 2 program will be approximately $15 to $18 million.

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 have initiated our AEROSURF phase 2b clinical trial. Our lead projects, including the potential timing and anticipated milestones, are also discussed in our 2015 Form 10-K, “Item 1 – Business – Business Strategy,” and in this Quarterly Report on Form 10-Q, “Item 2 – Overview,” and “Overview – Business and Pipeline Program Updates.” We plan in the future to make investments in preparation for our potential phase 3 clinical program, and in our development capabilities, including for manufacturing development of our lyophilized KL4 surfactant, further development of our ADS under our collaboration agreement with Battelle, and the conduct of the ongoing and planned clinical trials. In particular, if we are successful, 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 and execute the later stages of the planned AEROSURF clinical development program.

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 the value of our company and our financial condition and results of operations will be substantially harmed.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended March 31,	
	2016	**2015**
Selling, General and Administrative Expenses	$ 3,657	$ 3,353

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 March 31, 2016 increased $0.3 million compared to the same period in 2015 due to $1.2 million of severance charges associated with the termination of our former CEO during the first quarter of 2016, offset by the elimination of sales and marketing expenses associated with our decision in April 2015 to cease manufacturing and commercial activities for SURFAXIN and focus our limited resources on the development of our aerosolized KL4 surfactant, beginning with AEROSURF.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended March 31, 2016	2015
Change in fair value of common stock warrant liability	$ 223	$ (31)

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) Topic 815 *Derivatives and Hedging – Contracts in Entity's Own Equity* (ASC 815), either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued at the date of initial issuance and as of each subsequent balance sheet date using the trinomial pricing model, based on the terms of the applicable warrant agreement. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability." *See*, Note 5, "Common Stock Warrant Liability," and "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Change in Fair Value of Common Stock Warrant Liability" in our 2015 Form 10-K.

Changes in the fair value of common stock warrant liability generally are due to changes in our common stock share price during the periods presented. The change for the quarter ended March 31, 2016 represents the write-off of the derivative liability upon expiration of the underlying warrants in February 2016.

Other Income and (Expense)

(in thousands)	Three months ended March 31, 2016	2015
Interest income	$ 7	$ 1
Interest expense	(622)	(1,208)
Other income/(expense)	433	232
Other income/(expense), net	$ (182)	$ (975)

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

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

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

(in thousands)	Three months ended March 31, 2016	2015
Cash interest expense	$ –	$ 647
Amortization of prepaid interest expense	544	–
Non-cash amortization of debt discount	–	554
Amortization of debt costs	–	5
Total interest expense	$ 544	$ 1,206

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. Amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan.

LIQUIDITY AND CAPITAL RESOURCES

Overview

As of March 31, 2016, we had cash and cash equivalents of approximately $29.4 million, current accounts payable and accrued expenses of $14.6 million, including $4.1 million (of which $0.1 million is interest accrued at a rate of 12% per annum) due to 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). The principal portion of the Deerfield Loan is payable in two equal installments in February 2018 (subject to potential deferral in certain circumstances) and February 2019. In addition, as of March 31, 2016, we had negative stockholders' equity of $5.0 million. We have incurred substantial losses since inception, due to investments in research and development, manufacturing, the commercialization of SURFAXIN, and we expect to continue to incur substantial losses over the next four to five years. Before any additional financings or other transactions, we anticipate that we will have sufficient cash available to support our development programs, business operations and debt service obligations through the first quarter of 2017.

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. In the future, our ability to continue as a going concern is dependent on our ability to raise additional capital to fund our research and development programs and meet our obligations on a timely basis. To be able to raise additional capital, however, we believe that we will need to successfully complete our ongoing phase 2b clinical trial and release positive top line data in the first quarter of 2017, in accordance with our plan. If we are unable to complete the trial as planned, 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 required capital, which could significantly limit our ability to continue as a going concern. As of March 31, 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 in existence.

To potentially mitigate the risk that we may be unable to continue as a going concern, we plan to pursue all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions (including potentially a merger, acquisition or other corporate transaction). We also may seek additional capital through public or private equity offerings (including our ATM Program), which could have a dilutive impact on our stockholders and 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 in addition to the timing and outcomes of our clinical activities, including whether we will be able to maintain compliance with the Nasdaq listing requirements, limitations on our ability to use our 2014 Universal Shelf and conditions in the broader financial markets, may present significant challenges to accessing the capital markets at a time when we would like or require. Even if we are able to secure additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. If none of the foregoing alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we may be forced to limit or cease our development activities.

We have in the past 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 and 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 continue to pursue such funding opportunities 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 our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, 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.

Our ability to secure capital under our ATM Program or pursuant to public offerings under our 2014 Universal Shelf is constrained by the value of our equity securities held by nonaffiliated persons and entities (public float), which as of May 10, 2016 is approximately $17.5 million. Our 2014 Universal Shelf was filed on Form S-3, which limits the size of primary securities offerings conducted by companies that have a public float of less than $75 million to no more than one-third of their public float in any 12-month period. Accordingly, we are presently able to raise no more than approximately $5.8 million in a primary offering under our 2014 Universal Shelf. To raise capital, we may be required to seek other forms of transactions, 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. In addition, although we have regained compliance with the Minimum Bid Price Requirement of the Nasdaq Listing Rules, we anticipate that we may receive a delisting notice from the Nasdaq Capital Market based on our failure to maintain at least one of the requirements contained in Nasdaq Listing Rule 5550(b), specifically maintaining a minimum market capitalization of at least $35 million or stockholders' equity of at least $2.5 million. Failure to regain compliance with at least one these requirements could lead to delisting of our Common Stock and would likely further depress the value of our stock.

In addition, to be able to raise sufficient capital to support our activities in the near term through strategic alliances or other strategic transactions involving the issuance of our capital stock, or through public or private equity offerings, given our current per share market price, we expect to seek approval from our stockholders to increase the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation. In addition, if any such offering were to involve the issuance of common stock in excess of 20% of our outstanding common stock, 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.

As of March 31, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire purchase 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 March 31, 2016, there were 36 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation and approximately 17.0 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Cash Flows

As of March 31, 2016, we had cash and cash equivalents of $29.4 million compared to $38.7 million as of December 31, 2015. Cash outflows for the three months ended March 31, 2016 consisted of $9.2 million used for ongoing operating activities and $0.1 million for investing activities.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2016 and 2015 was $9.2 million and $8.7 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2016 and 2015 represents capital expenditures of $0.1 million and $0.5, respectively.

Financing Activities

Net cash used in financing activity for the three months ended March 31, 2015 was $20,000 and represents repayment of principal amounts due under an equipment loan.

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 March 31, 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. 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 our discretion and at such times that we may determine from time to time, may sell a maximum of $25 million of our common stock over a three-year period ending February 11, 2016. The ATM Program Agreement (ATM Agreement) was amended on February 11, 2016 so that the ATM Agreement 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. As of March 31, 2016, approximately $23 million shares of common stock remained available under the ATM Program. *See*, “– Overview.”

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended March 31, 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 elsewhere in this Quarterly Reports on 10-Q. The risks and uncertainties discussed in our 2015 Form 10-K and Quarterly Reports on Form 10-Q are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. If any of the risks and uncertainties discussed in our 2015 Form 10-K and the Quarterly Reports on Form 10-Q actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in "Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Overview."

ITEM 6. EXHIBITS

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

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: May 11, 2016

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

Date: May 11, 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.	Filed herewith.
101.1	The following consolidated financial statements from the Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2016 and March 31, 2015 (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2016 and March 31, 2015, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 11, 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: May 11, 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 March 31, 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: May 11, 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.