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

FORM 10-K

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

For the fiscal year ended December 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.

(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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	**The Nasdaq Capital Market**
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. YES ☐ NO ☒

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 (§ 232.405 of this chapter) 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 the 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	☐	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 ☒

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2016 (based on the closing price for shares of the registrant's common stock as reported on The Nasdaq Capital Market under the symbol WINT on that date) was approximately $15.9 million. In determining this amount, the registrant has assumed solely for this purpose that all of its directors, executive officers and persons beneficially owning 10% or more of the outstanding shares of common stock of the registrant may be considered to be affiliates. This assumption shall not be deemed conclusive as to affiliate status for this or any other purpose.

As of March 23, 2017, there were 9,439,365 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

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

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations and continue as a going concern. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to our development and potential regulatory plans to secure marketing authorization for AEROSURF®, if approved, and other potential future products that we may develop; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant product candidates, our aerosol delivery system (ADS) based on our proprietary aerosol technology for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs), materials and medical devices; plans regarding potential strategic alliances and collaborative arrangements to develop, manufacture and market our products, and other potential strategic transactions.

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

Risks Related to Capital Resource Requirements

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

- the risk that we currently have sufficient capital resources to fund our research and development programs, support our business operations and pay our debt service obligations on a timely basis to mid-year 2017, and, if for any reason we are unable to raise additional capital before our resources are exhausted, we would likely experience a liquidity shortfall that would severely limit our ability to continue as a going concern;

- the risk, given our limited cash resources, should we experience any further delay in completing the AEROSURF phase 2b clinical trial or should any other complications arise, including , for example, with respect to the pace of patient enrollment, regulatory requirements, drug and device availability, clinical supplies, and device performance, we likely would be compelled to end the phase 2b clinical trial earlier than planned, which may potentially have a negative impact the results of the trial. Under such circumstances, we may find it difficult to raise additional capital needed to continue our development programs and support our operations, which could have a material adverse effect on our business and operations;

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

- the risk that we may be unable to regain compliance with The NASDAQ Stock Market (Nasdaq) listing requirements within the time provided, in particular, (i) the minimum stockholders' equity requirement ($2.5 million) with respect to which, after receiving an initial deficiency notification on May 19, 2016, we recently received a second extension from a Nasdaq Hearings Panel until May 15, 2017, subject to certain requirements, or (ii) the alternative minimum market value of outstanding shares requirement ($35 million); if we fail to regain compliance on or before May 15, 2017, our common stock will be delisted and the value of our common stock may decrease;

- the risk that our ability to raise additional capital is subject to certain other risks, including (i) limitations on the amount that we can raise under our 2014 universal shelf registration statement on Form S-3 (2014 Universal Shelf), including under our "at-the-market" equity sales program (ATM Program); (ii) the risk that our stockholders may not approve a financing transaction priced at a discount and involving issuance of more than 20% of our outstanding common stock, and for which stockholder approval is required under Nasdaq listing rules; (iii) that our 2014 Universal Shelf will expire on June 12, 2017 and we may be unable to file a replacement universal shelf if our common stock is no longer listed on Nasdaq, and, in such event, we would lose access to our ATM Program; (iv) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (v) that unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution of stockholders' interests;

- risks relating to our pledge of substantially all of our assets to secure our obligations under our $25 million secured loan with affiliates of Deerfield Management Company, L.P. (Deerfield), which could make it more difficult for us to secure additional capital 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 relating to our ability to manage our limited resources effectively and timely modify our business strategy as needed to respond to developments in our research and development activities, as well as in our business, our industry and other factors;

Risks related to Development Activities

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

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

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

Risks Related to Strategic and Other Transactions

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

Risks related to Manufacturing

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

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

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

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

Other Risks Affecting our Business

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

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

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

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

- other risks and uncertainties detailed in "Risk Factors" and elsewhere in this Annual Report on Form 10-K, 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.

WINDTREE THERAPEUTICS, INC.

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For the Fiscal Year Ended December 31, 2016

PART I

ITEM 1. BUSINESS.

COMPANY OVERVIEW

Windtree Therapeutics, Inc. (referred to as "we," "us," or the "Company") is a Delaware corporation, with our principal offices located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania. We were incorporated as a Delaware corporation in 1992. Our telephone number is 215-488-9300 and our corporate website address is www.windtreetx.com. Our common stock is listed on The Nasdaq Capital Market® (Nasdaq), where our symbol is WINT.

We are 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 that are designed to deliver aerosolized KL4 surfactant without invasive procedures. 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 utilizing our proprietary technology platform is AEROSURF® (lucinactant for inhalation), which is an investigational combination drug/device product that is being developed for the treatment of respiratory distress syndrome (RDS) in premature infants. AEROSURF has the potential to enable administration of aerosolized KL4 surfactant to premature infants receiving nasal continuous positive airway pressure (nCPAP), without invasive intubation and mechanical ventilation, which are required to administer current FDA-approved surfactants. In September 2016, the FDA granted Fast Track designation for AEROSURF. The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs.

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

Initial Focus – Respiratory Distress Syndrome (RDS) in Premature Infants

AEROSURF is focused on improving the management of RDS in premature infants, the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS is a serious condition in premature infants born prior to 37 weeks gestational age who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. RDS can result in long-term respiratory problems, developmental delays and death. Although a higher incidence and severity of RDS is correlated with younger gestational ages, RDS can occur in any premature infant. Our independent third party market research and other third party data sources (e.g., IMS Health) indicate that 120,000 to 135,000 premature infants are given respiratory support after birth each year in the United States because they have or are at risk for RDS and a significantly greater number globally.

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 must be 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 with complications such as increased intracranial pressure and risk for brain injury. Mechanical ventilation can result in ventilator-associated lung injury, chronic lung disease and increased risk of infection.

To avoid the risks of intubation and mechanical ventilation, many premature infants are initially treated with noninvasive respiratory support, such as nCPAP. Unfortunately, nCPAP alone does not address the underlying surfactant deficiency. Many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to premature infants earlier in their course of treatment and without exposing them to the risks associated with intubation and mechanical ventilation.

In April 2016, we completed a multi-year analysis of data collected in a Noninterventional Observational Study (the Observational Study) on the treatment and outcomes of over 2,000 premature infants 26 to 34 week gestational age with RDS. The results of the study have better informed our assessment of the unmet medical need in RDS, the design of a potential Phase 3 trial, and the RDS market opportunity. Based on this study, we have enhanced some of the operational aspects of the AEROSURF phase 2 program.

We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing (KL_4) surfactant and a less-invasive method of surfactant administration. 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. *See*, "– Surfactant Therapy – The RDS Market."

Beyond RDS

In the future, we believe that we may be able to develop a pipeline of KL_4 surfactant products to address serious critical care respiratory conditions in children and adults. While we remain focused on AEROSURF, we have received support, and plan to seek additional support, from the NIH and other government sources to explore with recognized educational and research institutions the utility of our KL_4 surfactant to address a variety of respiratory conditions.

We believe that our aerosolized KL_4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, although there can be no assurance, we may explore opportunities to apply KL_4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance, however, that we will secure the additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, we will be successful.

BUSINESS STRATEGY AND UPDATES

We continue to focus our drug research and development activities primarily on the management of RDS in premature infants. Our current primary focus is on completing the AEROSURF phase 2b clinical trial in mid-2017, as planned, and obtaining results that are sufficiently positive to warrant further development of AEROSURF and to support a strategic transaction and/or equity financing to fund our continuing operations and our planned AEROSURF clinical development programs.

Although we currently believe that we will be successful in timely completing our ongoing AEROSURF phase 2b clinical trial and that the results will support continuing our planned AEROSURF clinical development program and potential registration of AEROSURF in the U.S. and potentially other selected markets; that we will be able to manufacture a sufficient supply of lyophilized KL_4 surfactant and ADSs and related components to support the remainder of our AEROSURF clinical development program; and that we will be able to secure the additional capital that we require to achieve our business objectives, including potentially through a strategic alliance or other strategic transaction, there can be no assurance that we will be successful. Our activities involve significant risks and uncertainties that could cause the results of our efforts to differ from our expectations. *See*, "Item 1A – Risk Factors."

AEROSURF Phase 2a Clinical Trial

We currently are focused primarily on advancing the AEROSURF clinical development program for the treatment of RDS. We filed an investigational new drug application (IND) with the FDA and initiated a phase 2 clinical development program for AEROSURF for the treatment of RDS in premature infants in November 2013.

In May 2015, we announced the results of an initial AEROSURF phase 2a open label clinical trial conducted in 48 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS. This trial was designed to evaluate safety and tolerability of a single exposure of aerosolized KL_4 surfactant administered to premature infants with RDS in three escalating inhaled doses (15, 30 and 45 minutes), compared to infants receiving nCPAP alone. A key objective of this clinical trial was to establish proof of concept for our proprietary technology platform through assessments of (i) physiological safety data suggesting that aerosolized KL_4 surfactant is being delivered into the lung of premature infants and potentially improving gas exchange, and (ii) the overall performance of the novel ADS in the NICU. Reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS and comparable to the control group. In addition, parameters related to timing and frequency of the need for invasive surfactant therapy suggest that a single dose of AEROSURF may delay the time to invasive surfactant therapy due to nCPAP failure. Based on these encouraging safety and performance results, we initiated a further study to explore whether multiple or increased doses of AEROSURF may potentially reduce the need for invasive surfactant therapy.

In November 2015, after completing an AEROSURF phase 2a clinical expansion trial in 32 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS, we announced top-line data from our overall phase 2a clinical development program in premature infants 29 to 34 week gestational age, including the previously announced data from the initial phase 2a clinical trial. The expansion study was designed to evaluate safety and tolerability of administering aerosolized KL_4 surfactant in higher (60 and 90 minutes) doses compared to infants receiving nCPAP alone. As before, we also assessed physiological data. The overall data suggested that aerosolized KL_4 surfactant delivered to premature infants with RDS generally appeared safe and well tolerated and may be reducing the incidence of nCPAP failure. Reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS and comparable to the control group. Through 72 hours after the start of treatment, AEROSURF treated patients, predominantly receiving a single dose, had lower rates of nCPAP failure compared to control in each of the last three dose groups studied. NCPAP failure rates were 53% in the control group (n=40) compared to 38% (n=8), 14% (n=7, excluding one patient who was inappropriately enrolled) and 38% (n=8) in the 45, 60 and 90 minute AEROSURF dose groups, respectively.

We are enrolling a third dose group in a phase 2a multicenter, randomized, open-label, controlled clinical study in premature infants 26 to 28 week gestational age receiving nCPAP for RDS. This clinical trial is designed to assess safety and tolerability of aerosolized KL_4 surfactant administered to premature infants, initially in two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to infants receiving nCPAP alone. The trial protocol provides for two additional doses (60 and 90 minutes), if required. As with our previous phase 2a clinical trials, we are assessing available physiological safety data for indications 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. Enrollment in this trial has required additional time and we now expect to complete this trial mid-second quarter 2017. Although we expected a higher proportion of this age group (as compared to infants 29 to 34 week gestational age) would be eligible for enrollment, we have observed that more of these infants are intubated very quickly, even in the delivery room, such that fewer infants than expected are eligible for enrollment.

We completed the second dose group (45 minutes) in September 2016. The Safety Review Committee assessed the available data and determined that safety and tolerability objectives have been met and the younger infants are eligible for inclusion in the ongoing phase 2b clinical trial (discussed below).

In addition to assessing safety and tolerability of a drug product candidate, a key goal of any phase 2 clinical trial is to identify the appropriate tolerable dose range for the patient population and potentially the doses that impact relevant outcomes. Through the first two dose groups of this trial, we observed a potential early effect of AEROSURF on prolonging time to nCPAP failure. However, we did not observe a durable effect over time that is sufficient to achieve the desired reduction of nCPAP failure rates through 72 hours. To better understand the dose range for this younger group, instead of enrolling these infants in the phase 2b clinical trial as planned, we decided to initiate the third dose group (60 minutes) in the younger infants. After the third dose group is completed this clinical trial will end. When we have completed the phase 2b clinical trial in the older gestational age infants, we plan to consider whether potential additional dose-response evaluations in the 26-28 week gestational age infants are required.

AEROSURF Phase 2b Clinical Trial

The ongoing AEROSURF phase 2b clinical trial is a multicenter, randomized, controlled study with masked treatment assignment in up to 240 premature infants that was designed to evaluate aerosolized KL_4 surfactant administered to premature infants 26 to 32 week gestational age in two dose groups (25 and 50 minutes), with up to two potential repeat doses, compared to infants receiving nCPAP alone.

The key objectives of this trial are to:

- identify an acceptable endpoint by evaluating the following potential endpoints for evidence of efficacy: (i) time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy), (ii) incidence of nCPAP failure, and (iii) physiological parameters indicating the effectiveness of lung function;
- define the dose regimen for the planned phase 3 clinical program; and
- provide an estimation of the expected efficacy margin of AEROSURF treatment

This trial is being conducted in approximately 50 clinical sites in the U.S., Canada, the European Union (EU) and Latin America. With the continuation of the phase 2a clinical trial in premature infants 26 to 28 week gestational age into a third dose group (discussed above), in the second half of 2016 we implemented the following adjustments to our phase 2b clinical plan: (i) we are including in this trial premature infants 28 week gestational age and enrolling only premature infants 28 to 32 week gestational age, (ii) we do not plan to enroll premature infants 26 to 27 week gestational age, (iii) to maintain the best opportunity to determine differences between treatment groups and potentially provide a stronger data set, we continue to plan for enrollment of up to 240 premature infants, (iii) we expect to release top-line data in mid-year 2017.

Liquidity and Capital Needs

As a development company, we will require significant additional capital and resources to advance our AEROSURF development program, support our operations, manufacture our drug product and medical devices, and, if approved, support the commercial introduction of our approved products in markets around the world. We continue to assess potential strategic and financial opportunities, including public and private equity offerings, that could provide capital resources and strengthen our capabilities. If the results of our AEROSURF phase 2b clinical trial are positive, we expect that we will be better positioned to identify and potentially enter into one or more strategic transactions with medium-to-large companies focused in such areas as neonatology, acute critical care, or hospital and/or pulmonary care.

We are actively pursuing all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction). We are currently focused on identifying licensing opportunities in select geographic markets that could bring strategic partners with local development and commercial expertise to support development of AEROSURF in various markets, and financial resources to support our AEROSURF development program. We also would consider licensing arrangements for our other KL4 surfactant products. Financial resources provided by such arrangements could take the form of capital investments, upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. We are currently actively engaged in discussions with one potential partner that has committed to negotiate in good faith a licensing arrangement for select markets in Asia.

We plan to continue closely managing our cash resources and will need significant additional capital to maintain and strengthen our financial position. However, our ability to adequately fund our activities may be constrained by several factors, including: (i) our 2014 Universal Shelf on Form S-3 will expire June 12, 2017 and our ability to file a replacement shelf registration statement may depend in large part on whether our common stock continues to be listed on Nasdaq, (ii) since the market value of our common stock held by non-affiliated persons (public float) is less than $75 million, the rules governing our universal shelf registration statement on Form S-3 (File No. 333-196420, declared effective on June 13, 2014 (2014 Universal Shelf)) provide for a "limited offering" rule that limits the size of primary securities offerings that we may conduct in any 12-month period to no more than one third of our public float calculated based on a closing price of our common stock within 60 days of a transaction, or approximately $3.9 million based on the closing price of our common stock on March 13, 2017. Transactions under our at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) are subject to this limitation; (iii) the number of authorized shares currently available for issuance under our Amended and Restated Certificate of Incorporation, as amended, likely would be insufficient to fund our activities through equity offerings alone; (iv) if in a non-public financing (as defined under Nasdaq rules), we seek to issue a number of shares of common stock that exceeds 20% of our outstanding shares of common stock at a price less than the current market value per share, we may be required under Nasdaq listing requirements to first seek approval of our stockholders, a time-consuming and expensive process; (v) if we fail to regain and maintain compliance with the Nasdaq listing requirements, including with respect to the minimum stockholders' equity requirement or the minimum value of listed securities, our common stock will be subject to delisting, which could affect the liquidity and value of our common stock; and (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may impair our efforts to conduct equity-based offerings in the future. (*See*, "Item 7 – Management's Discussion and Analysis – Liquidity and Capital Resources," and "— Liquidity and Capital Resources – Financings Pursuant to Common Stock Offerings").

We have a February 2013 secured loan agreement with affiliates of Deerfield Management Company, L.P. (Deerfield), under which we secured long-term debt of $25 million (Deerfield Loan) payable in two equal installments of $12.5 million in February 2018 and February 2019. The principal payment due February 2018 may be deferred one year if on the payable date our total market capitalization equals or exceeds $250 million. The loan agreement includes certain negative covenants that may require us to seek Deerfield's consent before entering into certain strategic transactions, which could impair our ability to enter into certain strategic transactions. *See*, "Item 7 – Management's Discussion and Analysis – Liquidity and Capital Resources – Deerfield Loan."

Effective February 13, 2017, we entered into agreements for a private placement of 7,049 units at a per unit price of $1,495, resulting in net proceeds to us of approximately $10.5 million. The proceeds included $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares); and (ii) 1,000 Series A-1 Warrants (Series A-1Warrants) to purchase one share of common stock at an exercise price equal to $1.37. Each Preferred Share may be converted at the holder's option at any time into 1,000 shares of common stock at $1.37 per share. In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings under our ATM Program, resulting in net proceeds to us of $0.9 million. *See*, "Item 7 – Management's Discussion and Analysis – Liquidity and Capital Resources – Financings Pursuant to Common Stock Offerings."

We plan to continue pursuing potential U.S. Government-funded research and preclinical development initiatives that provide non-dilutive funding to explore the use of our KL_4 surfactant in the treatment of a range of respiratory diseases. In July 2016, we were awarded the third and final $1.0 million funded by the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH under a 2014 $3.0 million phase II SBIR to support continued development of aerosolized KL_4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. The initial two awards under this grant were received during the third quarter of each of 2014 and 2015, respectively.

In August 2016, we announced a three-year phase II SBIR grant valued at up to $2.6 million from the National Heart, Lung and Blood Institute (NHLBI) to support the AEROSURF phase 2b clinical trial. We were awarded the initial $1 million under this grant, with up to an additional $1.6 million potentially available in the following two years. In 2016, we received and expended $0.9 million of this award. *See also*, "– Surfactant Therapy – Serious Respiratory Indications Associated with Inflammation of the Lungs."

Beyond RDS Strategy

We believe that our KL4 surfactant technology may potentially support a product pipeline to address a variety of debilitating respiratory conditions and diseases that could represent potentially significant market opportunities. While we remain focused on RDS, we have participated in investigator-initiated research programs and government-funded research and preclinical development initiatives that explore the use of our KL4 surfactant in the treatment of a range of respiratory diseases. We have participated in partially-funded U.S. Government preclinical studies (discussed above) to assess whether aerosolized KL4 surfactant may mitigate the effects of radiation-induced, chemical-induced and/or viral-induced lung injury. Although there can be no assurance, we may in the future support development activities to establish a proof-of-concept and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or pursue other financial alternatives to fund further development and, if approved, commercialization of additional KL4 surfactant indications.

Our estimates of market size and business opportunities included in this Item 1 – Business and elsewhere in this Annual Report on Form 10-K are based in part on our analysis of data derived from the following sources, among others: third party market research conducted for us by Deerfield Institute, Defined Health and Compass Consulting with U.S. and European Union (EU) based neonatologists in 2014; Annual Summary of Vital Statistics: 2010, *Pediatrics*, Martin et. al.; CDC National Vital Statistics, 2013; IMS Midas Data MAT, December 2013; HCUP Hospital Discharge data, 2013; Obstetric and Neonatal Care Practices for Infants 501 to 1500 g From 2000 to 2009; *Pediatrics*, July 2013, Soll; Hospital Insurance Claim Database, 2009; Management and Outcomes of Very Low Birth Weight, *New England Journal of Medicine* (NEJM), 2008, Eichenwald, Stark; Cost of hospitalization for preterm and low birth weight infants in the United States, *Pediatrics* 2007, Russell RB; Market Intelligence Report on Number of ICU Beds in EU5 Countries; The Cystic Fibrosis Foundation website; Vermont Oxford Network Data, 2006; Population Reference Bureau website; CIA website; March of Dimes website; and estimates from other companies with information on surfactant sales in countries where IMS data reporting is often incomplete or non-existent; independent third-party market research provided by a potential strategic partner; and Windtree Therapeutics, Inc. Primary Market Research, December 2010 and May 2011; as well as our analysis of the SELECT and STAR trials described below. Although we believe that the information contained in these sources is reliable as of the date of this Annual Report on Form 10-K, we have not independently verified such data and do not guarantee the accuracy or completeness of such information. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, and economics and anticipated potential pharmacoeconomic benefits of our products, if approved. We provide estimates and projections to give the reader an understanding of our strategic priorities, but we caution that the reader should not rely on our estimates and projections. These estimates and projections are forward-looking statements, which we intend to be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. For a discussion of forward-looking statements, *see*, "Forward-Looking Statements" on page ii of this Annual Report on Form 10-K, and "Item 1A – Risk Factors."

SURFACTANT THERAPY

The RDS Market

The pulmonary surfactants currently available commercially in the U.S. were introduced in the 1990's; are all animal-derived and have been approved by the FDA for RDS in premature infants.[1] These surfactants must be administered invasively using endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Treatment options for RDS have not improved significantly, nor have mortality and morbidity rates for RDS meaningfully improved since the introduction of pulmonary surfactants.

[1] Our initial development program was for SURFAXIN, which was approved by the FDA in 2012. We ceased commercial and manufacturing activities for SURFAXIN in April 2015 in order to allocate our limited resources to advancing the AEROSURF clinical development program and our other aerosolized KL4 surfactant products.

The current surfactant market for RDS is estimated to be approximately $70 to $90 million annually in the U.S. and approximately $400 million annually worldwide. However, we believe that this market has been constrained, in part, by the risks associated with surfactant administration and lack of medical innovation. We estimate that approximately 350,000 to 400,000 low birth weight premature infants are born annually in the U.S. (and approximately 750,000 to 850,000 in the major U.S., European and Japanese medical markets). In addition, our current market data suggests that the number of low birth weight premature infants born annually in the Latin America, Asia and Pacific markets may represent opportunities similar to or greater than Europe and Japan and we plan to conduct further market research on this topic. In the U.S., we estimate that approximately 120,000 to 135,000 premature infants are given respiratory support each year because they have or are at risk for RDS. Approximately 40% (50,000 to 60,000) of these infants currently are treated with surfactant as the initial therapy for RDS, usually within the first hours of life, generally because the perceived benefits of surfactant therapy for these very fragile infants outweigh the increased risks associated with invasive intubation and mechanical ventilation. The remaining infants are usually treated initially with respiratory support (such as nCPAP) alone. As discussed above, a large percentage of these patients (approximately 25% - 30%) experience nCPAP failure and require delayed surfactant therapy administered via intubation and mechanical ventilation. We estimate that approximately 20,000 to 25,000 infants will receive delayed surfactant therapy (post-nCPAP failure), bringing the total number of premature infants in the U.S. who are treated with surfactants for RDS to approximately 70,000 to 85,000.

Third party market research conducted for us with 278 neonatologists in the U.S. and EU suggests that, if AEROSURF were approved, instead of providing only respiratory support to the 120,000 to 135,000 premature infants in the U.S. who have or are at risk for RDS, 40% to 45% of these infants would be expected to receive respiratory support together with aerosolized KL_4 surfactant as the initial treatment for RDS. This easier, non-invasive, less costly method of administering aerosolized KL_4 surfactant also may potentially support a higher price than currently available surfactants, which must be administered using invasive and costly intubation and mechanical ventilation. We also believe that this easier method of administration may result in the treatment of an increased number of premature infants who are currently not treated for their underlying surfactant deficiency. We believe that the estimated RDS worldwide market represents an annual market opportunity of $800 million to a $1.2 billion.

Potential Pharmacoeconomic Benefits of AEROSURF

In addition to the potential clinical benefits of aerosolized KL_4 surfactant, AEROSURF has the potential to provide significant pharmacoeconomic benefits for hospitals, payers and healthcare systems. In the U.S., for example, the cost to support a mechanically ventilated premature infant (an estimated $55,000 per patient), is much greater than the cost to manage a premature infant who does not need mechanical ventilation (an estimated $15,000 per patient). These costs increase even more if complications associated with intubation and mechanical ventilation should develop, including bronchopulmonary dysplasia. Other healthcare system costs include the need to transport RDS patients who require intubation and mechanical ventilation to tertiary care neonatal intensive care units as well as family relocation costs. Accordingly, by providing clinical and pharmacoeconomic benefits through the reduction or elimination of the need for intubation and mechanical ventilation to treat RDS, we estimate that AEROSURF may, over time, expand the size of the global surfactant market.

Serious Respiratory Indications Associated with Inflammation of the Lungs

Many respiratory diseases are associated with an inflammatory event that causes surfactant dysfunction and a loss of patency of the conducting airways. Scientific data support the premise that the therapeutic use of surfactants in aerosol form has the ability to reestablish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. (Wolfson MR, Malone DJ, Wu J, Gregory T, Mazela J, Shaffer TH. Aerosurf™ delivery during CPAP improves lung mechanics and reduces inflammation in spontaneously breathing preterm lambs. Pediatric Academic Societies, Honolulu, HI, May, 2008. E PAS2008:633763.19.) For this reason, we believe that our aerosolized KL_4 surfactant is a highly promising product candidate and that, with the knowledge that we gain from our ongoing development activities for AEROSURF, we may be able to further develop our technology potentially to address serious respiratory conditions affecting pediatric and adult patient populations. We believe that our proprietary aerosolized KL_4 surfactant technology may be effective as a preventive measure to treat patients at risk for ALI and, possibly in the future, other conditions, such as COPD and CF.

Acute Lung Injury

ALI is associated with conditions that either directly or indirectly injure the air sacs of the lung. ALI is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer. Among the causes of ALI are complications typically associated with certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), smoke inhalation, radiation exposure, chemical injury, pneumonia and sepsis. There are a significant number of patients in the U.S. at risk for ALI annually and there are no currently approved therapies other than supportive respiratory care.

We have collaborated on a number of preclinical studies funded through various U.S. Government-sponsored, biodefense-related initiatives, including without limitation: (i) University of Pennsylvania, funded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) to assess the ability of KL4 surfactant to mitigate effects of acute radiation exposure to the lung (award number R44AI102308); (ii) University of Rochester, to evaluate the use of KL4 surfactant to protect the lung in a radiation-induced multi-organ dysfunction animal model; (iii) a facility's contract with the U.S. Department of Defense through the NIH Office of the Director and the Countermeasures Against Chemical Threats (CounterACT) program, to assess the utility of KL4 surfactant for the treatment of chemical-induced ALI; and (iv) a program funded by NIAID, to investigate the use of KL4 surfactant as a treatment for influenza-induced ALI.

We may in the future invest in or support additional studies of these and other indications. If a proof-of-concept should be established, we then would determine whether to pursue strategic alliances, collaboration arrangements or other alternatives to fund their further development. There can be no assurance that we will invest in or support additional studies in these indications in the future, that we will secure the necessary capital even if we wish to invest, whether through government-sponsored grants or otherwise, that any such development efforts will be successful, or that we will be able to conclude any such strategic alliance, collaboration arrangement or other financial alternatives.

PROPRIETARY PLATFORM – KL4 SURFACTANT AND AEROSOL TECHNOLOGIES

Our KL4 Surfactant Technology

Pulmonary surfactants are protein and phospholipid compositions that form naturally in the human lung and are critical to survival and normal respiratory function. They spread in a thin mono-layer to cover the entire surface of the air sacs, or alveoli, of the lungs and the terminal conducting airways that lead to the alveoli. Surfactants facilitate breathing by continually modifying the surface tension of the fluid that lines the inside of the lungs. If the lungs have a surfactant deficiency, as frequently occurs in premature infants, or experience surfactant degradation, generally due to disease, lung insult or trauma, the alveoli in the lungs will tend to collapse and will not absorb enough oxygen, resulting in severe respiratory diseases and disorders. In addition to lowering alveolar surface tension, surfactants contribute in other important ways to respiration including, for example, by lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Many respiratory disorders are associated with surfactant deficiency or surfactant degradation. However, surfactant therapy is currently approved by the FDA only to manage RDS in premature infants.

Our proprietary KL4 surfactant technology produces a synthetic surfactant that is structurally similar to human pulmonary surfactant and contains a synthetic peptide, KL4 (sinapultide), a 21-amino acid peptide that is designed to imitate the essential attributes of the human surfactant protein B (SP-B), one of four known surfactant proteins and the most important for proper functioning of the respiratory system. Our synthetic surfactant is manufactured to rigorous specifications, with minimal lot-to-lot variability, and is currently approved by the FDA in liquid instillate form. For AEROSURF, we are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that can be stored as a dry substance and reconstituted to liquid form just prior to use and is being developed potentially to improve ease of use for healthcare providers, prolong shelf life and reduce the need for cold-chain storage and handling. We hold an exclusive worldwide license and sublicense to this technology, which was invented at The Scripps Research Institute and exclusively licensed to Johnson & Johnson, Inc. (J&J) and further developed by an affiliate of J&J. We have also been active in seeking patent protection for our innovations relating to improved dosage forms, formulations and methods of manufacturing and delivery of aerosolized pulmonary surfactant.

We previously demonstrated in preclinical studies that our KL4 surfactant may possess certain beneficial properties, including modulation of the inflammatory process, antimicrobial properties and non-immunogenicity. (Wolfson, M.R., Wu, J., Hubert, T.L., Gregory, T.J., Mazela, J., & Shaffer, T.H. (2012), "Lucinactant attenuates pulmonary inflammatory response, preserves lung structure, and improves physiologic outcomes in a preterm lamb model of RDS." *Pediatr Res*, 72(4), 375-383; Black C, Leon C, Pluim J. Bactericidal properties of the novel, peptide-containing surfactant - Surfaxin®. Pediatric Academic Societies, Honolulu, HI, May, 2008. E-PAS2008:633756.11; and Clayton RG, Cochrane CG, Gregory TJ. Surfaxin® (lucinactant) does not induce an immune response in a standardized preclinical model. Pediatric Academic Societies, Honolulu, HI, May, 2008. E-PAS2008:633756.12.) We believe these properties may be important attributes as we seek to develop our KL4 surfactant technology potentially to address a broad range of respiratory conditions that represent significant unmet medical needs. However, the clinical relevance of such attributes has not been adequately established and, accordingly, warrants further study.

KL4 Surfactant Dosage Forms

Surfactants currently marketed in the U.S. are liquid instillate and must be stored in refrigerated conditions, warmed prior to use, and administered using endotracheal intubation and mechanical ventilation. Our KL4 surfactant can be lyophilized (freeze-dried), held in cold chain storage, and reconstituted to a liquid just prior to administration. We currently maintain continuous cold chain storage. We plan to conduct studies to assess potential reduction of cold chain storage and refrigeration requirements in the hospital. We have demonstrated in laboratory experiments that our lyophilized KL4 surfactant retains many of the key attributes and characteristics of our liquid instillate. We believe that it may provide additional benefits in a clinical setting, including potentially:

- improved ease of use for healthcare practitioners, including potential elimination of the drug warming process allowing for shortened preparation time; and potential reduction of continuous cold chain storage and refrigeration requirements;
- potential for extended shelf life; and
- relatively lower viscosity than that of a liquid instillate, which may aid and/or improve the distribution of KL4 surfactant throughout the lung and potentially may reduce the frequency of transient peri-dosing events typically observed during administration of surfactants.

We have demonstrated that we can aerosolize both the liquid and lyophilized dosage forms of our KL4 surfactant and that our aerosolized KL4 surfactant product candidate has the following important characteristics:

- full retention of the surface-tension lowering properties of a functioning surfactant necessary to restore lung function and maintain patency of the conducting airways;
- full retention of the surfactant composition upon aerosolization; and
- drug particle size believed to be suitable for deposition into the lung.

We are using lyophilized KL4 surfactant in our AEROSURF development program to treat RDS in premature infants.

The Safety and Efficacy Profile of SURFAXIN for the Prevention of RDS in Premature Infants at High Risk for RDS

The drug product component of our AEROSURF combination product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant drug product that was approved as a liquid instillate 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. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA for use in neonatal medicine in the U.S. In the second quarter of 2015, we ceased our commercial and manufacturing activities for SURFAXIN in order to focus our limited resources on advancing the AEROSURF clinical development program and our other potential aerosolized KL4 surfactant product candidates.

Our new drug application (NDA) for SURFAXIN was supported by a phase 3 pivotal trial (SELECT) to evaluate the safety and efficacy of SURFAXIN for the prevention of RDS in premature infants. Co-primary endpoints were the incidence of RDS at 24 hours and RDS-related mortality at 14 days. The primary comparator was Exosurf® (colfosceril palmitate) with the intent of demonstrating superiority. SURFAXIN demonstrated a statistically significant improvement in both RDS at 24 hours and RDS-related mortality through day 14. Survanta® (beractant) served as an additional active comparator. SURFAXIN demonstrated a statistically significant reduction in RDS-related mortality through day 14 versus Survanta. We also conducted a multicenter, double-blind, active-controlled, phase 3 clinical trial (STAR) which was designed as a non-inferiority trial comparing SURFAXIN to Curosurf® (poractant alfa), a surfactant derived from pig lung, and was used to support the safety of SURFAXIN.

The SELECT and STAR trials, as well as a pooled phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*, the Official Journal of the American Academy of Pediatrics and a premier medical journal for pediatric healthcare practitioners. Post-hoc analysis of data from our SELECT and STAR phase 3 clinical trials indicates that premature infants with RDS who were extubated after treatment with surfactant and who later required reintubation had a significantly higher rate of mortality than those infants who did not require reintubation. The data also indicate that premature infants treated with SURFAXIN may require less reintubation than currently approved animal-derived surfactants. Moreover, pharmacoeconomic analysis suggests that lower reintubation rates may result in significant hospital cost savings associated with reduction in time spent on mechanical ventilation and reduced rates of bronchopulmonary dysplasia (BPD), air leak, sepsis, necrotizing enterocolitis (NEC), or intraventricular hemorrhage (IVH).

Our Aerosolization Delivery Technologies

Aerosol Delivery System (ADS)

We own worldwide exclusive rights to the medical device component of our AEROSURF product candidate for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions. In the U.S., we also hold exclusive rights to this technology for use with non-surfactant drugs to treat certain other pediatric and adult respiratory indications in hospitals and other health care institutions. We are currently developing a new version of the ADS (NextGen) potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. Our ADS is protected by a portfolio of patents that extends to at least 2033 covering the core components of the system.

Our technology supports an ADS that is designed to aerosolize KL_4 surfactant. The ADS has been demonstrated to produce consistent and controlled output rates, particle size, and other aerosol characteristics throughout extended KL_4 surfactant dosing periods. An aerosol is created by pumping KL_4 surfactant through a heated capillary, after which the aerosol cools and slows in velocity, yielding a dense aerosol with a defined particle size suitable for respiration. In our AEROSURF phase 2a clinical trials, we assessed physiological data suggesting that AEROSURF may be delivering surfactant into the lung (where it needs to act) and reducing the incidence of nCPAP failure. We believe that our ADS is capable of delivering our KL_4 surfactant to the lungs of premature infants with RDS without having to resort to invasive intubation and mechanical ventilation, procedures that are currently required to administer surfactants. We believe the ADS represents a robust platform to support reliable and reproducible clinical development, potential commercialization of our AEROSURF combination drug/device product, if approved, and, in the future, further life-cycle product development.

In October 2014, we entered into a Collaboration Agreement with Battelle to provide for the development of the NextGen ADS. *See*, "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

In October 2016, we released data from a lung deposition study conducted in non-human primates (NHPs) that demonstrate that the ADS is capable of delivering aerosolized KL_4 surfactant throughout all regions of the lung. The study consisted of a series of experiments conducted in three NHPs (cynomolgus macaques) which were exposed to aerosolized KL_4 surfactant using the same model ADS as is currently being used in the phase 2b clinical trial. After administration of KL_4 surfactant, researchers immediately acquired 2-D and 3-D images, 2-D planar images followed by 3-D SPECT images and then a second 2-D planar image to assess overall pulmonary distribution. In addition, the 3-D SPECT lung data were analyzed using a quantitative methodology whereby regional distribution was assessed across ten equally sized shells (or layers) of the lung, from the innermost shell through the outermost shell. Results from analysis of the images show that aerosolized KL_4 surfactant delivered using the ADS via nCPAP was generally uniformly deposited in all regions of the NHPs lungs. A quantitative analysis further demonstrated that KL_4 surfactant was also generally uniformly distributed in all regions of the lung. We believe that the results of this study serve as validation of the capabilities of our ADS technology and support the potential for further development of the ADS to treat a range of respiratory conditions.

Aerosol-Conducting Airway Connector

We also developed a novel disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL_4 surfactant) and other inhaled therapies to critical-care infants requiring ventilatory support. This device which is registered under the trade name AFECTAIR®, introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit and is being used in the AEROSURF phase 2 clinical development program. *In vitro* studies have demonstrated that this connector increases the delivery of inhaled therapies to infants requiring ventilatory support. We therefore believe that using a device such as AFECTAIR in the nCPAP circuit would facilitate the delivery of our KL_4 surfactant to premature infants with RDS.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are directed to developing our proprietary KL_4 surfactant, ADS, and aerosol delivery technologies into a series of KL_4 surfactant pipeline programs that potentially could support a significant respiratory critical care franchise. We are initially focused on the management of RDS in premature infants. We continually reassess our research and development investments and priorities in light of a number of factors, including without limitation the results of our clinical trials and preclinical research and related activities; advances in technology, progress in our device development programs, and relationship of a project to our near-term objectives; our cash flow requirements, financial liquidity and ability to secure necessary capital; and the potential for development of partnerships, collaboration agreements and other strategic transactions. As part of our assessments, we expect to modify and adapt our research and development plans from time to time and anticipate that we will continue to do so in the future.

Our research and development resources currently are focused primarily on our AEROSURF development program to address RDS. We are currently enrolling a phase 2a clinical trial in premature infants 26 to 28 week gestational age and a phase 2b clinical trial in premature infants 28 to 32 week gestational age. We are also working with our CMO to conduct further manufacturing development work and to assure a sufficient supply of lyophilized KL_4 surfactant for use in our post-phase 2b activities. We also are working with Battelle under the Collaboration Agreement to develop a new version of ADS (NextGen) for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. The design verification and validation of this device is expected in the second half of 2017.

Outside the U.S., we plan to seek regulatory advice and discuss with international regulatory authorities a potential AEROSURF development plan to advance AEROSURF in selected major markets around the world. We also would invest in research and development activities to support a significant strategic alliance for the development and, if approved, commercial introduction of AEROSURF in various markets.

To support our research and development activities, we have:

- physicians and scientists on staff and available under consulting arrangements who have expertise in pediatric and pulmonary medicine and extensive contacts in the neonatal medical community;
- expertise in the design and execution of preclinical experiments and studies to support drug development. We conduct certain development-related experiments and bench studies in-house and also engage professional research laboratories and collaborate with academic scientific centers to conduct animal studies and experiments requiring specialized equipment and expertise;
- expertise in the design, development and management of clinical trials. We have our own scientific, medical, biostatistics, and trial and data management capabilities. For the initial phase of the AEROSURF program, we managed our clinical trial data, supported by third-party technology systems and independent consultants, and monitored all clinical activities using our clinical operations capabilities. We also have retained contract research organizations (CROs) to support our ongoing multi-center AEROSURF trials, including in the U.S., EU, Latin America and Canada. We rely on scientific advisory committees and other medical and consulting experts to assist in the design and monitoring of clinical trials;
- regulatory personnel with expertise in FDA regulatory matters. We also consult extensively with independent FDA and international regulatory experts, including former senior scientific staff of the FDA;
- engineering expertise to support development of our ADS and aerosol delivery technologies. We have our own team of engineering professionals who are focused on further optimizing our ADS and overseeing the collaboration with Battelle, which has significant expertise in developing and integrating aerosol device technologies;
- quality operations expertise to assure compliance of our drug and device development activities with applicable U.S. and international regulations;
- CMOs to produce our lyophilized KL_4 surfactant, APIs and other materials for our drug product. We plan to rely on third-party manufacturers to manufacture and assemble our ADS and related components; and
- our own analytical testing laboratory and research and medical device development laboratory. We also rely on a number of third-party analytical and testing laboratories to support our research activities and provide certain laboratory services in support of our manufacturing activities.

Research and development costs are charged to operations as incurred. During the years ended December 31, 2016, and December 31, 2015, we invested approximately $31.7 million and $28.9 million, respectively, for research and development expense, which includes (i) product development and manufacturing, (ii) medical and regulatory operations, and (iii) direct preclinical and clinical development programs.

Manufacturing and Distribution

We use third parties for the manufacture of our lyophilized KL4 surfactant, ADS and related components, AFECTAIR aerosol-conducting airway connector and related components. To support our manufacturing operations, we maintain our own analytical and technical support laboratory at our headquarters in Warrington, Pennsylvania (Warrington Laboratory). In addition to the Warrington Laboratory, we engage third party analytical and testing laboratories to support certain manufacturing activities. We work with third party service providers for clinical supply labeling, packaging, warehousing and distribution.

KL4 Surfactant

Our KL4 surfactant product must be made in a manner consistent with current good manufacturing practices (cGMP) established by the FDA and other international regulatory authorities, as applicable. KL4 surfactant is comprised of four active pharmaceutical ingredients (APIs) that must be aseptically manufactured as a sterile liquid suspension, subjected to release testing using a number of complex analytical methodologies and then subjected to ongoing monitoring of drug product stability and conformance to specifications. We currently rely on single source suppliers for our drug product and API manufacturing. Our API suppliers are Bachem California, Inc., Corden Pharma, and Avanti Polar Lipids, Inc. We have separate product supply agreements for KL4 and POPG, two of our four APIs, and source the other two APIs under purchase orders that we issue from time to time. To mitigate our risk, we plan to qualify secondary suppliers for our APIs over the next several years. Our risk of losing a source for our APIs other than KL4 is somewhat mitigated by our decision to maintain a large safety stock. We have developed a proprietary manufacturing process with our CMO for KL4 and plan to provide for additional inventories when needed to assure that we maintain adequate supplies of KL4.

We manufacture our lyophilized KL4 surfactant at our CMO, Patheon Manufacturing Services LLC (Patheon), under a development agreement providing for development and manufacture of our drug product through completion of process validation and qualification, and which is expected to involve manufacture of sufficient drug product to complete the planned phase 3 clinical trial. We have manufactured a sufficient clinical supply of KL4 surfactant to support our planned phase 2 clinical development program and other development activities. Due to changes at Patheon, we are conducting a second technology transfer of our lyophilized KL4 surfactant manufacturing process to another facility at Patheon, where we expect to manufacture our lyophilized KL4 surfactant for use in our ongoing AEROSURF development program. Under our arrangement with Patheon, we provide the APIs and Patheon purchases excipients and other materials required to manufacture our lyophilized KL4 surfactant. If AEROSURF is approved, we plan to enter into a commercial supply agreement with Patheon for the manufacture of lyophilized KL4 surfactant.

In our Warrington Laboratory, we conduct certain analytical development and quality control activities, including release testing of all APIs and release and stability testing of our lyophilized KL4 surfactant clinical drug product. Our Warrington Laboratory also provides analytical testing and quality system support for our lyophilized and aerosolized KL4 surfactant dosage forms and performs limited research to identify and protect our intellectual property, including studying other potential KL4 surfactant product candidates. We also work with a number of third-party institutions and laboratories that perform various studies as well as quality control release and stability testing and other activities related to our KL4 surfactant development and manufacturing activities. At the present time, several of these laboratories are single-source providers.

Aerosol Delivery Devices

The ADS currently in development under our Collaboration Agreement with Battelle (NextGen ADS) is comprised of a durable reusable device that contains the heater, software and other componentry, and disposable parts that include the critical drug product-contact components that are either patient or dose specific and must be manufactured or cleaned in an environmentally controlled, clean area. Each ADS is tested for conformance to designated product specifications during assembly, must conform to designated product specifications and meet quality control standards prior to release.

We began working with Battelle in 2012 on a development program focused on design, development and testing of a clinic-ready ADS for use in our AEROSURF phase 2 clinical trials. Battelle manufactured ADSs for the AEROSURF phase 2 clinical trials and is working with us to assess the ADS in different clinical settings in the field and modifying and refining our operating procedures and device design requirements as needed.

In October 2014, we entered into a Collaboration Agreement with Battelle to develop our NextGen ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. The collaboration provides us the continued benefit of Battelle's expertise in developing and integrating aerosol devices using innovative and advanced technologies. We are on track to complete the development objectives in line with the time line for our AEROSURF clinical development program. We have agreed with Battelle to negotiate in good faith for the manufacture of the NextGen ADS. We are also assessing other potential CMOs to assure continued availability of NextGen ADS for our future development activities, including potentially our planned phase 3 clinical trial, and, if approved, initial commercial activities. *See*, "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

We hold sufficient quantities of our AFECTAIR aerosol-conducting airway connector to support our AEROSURF phase 2b clinical trial. Our supplier for AFECTAIR is Lacey Manufacturing Company, a division of Precision Products, LLC.

Distribution

We are currently receive labeling, packaging and distribution services to support our AEROSURF clinical activities in the U.S., Canada, European Union (EU) and Latin America from Almac Group Limited under a master services agreement dated October 15, 2013, and related technical agreements.

Our collaboration with Laboratorios del Dr. Esteve, S.A. (Esteve) provides that Esteve has responsibility for distribution of specified KL_4 surfactant products in Andorra, Greece, Italy, Portugal and Spain. *See*, "– Strategic Alliances and Collaboration Arrangements – Laboratorios del Dr. Esteve, S.A." In other parts of the world, we expect to contract for third-party distribution services prior to commercializing in those regions.

Strategic Alliances and Collaboration Arrangements

Battelle Collaboration Agreement

We entered into a Collaboration Agreement with Battelle in October 2014 for the development of a new version (NextGen) of our ADS. Under the Collaboration Agreement, we and Battelle have agreed to share development costs for a three-stage development plan.

The Collaboration Agreement development plan includes the following activities: (i) define the requirements of the NextGen ADS and develop a detailed project plan (Stage 1), (ii) execute the development plan (Stage 2), and (iii) complete all required testing, verification and documentation (Stage 3); to be in a position to manufacture NextGen ADSs potentially to support the AEROSURF development activities that follow the phase 2b clinical trial and, if approved, the initial commercial activities. We agreed to negotiate in good faith potentially to enter into a manufacturing agreement for the production of NextGen ADS, and, if AEROSURF is approved, to negotiate in good faith potentially to enter into a supply agreement providing for an initial commercial supply of ADSs.

We established a Steering Committee, comprised of an equal number of members appointed by each party, to oversee the project. Nevertheless, we have retained final decision-making authority on all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of ADS. We and Battelle shared equally in the costs of the design input stage, Stage 1, and thereafter agreed on a detailed project plan, including projected costs. We agreed to share equally in the costs of the agreed project plan for the development and final testing and documentations stages of the program (Stages 2 and 3). Under the agreement, Battelle will bear the entire cost of any cost overruns associated with execution of the project plan and we will bear the entire cost of any increase in the agreed upon project plan costs resulting from changes in the scope of the product requirements as initially agreed.

We amended the Collaboration Agreement in August 2015, and March 2016, among other things, to adjust the anticipated costs of the project plan and, to better align the completion of the project plan with the anticipated completion of the phase 2b clinical trial, change the target date for completion of the final stage (Milestone Date). (If the Milestone Date is met, a second warrant issued at the time of execution (discussed below) becomes exercisable.) As a result of the latest amendment, the Milestone Date is November 15, 2016 and has not been further amended. After adding certain additional activities, the anticipated project plan costs have been increased to an amount between $11.2 million and up to $12.3 million. Our agreed share for Stages 2 and 3 is currently an amount between $5.6 million and $6.1 million. As of December 31, 2016, if the 3-stage development project is successfully completed, we expect our costs for the three stages of development activities under the project plan will total approximately $7.0 million, subject to certain rights of termination outlined in the Collaboration Agreement.

In connection with the Collaboration Agreement, we issued to Battelle two warrants to purchase shares of our common stock, each having an exercise price of $70 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 71,429 shares of our common stock, exercisable upon successful completion by Battelle of the Stage 3 activities (Initial Warrant), and (ii) a warrant to purchase up to 35,714 shares of our common stock (Additional Warrant, and together with the Initial Warrant, the Battelle Warrants), exercisable if and only if Battelle successfully completes the Stage 3 activities no later than the Milestone Date (November 15, 2016), which date may be adjusted as provided in the Collaboration Agreement. We and Battelle also agreed to enter into a registration rights agreement providing for the registration of the resale of shares underlying the Battelle Warrants, which has not been executed. The Battelle Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Battelle Warrants may be exercised on a cashless basis.

In addition, if Battelle successfully completes the Stage 3 activities, we agreed to pay Battelle royalties equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of $25 million. The term of the Collaboration Agreement will end at the time we fulfill our payment obligations to Battelle, unless sooner terminated by a party as provided in the Collaboration Agreement, including for a "failure of purpose" (as defined therein) or a material breach by either party.

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of a broad portfolio of potential KL_4 surfactant products in Andorra, Greece, Italy, Portugal, and Spain (collectively, the territory). Antonio Esteve, Ph.D., a principal of Esteve, served as a member of our Board of Directors from May 2002 until January 2013. Under the alliance, Esteve will pay us a transfer price on sales of our KL_4 surfactant products. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the territory. Esteve is obligated to make stipulated cash payments to us upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to phase 3 clinical trials for the covered products by conducting and funding development performed in the territory. As part of a 2004 restructuring in which Esteve returned certain rights to us in certain territories (Former Esteve Territories), we agreed to pay Esteve 10% of any cash up front and milestone fees (up to a maximum aggregate of $20 million) that we receive in connection with any strategic collaborations for the development and/or commercialization of certain of our KL_4 surfactant products in the Former Esteve Territories. In addition, with respect to our aerosolized KL_4 surfactant administered using nCPAP, Esteve will pay us $500,000 upon the initial filing for regulatory approval with the European Medicines Agency and $500,000 upon the approval; also, Esteve has agreed to contribute up to $3 million to support the phase 3 clinical trial in the territory. The alliance will terminate as to each covered product, on a country-by-country basis, upon the latest to occur of: the expiration of the last patent claim related to a covered product in such country; the first commercial sale in such country of the first-to-appear generic formulation of the covered product, and the tenth anniversary of the first sale of the covered product in such country. In addition to customary termination provisions for breach of the agreement by a party, the alliance agreement may be terminated by Esteve on 60 days' prior written notice, up to the date of receipt of the first marketing regulatory approval, or, on up to six months' written notice, if the first marketing regulatory approval has issued. We may terminate the alliance agreement in the event that Esteve acquires a competitive product (as defined in the agreement).

LICENSING, PATENTS AND OTHER PROPRIETARY RIGHTS AND REGULATORY DESIGNATIONS

We continue to invest in maintaining and enforcing our potential competitive position through a number of means: (i) by protecting our exclusive rights in our KL4 surfactant, ADS and aerosol-conducting airway connector technologies through patents and patent term restorations, (ii) by seeking regulatory exclusivities, including potential orphan drug and new drug product exclusivities, and (iii) through protecting our trade secrets and proprietary methodologies that support our manufacturing and analytical processes.

Patents and Proprietary Rights

Johnson & Johnson, Ortho Pharmaceutical Corporation and The Scripps Research Institute

Our precision-engineered KL4 surfactant technology was invented at The Scripps Research Institute (Scripps) and was exclusively licensed to and further developed by J&J. We received an exclusive, worldwide license and sublicense from J&J and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, to a series of over 30 patents and patent filings (worldwide) for the life of the patents (J&J Patents). Most J&J Patents have expired and the remaining eight patents will expire between March 2017 and January 2018. Under the license agreement, we are obligated to pay the licensors fees of up to $2,950,000 in the aggregate upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for certain designated products. We have made milestone payments totaling $950,000 to date. In addition, the agreement provides that we are required to pay royalties at different rates based on the type of revenue and country, in amounts in the range of a high single-digit percent of net sales (as defined in the agreement) of licensed products sold by us or sublicensees, or, if greater, a percentage of royalty income from sublicensees in the low double digits. The license agreement provides that the license will expire, on a country-by-country basis, upon the payment of royalties for all licensed products for ten years beginning on the date of the first commercial sale of the first licensed product in such country. Thereafter, the license agreement provides that royalties shall be paid in respect of a licensed product until the expiration of the last licensed patent containing a valid claim covering the licensed product in such country. For countries in the EU in which royalties are paid only by virtue of licensed know-how, royalties shall be payable commencing from the date of first commercial sale of the first licensed product in such country and ending on the earlier of (i) the date on which the licensed know-how becomes public or (ii) the tenth anniversary of the first commercial sale of the first licensed product in any country of the EU. In addition to customary termination provisions for breach of the agreement by a party, we may terminate the agreement, as to countries other than the U.S. and Western Europe territories (as defined in the agreement), on a country-by-country basis, on six months' prior written notice; and as to the entire agreement, on 60 days' prior written notice.

In the first quarter of 2016, we conducted a full assessment of our patent portfolios and determined to abandon certain patents based, among other things, on the remaining term and the likelihood that we would be in a position to realize value prior to expiration. The patents we have abandoned or plan to abandon include certain patents and pending applications that relate to combination therapies of pulmonary surfactant and other drugs, and methods of use issued in the U.S. and a number of foreign jurisdictions.

Our KL4 -Related Patents and Patent Rights

We have been active in seeking patent protection for our innovations relating to new dosage forms, formulations and methods of manufacturing and delivering synthetic peptide containing pulmonary surfactants. Our patent activities have focused particularly on improved dosage forms and delivery of aerosolized pulmonary surfactant.

In November 2005, we filed U.S. and International patent applications (US 11/274,701 which is now U.S. Patent No. 7,582,312 issued on September 1, 2009 and PCT US/2005/041281, now entered national phase), directed to lyophilized formulations of synthetic peptide containing pulmonary surfactants and methods of manufacture. U.S. Patent No. 7,582,312 will expire on November 15, 2025.

In January 2006, we filed U.S. and International patent applications (US 11/326,885 which is now U.S. Patent No 7,541,331 issued on June 2, 2009 and PCT/US06/000308, now entered national phase), directed to a surfactant treatment regimen for BPD. U.S. Patent No 7,541,331 will expire on January 6, 2026.

In September 2007, we filed U.S. and International patent applications (US 11/901,866 which is now U.S. Patent No. 8,221,772 and PCT US/2007/020260, now entered national phase) directed to surfactant compositions and methods of promoting mucus clearance and treating pulmonary disorders such as cystic fibrosis. U.S. Patent No. 8,221,772 will expire on September 19, 2027.

In March 2013, we filed International patent applications (PCT/US13/34364 and PCT/US13/34464, now entered national phase and commenced expedited examination in U.S. and EU) directed to lyophilized pulmonary surfactant and methods of manufacture. In this patent family, two U.S. Patents Nos. 8,748,396 and 8,748,397 were issued on June 10, 2014, European patent 2723323B1 issued on September 23, 2015, another U.S. Patent No. 9,554,999 B2 issued on January 31, 2017 and multiple foreign counterparts are pending. U.S. Patents Nos. 8,748,396; 8,748,397 and 9,554,999 B2 and European patent 2723323B1will expire on March 28, 2033.

Philip Morris USA Inc. and Philip Morris Products S.A.

In 2008, to restructure a December 2005 strategic alliance, we entered into an Amended and Restated License Agreement with Philip Morris USA, Inc. (PMUSA) with respect to the U.S. (U.S. License Agreement), and, as PMUSA had assigned its ex-U.S. rights to Philip Morris Products S.A. (PMPSA), effective on the same date and on substantially the same terms and conditions, we entered into a license agreement with PMPSA with respect to rights outside of the U.S. (together with the U.S. License Agreement, the PM License Agreements).

The remaining J&J Patents covering our proprietary surfactant technology include U.S. Patent No. 5,952,303 (expires March 29, 2017); U.S. Patent No. 6,120,795 (expires March 4, 2017 along with a corresponding issued foreign counterpart expiring March 24, 2017); U.S. Patent No. 6,013,619 (expires April 28, 2017 along with certain corresponding issued foreign counterparts expiring January 29, 2018); U.S. Patent No. 6, 613,764 (expires June 25, 2017)(along with a corresponding issued foreign counterpart expiring July 16, 2017); U.S. Patent No. 6,492,490 (expires June 25, 2017); and U.S. Patent No. 8,217,142 (expires June 25, 2017). These patents relate to methods of manufacturing KL4 surfactant and KL4 peptide, methods of treating respiratory distress syndrome (RDS) with KL4 surfactant including, a pulmonary lavage method of treating RDS, and other aspects of our precision-engineered surfactant technology.

Under the PM License Agreements, we are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field (*see*, "– Aerosol Technology Patents and Patent Rights.") in the territories. In connection with exclusive undertakings of PMUSA and PMPSA not to exploit the aerosol technology for all licensed uses, we are obligated to pay royalties on all product sales, including sales of certain aerosol devices that are not based on the licensed aerosol technology; provided, however, that no royalties are payable to the extent that we exercise our right to terminate the license with respect to a specific indication. We also have been required to pay minimum royalties quarterly beginning in 2014, but are entitled to reduce future quarterly royalties above the quarterly minimums in the amount of the true-up payments we make to satisfy minimum royalties for prior quarters. Our license rights extend to innovations to the aerosol technology that are made under the PM License Agreements. We believe that our AEROSURF aerosolized KL4 surfactant can be developed to potentially address a broad range of serious respiratory conditions. We are developing AEROSURF to treat premature infants with RDS using the proprietary aerosol technology.

In addition to customary termination provisions for breach of the agreements, we may terminate the PM License Agreements, in whole or in part, upon advance written notice to the licensor. In addition, either party to each PM License Agreement may terminate upon a material breach by the other party (subject to a specified cure period). Our license under each PM License Agreement, unless terminated earlier, will expire as to each licensed product, on a country-by-country basis, upon the latest to occur of: the date on which the sale of such licensed product ceases to be covered by a valid patent claim in such country; the date a generic form of the product is introduced in such country; or the tenth anniversary of the first commercial sale of such licensed product.

Aerosol-Conducting Airway Connector Technology Patents and Patent Rights

In March 2009, we filed International patent application (PCT US/2009/037409, now entered national phase) directed to aerosol-conducting airway connectors and improvements of an aerosol delivery system using AFECTAIR. The claims of this application are directed to a novel ventilation circuit adaptor (an aerosol-conducting airway connector) and related aerosol circuitry that are intended to increase the efficiency of aerosol delivery to the patient by allowing more efficient delivery of aerosols to the patient, reduce drug compound dilution and wastage and result in more precise aerosol dosing. In this patent family, U.S. Patent No. 8,701,658 was issued on April 22, 2014, European patent No. 2265309 was issued on December 16, 2015, U.S. Patent No. 9,352,114 was issued on May 31, 2016, U.S. Patent No. 9,592,361 was issued on March 14, 2017 and several foreign patents have issued during 2011 through 2015. U.S. Patent No. 8,701,658 and U.S. Patent No. 9,352,114 will expire on March 17, 2029. U.S. Patent No. 9,592,361 will expire on September 9, 2033.

See, "Item 1A – Risk Factors – If we cannot protect our intellectual property, other companies could use our technology in competitive products. Even if we obtain patents to protect our products, those patents may not be sufficiently broad or they may expire and others could then compete with us;" "– Intellectual property rights of third parties could limit our ability to develop and market our products;" and "– If we cannot meet requirements under our license agreements, we could lose the rights to our products."

Trademarks

AEROSURF®, AFECTAIR®, DISCOVERYLABS®, SURFAXIN®, SURFAXIN LS™, WARMING CRADLE®, WINDTREE™ and WINDTREE THERAPEUTICS™ are our registered and common law trademarks.

Trade Secrets

In addition to our patent exclusivities, we rely on trade secrets to protect and maintain our competitive position. We take measures to protect and maintain our trade secrets and know-how licensed to us or developed by us by entering in confidentiality agreements with third parties. Our trade secrets and know-how include information related to manufacturing processes for our drug products and devices, analytical methods and procedures, research and development activities, provisional patent applications, as well as certain information provided to FDA that was not made public which relates to our regulatory activities and clinical trials.

Other Regulatory Designations

Orphan Drug and Orphan Medicinal Product Designations

"Orphan Drugs" are pharmaceutical products that are intended to address diseases affecting fewer than 200,000 patients in the U.S. The Office of Orphan Products Development of the FDA determines whether to designate a drug as an Orphan Drug. If a drug is designated as an Orphan Drug, it is eligible to obtain certain benefits, including, but not limited to, seven years of market exclusivity upon approval of the drug for the orphan indication, certain tax incentives for clinical research and grants to fund testing of the drug. The FDA has granted Orphan Drug designation for (i) our KL_4 surfactant (lucinactant) for the treatment of RDS in premature infants, (ii) our KL_4 surfactant for the prevention and treatment of BPD in premature infants, (iii) our KL_4 surfactant for the treatment of acute respiratory distress syndrome (ARDS) in adults, and (iv) our KL_4 surfactant for the treatment of CF.

The European Commission (EC) grants "Orphan Medicinal Product" designation for pharmaceutical products for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people which provides for exclusive marketing rights for indications in Europe for 10 years (subject to revision after six years) following marketing approval by the European Medicines Agency (EMA). In addition, the designation would enable us to receive regulatory assistance in the further development process, and to access reduced regulatory fees throughout its marketing life. The EC has granted Orphan Medicinal Product designation for (i) our KL4 surfactant for the prevention of RDS in premature neonates of less than 32 weeks gestational age, (ii) our KL4 surfactant for the treatment of RDS in premature neonates of less than 37 weeks gestational age, (iii) our KL4 surfactant for the treatment of ALI (which in this circumstance encompasses ARDS), and (iv) our KL4 surfactant for the treatment of CF. In submitting the requests to the EMA for Orphan Medicinal Product designations, instead of listing the drug product under the USAN name (lucinactant) as we have in the U.S., we were required to submit our requests under the names of the four APIs in our KL4 surfactant (lucinactant) as follows: sinapultide (KL4), dipalmitoylphosphatidylcholine, palmitoyl-oleoyl phosphatidylglycerol and palmitic acid.

Fast Track Designations and Priority Review

Designation as a "Fast Track" product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA may grant priority review for an NDA for a drug granted Fast Track designation if relevant criteria are met, and rolling review, which means that the review goal for the NDA would be six months.

The FDA granted "Fast Track" designation for (i) our KL4 surfactant (lucinactant) for the prevention and treatment of BPD in premature infants, (ii) our KL4 surfactant for ARDS in adults, and (iii) in September 2016, our KL4 surfactant for the treatment of RDS. We believe that other of our products may qualify for Fast Track or other designations, including potentially breakthrough therapy, accelerated approval and priority review. These designations and programs are intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions.

COMPETITION

We are engaged in the highly competitive fields of pharmaceutical research and development. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We compete with conventional pharmaceutical companies, among others. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. *See*, "Item 1A – Risk Factors – Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete."

Currently, the FDA has approved surfactants as therapy only for the prevention and/or treatment of RDS in premature infants. Administration of these surfactants requires invasive intubation and mechanical ventilation. Curosurf (poractant alfa), which is derived from a chemical extraction process of porcine (pig) lung is the market leader, and Survanta (beractant), which is derived from a chemical extraction process of bovine (cow) lung. Curosurf is marketed in Europe and elsewhere by Chiesi Farmaceutici S.p.A. and in the U.S. by its wholly-owned subsidiary, Chiesi USA, Inc. In addition to an animal-derived surfactant, Chiesi has published the results of a preclinical study in an early-stage effort to develop a synthetic surfactant (Sato A, Ikegami M (2012) SP-B and SP-C Containing New Synthetic Surfactant for Treatment of Extremely Immature Lamb Lung. PLoS ONE 7(7):e39392.doi:10.1371/journal.pone.0039392(Sato and Ikegami)). Chiesi has also completed a first-in-human clinical trial to study the safety and tolerability of intratracheal administration of two different single doses of its investigational synthetic surfactant in preterm infants with RDS (clinicaltrials.gov). Phase 2 of this trial is underway (clinicaltrials.gov identifier: NCT01651637). Survanta is marketed internationally by AbbVie, Inc. ONY, Inc. markets Infasurf®, a surfactant derived from calf lung surfactant lavage, in the U.S.

We believe that efforts to aerosolize animal-derived surfactants have not been satisfactory due to limitations of conventional aerosolization technologies. To successfully aerosolize a surfactant for delivery to premature infants, recent studies suggest that it would be necessary to optimize the aerosol to a particular particle size range, use an aerosol generator with characteristics that are compatible with the patient's breathing, and employ a delivery system that delivers sufficient drug product to the patient (Mazela, et. al., Aerosolized Surfactants, Current Opinion in Pediatrics 2007, 19:155–162; Finer, et. al., An Open Label, Pilot Study of AEROSURF Combined with nCPAP to Prevent RDS in Preterm Neonate, Journal of Aerosol, Medicine and Pulmonary Drug Delivery, Volume 23, Number 5, 2010 (Finer Study)). In addition, it is important to maintain the particular particle size range and consistency of output throughout the aerosolized surfactant dosing period. In particular, for clinical registration trials, a surfactant aerosol delivery system must be capable of delivering a consistent dose to the patient throughout the individual dosing period as well as a consistent dose from device to device. There are a number of device manufacturers with aerosolization expertise, including PARI and Aerogen, Inc. These companies manufacture aerosol devices such as nebulizers, aerosol masks, and compressors.

Other potential competitors to our aerosolized surfactant drug delivery technology may be surfactant delivery via the so-called "minimally invasive surfactant therapy" (MIST) and "less invasive surfactant administration" (LISA). LISA and MIST are methods of exogenous surfactant delivery to the lung using brief catheterization of the trachea with an instillation catheter in a preterm infant, followed by extubation and reinstitution of CPAP. While thought to be less invasive than earlier delivery methods, these approaches still require passing a tube through vocal cords with a laryngoscope and may be associated with other side effects. A further potential competitor to our aerosolized surfactant drug technology may be administration of surfactant via laryngeal mask airway (LMA).

GOVERNMENT REGULATION

In the U.S., drug products, medical devices, and drug-device combination products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, clearance, labeling, promotion, advertising and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drug products, medical devices, and drug-device combination products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve or clear pending new submissions to market drugs or devices warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. Drug products, medical devices, and drug-device combination products must receive all relevant regulatory approvals or clearances before they may be marketed in the U.S. Drug products, medical devices, and drug-device combination products are subject to extensive regulation, including premarket review and marketing authorization, by similar agencies in other countries.

Drug Products

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Pursuant to the 21st Century Cures Act, which was enacted on December 13, 2016, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the law or the initiation of a Phase 2 or Phase 3 trial of the investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,038,000 for fiscal year 2017, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $97,000 per product and $512,000 per establishment for fiscal year 2017. While these fees are typically increased annually, they decreased for fiscal year 2017.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the NDA submission is filed, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee - typically a panel that includes clinicians and other experts - for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices, or cGMPs, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Fast Track Designation

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program, sponsors have the opportunity to engage in more frequent interactions with FDA. In addition, FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The Hatch-Waxman Act

Orange Book Listing: In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDC Act, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity: Market exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is entitled to NCE exclusivity if it contains a drug substance no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not receive for review an ANDA or file a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDC Act also provides three years of market exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions for use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension: After NDA approval, the owner of a relevant drug patent may apply for up to a five-year patent extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase, and an approval phase. The allowable patent term extension is calculated as half of the drug's testing phase - the time between the day the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval – up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, or REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, prescription drug manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Medical Device Products

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory which is: (i) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by FDA before they are marketed.

Generally, establishments that manufacture and/or distribute devices, including manufacturers, contract manufacturers, sterilizers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, initial importers, manufacturers of accessories and components sold directly to the end user, and U.S. manufacturers of export-only devices, are required to register their establishments with the FDA and provide FDA a list of the devices that they handle at their facilities.

Pre-market Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a premarket approval application, or PMA, prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market for Class III devices include the humanitarian device exception, or HDE, or a product development protocol or PDP.

Exempt Devices

If a manufacturer's device falls into a generic category of Class I or Class II devices that FDA has exempted by regulation, a premarket notification is not required before marketing the device in the U.S. Manufacturers of such devices are required to register their establishments and list the generic category or classification name of their devices. Some 510(k)-exempt devices are also exempt from Quality System Regulation, or QSR, requirements.

Post-market Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

Combination Products

A combination product is a product comprised of (i) two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (iii) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where, upon approval of the proposed product, the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (iv) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that FDA determine the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

International Approvals

Drug products, medical devices, and drug-device combination products are subject to extensive regulation, including premarket review and marketing authorization, by similar agencies in other countries. Regulatory requirements and approval processes are similar in approach to that of the U.S. but are not harmonized. International regulators are independent and not bound by the findings of the FDA and there is a risk that foreign regulators will not accept clinical trial design/results or may require additional data or other information not requested by the FDA. In addition, international regulators may require different manufacturing practices than the FDA's cGMPs.

Anti-Kickback, False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, medical devices, and combination products, several other types of state and federal laws have been applied to restrict certain marketing practices in the medical product industry in recent years. These laws include anti-kickback statutes, false claims statutes, and other statutes pertaining to health care fraud and abuse. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act, or PPACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, PPACA amended the healthcare program anti-kickback statute such that a violation can serve as a basis for liability under the federal false claims law. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror/payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the healthcare fraud statute, which prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

EMPLOYEES

As of March 23, 2017, we have 49 employees, including 8 part-time employees. All of our employees are based in the U.S. *See*, "Item 1A – Risk Factors – We depend upon key employees and consultants in a competitive market for skilled personnel. If we or our strategic partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements, certain and other information that we may file electronically with the SEC (*http://www.sec.gov*). We also make available for download free of charge through our website our Annual Report on Form 10-K, our quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we have filed it electronically with, or furnished it to, the SEC. We maintain our corporate website at http://www.windtreetx.com. Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and any of the other information set forth in this Annual Report on Form 10-K and in the documents incorporated herein by reference, before deciding to invest in shares of our common stock. The risks described below are not the only ones that we face. Additional risks that are not presently known to us or that we currently deem immaterial may also impair our business operations. The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time. If any of the following risks actually occurs, our business prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you could lose all or part of your investment.

Risks Related to Capital Resource Requirements

To be able to secure the additional capital that we will require, we are substantially dependent upon our ability to successfully complete enrollment in our ongoing phase 2b clinical trial and release top line data mid-year 2017. If we are unable to successfully complete enrollment and release top line data in accordance with our plan, or if the results of our clinical trial are inconclusive, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or safety profile, we may be unable to secure the additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt, which could have a material adverse effect on our business and our ability to continue as a going concern.

Our business and our ability to secure the significant additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt is highly dependent upon our ability to successfully develop our AEROSURF® combination drug/device product candidate for the treatment of respiratory distress syndrome (RDS) in premature infants. At the present time, we are conducting a phase 2b clinical trial, which is expected to be completed mid-year 2017. If for any reason, we should experience delays in successfully completing this clinical trial, whether due to slower rates of enrollment or failure to timely supply aerosol delivery systems (ADS) to our clinical sites as needed, we could have to prematurely end the trial, which potentially could adversely affect the results. Moreover, even if we are able to complete our phase 2b clinical trial on time and at planned enrollment levels, if we obtain results that are inconclusive, fail to achieve our stated endpoints, or otherwise present an inappropriate benefit risk profile, or if we suffer regulatory setbacks or delays, such events may jeopardize our ability to secure the additional capital that we require. Accordingly, failure to obtain acceptable and promising results within the required time could have a material adverse effect on our ability to secure the additional capital that we will require, through strategic transactions or otherwise, and likely adversely affect our ability to continue as a going concern.

We currently have sufficient capital to fund our research and development programs, support our business operations and pay our debt service obligations on a timely basis to mid-2017. If we do not secure additional capital to support our future activities before our existing cash resources are exhausted, we likely will be unable to continue as a going concern.

As of December 31, 2016, we had cash and cash equivalents of $5.6 million, current liabilities of $13.4 million, and $25 million of long-term debt under the Deerfield Loan. The principal portion of the Deerfield Loan is payable in two equal installments in February 2018 (subject to a potential one-year deferral in the event that our market value at the time is equal to at least $250 million) and February 2019. In February 2017, we completed a private placement offering for which we received net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration. Before any additional financings, including under our ATM Program or in connection with potential strategic transactions, we believe that we will have sufficient cash resources available to support our development activities, business operations and debt service obligations through completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 2017.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development programs, support our business operations and pay our debt service obligations on a timely basis. To secure the additional capital that we will require in the near term, we plan to seek additional capital through a combination of public or private equity offerings (including pursuant to the ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel)), and strategic transactions, including potential alliances and collaborations focused on various individual markets, as well as potential combinations (including by merger or acquisition) or other corporate transactions. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we likely will not have sufficient cash resources and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

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

Before any additional financings or other transactions, we believe that we will have sufficient cash resources to support our development programs, business operations and debt service obligations to mid- 2017. Since April 2015, we have focused our capital and resources primarily on the AEROSURF clinical development program, our lyophilized KL_4 surfactant and ADS. AEROSURF is our only clinical development program. We expect to continue to require significant additional infusions of capital to execute our business strategy until such time as revenues from the commercialization of AEROSURF, if approved, and from potential strategic alliance and collaboration arrangements, and other sources, are sufficient to offset our cash flow requirements. For the next several years, we do not expect to receive revenues from the sale of approved products, and our cash outflows for development programs, operations and debt service are likely to far outpace the rate at which we may generate revenues and other cash inflows from all available sources. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We plan to seek the additional capital that we require from potential strategic alliances, collaboration arrangements and other similar transactions, and through potential public and private offerings in the equity markets, which could have a dilutive impact on our stockholders. In such event, the issuance, or even potential issuance, of shares could have a negative effect on the market price of our common stock. However, a number of factors, including the timing and outcomes of our clinical activities, our status as a smaller reporting company under the SEC regulations, our ability to regain compliance with the listing requirements of The Nasdaq Capital Market, our capital structure which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock and $25 million of debt, as well as conditions in the global financial markets, may present significant challenges to accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for our at-the-market equity program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel), which can be cancelled at any time, including potentially by Stifel if our stock is no longer listed on Nasdaq, we do not have in place arrangements to obtain additional capital. Any financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, curtail or discontinue our research and development programs.

If we fail to regain compliance with the strict listing requirements of The Nasdaq Capital Market (Nasdaq), we will be subject to delisting. As a result, our stock price may decline and the liquidity of our securities likely would be impaired.

Our common stock currently trades on Nasdaq under the symbol WINT. If we fail to adhere to Nasdaq's strict continuing listing requirements (the Nasdaq Listing Requirements), our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock.

On May 19, 2016, we received a notification letter from the Staff notifying us that we are no longer in compliance with the minimum stockholders' equity Nasdaq Listing Requirement. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, we had reported stockholders' deficit of $5.0 million. The Staff noted that, as of May 19, 2016, we also did not meet either of the alternative compliance standards under Nasdaq Listing Rule 5550(b) of (i) a market value of listed securities of at least $35 million, or (ii) net income of $500,000 from continuing operations. Nasdaq granted us an extension to regain compliance until November 15, 2016. We did not regain compliance by that date, and the Staff provided a written delisting notification that our common stock would be delisted. At that time, we filed an appeal with the Nasdaq Hearings Panel, and were granted a hearing on January 12, 2017. The Nasdaq Hearings Panel determined to allow us continued listing on Nasdaq until May 15, 2017, during which time we must pursue our plan to regain compliance with all applicable Nasdaq Listing Requirements. During the extension, we are required to provide the Panel interim reports of our progress toward regaining compliance. If we fail to demonstrate a reasonable likelihood of regaining compliance on or before May 15, 2017, the Panel will issue a final delist determination and we will be suspended from trading on Nasdaq. We submitted our first status report on February 17, 2017. Any further appeal at that time would not stay the delisting of our stock from the exchange.

As of December 31, 2016, we had stockholders' deficit of $28.8 million and a market value of listed securities of $10.9 million, and as of March 23, 2017, we remained out of compliance with the Nasdaq Listing Rules. There can be no assurance that we will be able to regain compliance with the minimum stockholders' equity Nasdaq Listing Requirement. In addition, an alternate Nasdaq Listing Requirement requires that we maintain a market value of listed securities of at least $35 million. If we are unable to meet these requirements we would receive another delisting notice from Nasdaq for failure to comply with one or more of the Nasdaq Listing Requirements.

Our status under SEC regulations as a smaller reporting company and the related limitation on primary offerings under our universal shelf registration statement, which was filed with the SEC on Form S-3 (File No. 333-196420) and declared effective on June 13, 2014 (2014 Universal Shelf), or any successor universal shelf, may make it more difficult to raise additional capital in the public markets when needed, if at all, including under our ATM Program or pursuant to a public offering.

Our ability to use our ATM Program with Stifel or to raise additional capital from time to time through a public offering under our 2014 Universal Shelf or any successor universal shelf, may be constrained by restrictions under the Form S-3, which limits the value of primary securities offerings in any 12-month period by companies whose equity securities held by nonaffiliated persons and entities (public float) is less than $75 million, to no more than one-third of their public float. At March 13, 2017, our public float was approximately $11.8 million. To raise needed 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 privately placed, potentially with registration rights or priced at a discount to the market value of our stock, or contain other terms and conditions, or other transactions, any of which could result in substantial equity dilution of stockholders' interests. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

Our ability to use a universal shelf registration statement would be impaired if our common stock were delisted from Nasdaq.

Under the SEC rules governing use of a registration statement on Form S-3, the issuer is required to have a security listed on an exchange. If our common stock should be delisted from Nasdaq, we would be unable to make use of the Form S-3 after the date on which we next file our Annual Report on Form 10-K. Thereafter, to conduct a securities offering, we would be required to seek other forms of transactions, including, for example, under a registration statement on Form S-1, or privately placed, 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.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our ATM Program, stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, including the Series A Convertible Preferred Stock (Preferred Stock) issued in February 2017 and the pre-funded warrants issued in July 2015, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

We will require additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of preferred stock or common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. For example, in February 2017, we sold 7,049 Series A Convertible Preferred Stock units at a per unit price of $1,495. Each Series A Convertible Preferred Stock unit consists of: (i) one share of Series A Convertible Preferred Stock and (ii) 1,000 Series A-1 Warrants (Series A-1Warrants) to purchase one share of common stock at an exercise price equal to $1.37. Each share of Series A Convertible Preferred Stock may be converted at the holder's option at any time into 1,000 shares of common stock at a conversion price of $1.37 per share. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. The issuance of shares of our common stock in connection with a public financing, under the ATM Program, in connection with our compensation programs, and upon exercise of outstanding warrants will have a dilutive impact on our other stockholders and the issuance, or even potential issuance, of such shares could have a negative effect on the market price of our common stock.

We filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-196420) on May 30, 2014 (which 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. This universal shelf registration statement will expire on June 12, 2017. We may consider filing a replacement universal shelf or a registration statement on Form S-1 to cover the outstanding warrants and derivative securities previously issued pursuant to the 2014 universal shelf

The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

The rights of the holders of our common stock will be subordinate to our creditors and to the holders of our Preferred Stock in a liquidation. No assurance can be given as to the amount of assets, if any, that would be available for common stockholders in the event of a liquidation.

In liquidation, the rights of equity security holders like our common stockholders are subordinate to holders of our debt obligations. As of December 31, 2016, we had cash and cash equivalents of $5.6 million, current liabilities of $13.4 million, and $25 million of long-term debt under a secured loan with affiliates of Deerfield Management Company, L.P. (Deerfield). In addition, the holders of our Preferred Stock have a preference in liquidation over the holders of our common stock and are entitled to receive the greater of three times the amount of their initial investment or the amount to which they would be entitled on an as-converted basis. Accordingly, in the event of liquidation, no assurance can be given as to the amount of remaining assets, if any, available for payment to common stockholder.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- significant patient adverse reactions to our products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;

- changes in the U.S. or foreign political environment and the passage of laws, including tax, environmental or other laws, affecting the product development business;
- developments in patent or other proprietary rights, including any third-party challenges of our intellectual property rights;
- announcements of technological innovations or new products by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries; including healthcare reform in the U.S. and pricing and reimbursement policies globally;
- new accounting standards; and
- the occurrence of any of the risks described in these “Risk Factors” or elsewhere in this Annual Report on Form 10-K or our other public filings.

Our common stock is listed for quotation on The Nasdaq Capital Market®. During the year ended December 31, 2016, the price of our common stock ranged between $1.23 and $3.86. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the year ended December 31, 2016, the average daily trading volume in our common stock was approximately 83,312 shares. The instability observed in our daily volume and number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. Even if securities class actions that may be filed against us in the future were ultimately determined to be meritless or unsuccessful, they would involve substantial costs and a diversion of management attention and resources, which could negatively affect our business.

Our existing and future debt obligations could impair our liquidity and financial condition, and if we are unable to meet our debt obligations, the lenders could foreclose on our assets.

We have a secured loan (Deerfield Loan) from affiliates of Deerfield Management, L.P., in the amount of $25 million, which is secured by a security interest on substantially all of our assets. The principal amount is payable in two equal installments of $12.5 million in each of February 2018, subject to a one-year potential deferral if we have achieved a market capitalization of $250 million, and February 2019. Our debt obligations:

- could impair our liquidity;
- could make it more difficult for us to satisfy our other obligations;
- require us to dedicate cash flow to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- impose restrictions on our ability to incur other indebtedness, grant liens on our assets, other than permitted indebtedness and permitted liens, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes;
- impose restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;
- impose restrictions on us with respect to our ability to license our products in the U.S. as well as other markets around the world;
- could adversely affect our ability to enter into strategic transactions and similar agreements, or require us to obtain the consent of our lenders;
- make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets; and
- could place us at a competitive disadvantage when compared to our competitors who are not similarly restricted.

Should we fail in the future to make any required payment under the Deerfield Loan or fail to comply with the covenants contained in the loan agreement and other related agreements, we would be in default regarding that 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 the assets securing such debt and could significantly diminish the market value and marketability of our common stock and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.

Risks Related to our Development Activities

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

We are currently conducting phase 2 of our clinical development program for AEROSURF for which two phase 2 trials are ongoing. We are conducting a phase 2a clinical trial evaluating the safety and tolerability of aerosolized KL_4 surfactant administered using our proprietary ADS to premature infants 26 to 28 week gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for RDS, compared to infants receiving nCPAP alone. We are also conducting a phase 2b clinical trial in premature infants 28 to 32 weeks gestational age receiving nCPAP for RDS, which is designed to evaluate (i) the safety and tolerability of aerosolized KL_4 surfactant compared to infants receiving nCPAP alone and (ii) certain potential endpoints, including time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. These clinical trials are two of a series of clinical trials, including a planned pivotal phase 3 clinical development program, that we expect will be needed to gain marketing authorization for AEROSURF, if at all. Such development programs generally take up to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the U.S. Food and Drug Administration (the FDA) or a foreign regulator on the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a single pivotal phase 3 clinical trial in the U.S. and EU and potentially other markets. Conditions imposed by the FDA and foreign regulators on our clinical development program could significantly increase the time required to complete, and the costs of conducting, and the risks associated with clinical trials. For example, we may not be able to design a study that is acceptable to the FDA and EMA regulators, which would cause us to limit the scope of our geographical activities or greatly increase our investment. Even if we obtain promising preliminary findings or results in earlier preclinical studies and clinical trials, we may suffer significant delays or setbacks in any stage of our clinical trials. For example, we extended our phase 2a clinical trial in premature infants 26 to 28 week gestational age to a third dose group due to the failure to observe a durable effect sufficient to achieve the desired reduction of nCPAP failure rates through 72 hours in the first two doses. In addition, our phase 2b trial in premature infants 28 to 32 weeks gestational age receiving nCPAP for RDS was delayed as a result of changes to the clinical trial design, including our decision to not enroll premature infants 26 to 27 week gestational age. In addition, we may be unable to enroll patients quickly enough to complete any or all of these trials within an acceptable time frame. If any of the risks outlined in this risk factor and elsewhere in this Annual Report on Form 10-K, including with respect to regulatory requirements, institutional review board approval, clinical site initiation and supply, patient enrollment, drug manufacture, device development and performance, lack of compatibility with complementary technologies, or long treatment time required to demonstrate effectiveness, should delay the results, we would likely be forced to end this clinical trial earlier than we otherwise might like, which could adversely affect the results and potentially impair our ability to secure, additional capital to fund our development program. Moreover, even if we are able to complete the clinical trial within our anticipated time, if our results are inconclusive or non-compelling or otherwise insufficient to support a strategic or financing transaction, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business.

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

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

We have initiated a number of clinical sites outside the U.S. where we use the services of third party clinical trial consultants and third party contract research organizations (CROs) to carry out most of our clinical trial related activities and accurately report the results, which may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for substantially all of our clinical trial related activities and reporting. If our CROs do not successfully carry out their activities or meet expected deadlines, our trials may be delayed. If we fail to adequately manage the design, execution and regulatory aspects of our complex and diverse clinical trials, our studies and any potential regulatory approvals may be delayed, or we may fail to gain approvals for our product candidates.

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

Moreover, because AEROSURF is a combination drug-device product, the success of our clinical trial is highly dependent upon our ability to successfully develop and manufacture our synthetic lyophilized KL_4 surfactant and our ADS and related components. We continue our work with our contract manufacturing organizations (CMOs) to be in a position to manufacture sufficient drug supply for our clinical development program when needed. We also are engaged in development efforts with Battelle Memorial Institute (Battelle), which manufactured the phase 2 ADS and related components to support our phase 2 clinical development program, for the further development of our NextGen ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. We are conducting ongoing assessments of our medical device performance and have responded, and plan to respond, to events that may occur during the course of the clinical trial. If our ADS should fail to perform as designed, such failures could adversely affect the execution and results of our clinical development program. If we are unsuccessful in our development activities or if for any reason we are unable to obtain active pharmaceutical ingredients (APIs), manufacture our drug, medical device and related components to our specifications and on commercially reasonable terms, our clinical trials could be delayed or otherwise adversely affected.

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

The regulatory approval process for our products is expensive and time-consuming and the outcome is uncertain. We may not obtain required regulatory approvals to commercialize our products.

Before we can market our products, we must receive regulatory approvals for each product. The FDA and foreign regulators, such as the European Medicines Agency (EMA), extensively and rigorously regulate the testing, manufacture, distribution, advertising and marketing of drug products. This approval process includes (i) preclinical studies and clinical trials of each drug product candidate and API to establish its safety and effectiveness, and (ii) confirmation by the FDA and foreign regulators that we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable data are generated by clinical trials, the FDA or foreign regulator may not accept, file or approve a new drug application (NDA) or market authorization application (MAA) filed for a drug product on a timely basis or at all. *See*, "Item 1 – Business – Government Regulation."

We are currently conducting a phase 2 clinical development program for AEROSURF. There can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical trials will be concluded successfully. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. As a result, data we obtain from our phase 2a clinical trials may not accurately predict phase 2b or phase 3 trial results due to many factors such as differences in sample size, study arms, duration, endpoints and features of the ADS used. In addition, if the ADS to be used in our phase 3 program differs in potentially important ways from that used in our phase 2 trials, we may be required to conduct bridging studies or repeat important studies conducted with the earlier version. In addition, clinical data are susceptible to varying interpretations that may delay, limit or prevent regulatory approval. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF.

Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects or raise safety or other concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in the approved label, adversely affect placement within the treatment paradigm, or otherwise significantly diminish the commercial potential of the product candidate. Also, positive results in a registration trial may not be replicated in subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may disagree with our view of the data or require additional studies, may disagree with trial design or the endpoints employed in the trials, may fail to approve the processes used to manufacture a product candidate, may find the cGMP compliance status of a facility that manufactures a product candidate unsatisfactory, may fail to approve or delay approval of our product candidates, dosing or delivery methods, companion devices or may otherwise grant marketing approval that is more restricted than anticipated, including indications covering narrow patient populations and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies. The occurrence of any such events could result in the incurrence of significant costs and expenses, additional time and have an adverse effect on our business, including our financial condition and results of operations, or cause our stock price to decline or experience periods of volatility. Even if we are able to successfully develop new products or indications, we may make a strategic decision to discontinue development of such product or indication if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline.

For AEROSURF, we currently plan to pursue clinical development in the U.S., Canada, the European Union (EU), Latin America, and Asia Pacific regions and sell our products in the U.S. and potentially in other major markets. To accomplish this objective, we must obtain and maintain regulatory approvals and comply with regulatory requirements in each jurisdiction. To avoid the significant expense and lengthy time required to complete multiple clinical development programs, we expect to meet with relevant regulatory authorities. While we would prefer to design a single, global clinical development program that would satisfy the regulators in all of our target markets, there can be no assurance that our efforts will be successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our products in all of our selected markets.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, which may include:

- the FDA or a foreign regulator may disagree with the design or implementation of one or more clinical trials;
- the FDA or a foreign regulator may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- the FDA or a foreign regulator may not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- the FDA or a foreign regulator may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other applicable regulatory filing;
- the FDA or a foreign regulator may require additional preclinical studies or clinical trials;
- the FDA or a foreign regulator may identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- the FDA or a foreign regulator may grant approval contingent on the performance of costly additional post-approval clinical trials;
- the FDA or a foreign regulator also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- the FDA or a foreign regulator may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- the FDA or a foreign regulator may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or
- the FDA or a foreign regulator may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, which would preclude us from commercializing products in those markets. There may be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to comparative products can be shown. Also, legislative bodies or regulatory agencies could enact new laws or regulations or change existing laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. For example, the EU recently finalized legislation, which is expected to become effective in October 2018, related to the conduct of clinical trials. While the aim of the new legislation is to improve operational efficiency and streamline the overall clinical trial authorization process, the new requirements also provide for increased transparency of clinical trial results and submission of quality data relating to the products and product candidates used for such trials. Under the directive, sponsors will be required to submit detailed summaries of the study trial result within one year of termination of the clinical trial. The EMA will make certain clinical trial reports publicly available, which may limit our ability to protect competitively-sensitive information contained in our clinical trial reports. Failure to comply with new laws or regulations could result in significant monetary penalties as well as reputational and other harms. We are unable to predict when and whether any further changes to laws or regulatory policies affecting our business could occur, such as efforts to reform medical device regulation or the pedigree requirements for medical products or to implement new requirements for combination products, and whether such changes could have a material adverse effect on our business and results of operations. Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. Regulatory authorities could also add new requirements, such as the completion of additional studies, as conditions for obtaining approval or obtaining an indication. The imposition of additional requirements may delay our clinical development and regulatory filing efforts, and delay or prevent us from obtaining regulatory approval for new product candidates, new indications for existing products or maintenance of our current labels.

In addition, some countries, particularly those in the EU, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in health economics for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U.S. or the EU, we could be adversely affected.

Failure to complete the development of our NextGen ADS intended for future development activities and, if approved, initial commercial activities, in a timely manner, if at all, would have a material adverse effect on our efforts to develop AEROSURF as well as our other aerosolized KL4 surfactant products, and our business strategy.

We have developed a clinic-ready ADS that is suitable for use in our ongoing phase 2 clinical development program and currently are working with Battelle to further develop a version of the ADS (NextGen) potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not successfully develop a NextGen ADS that is acceptable for use in our remaining AEROSURF development activities, including our planned phase 3 clinical trial and, if approved, has levels of efficiency, consistent performance, reliability and cost appropriate for commercial activities, if at all, and on a timely basis.
- We will require access to sophisticated engineering capabilities. We have our own medical device engineering staff and we are currently working with Battelle, which is assisting us in certain aspects of our development program and has expertise in medical device development and medical device design and a successful track record in developing aerosolization systems for the medical and pharmaceutical industries. If for any reason we are unable to retain our own engineering capabilities, the agreement with Battelle is terminated, and we are unable to identify design engineers and medical device experts to support our development efforts, including for a clinic-ready ADS for use in our planned clinical development programs and, potentially, for commercial use and later versions of the ADS, it would have a material adverse effect on our business strategy and impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 surfactant products.
- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and potentially medical device development and commercialization expertise. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 surfactant products.

The realization of any of the foregoing risks would have a material adverse effect on our business.

Even though some of our product candidates have Fast Track designation, the FDA may not approve them at all or any sooner than other product candidates that do not have Fast Track designation.

The FDA has notified us that three indications of our KL4 surfactant (lucinactant) technology pipeline, treatment of RDS, BPD in premature infants and ARDS in adults, have been granted designation as “Fast Track” products. Fast Track designation does not accelerate clinical trials nor does it mean that the regulatory requirements are less stringent. Instead, Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. We believe that other potential products in our KL4 surfactant technology pipeline may also qualify for Fast Track or other designations, including potentially breakthrough therapy, accelerated approval and priority review. These designations and programs are intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. Our product candidates may cease to qualify for Fast Track designation and our other product candidates may fail to qualify for any such designation or program. Moreover, even if we are successful in gaining a designation that is intended to facilitate or expedite development or review of a product candidate, other factors could result in significant delays in our development activities with respect to our Fast Track products.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate a drug for relatively small patient populations as Orphan Drugs. Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which affects a patient population of fewer than 200,000 individuals in the United States.

The FDA has granted Orphan Drug designation for (i) our KL4 surfactant (lucinactant) for the treatment of RDS in premature infants, (ii) our KL4 surfactant for the prevention and treatment of BPD in premature infants, (iii) our KL4 surfactant for the treatment of acute respiratory distress syndrome (ARDS) in adults, and (iv) our KL4 surfactant for the treatment of CF.

If a drug that has Orphan Drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan Drug marketing exclusivity generally prevents the FDA from approving an NDA to market a drug containing the same active moiety for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan Drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Risks related to Manufacturing Development and Manufacturing

We currently do not have back-up facilities for our CMOs or back-up suppliers of APIs or excipients and other materials. If the parties we depend on for supplying our APIs, materials and excipients as well as manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to execute our development plans for our current and potential pipeline products. Such delays could adversely impact our operations and financial condition.

In most cases, we are dependent upon a single supplier to provide all of our requirements for our APIs, materials and excipients or one or more of our drug product device subcomponents, components and subassemblies manufacturing-related services. We rely on single CMOs to manufacture drug product that meets appropriate content, quality and stability standards for use in preclinical programs and clinical trials. Our ability to manufacture depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. The supply of any of our manufacturing materials may be interrupted because of supply shortages, poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in increased expenses.

We have supply agreements relating to continued access to APIs with only two of the four providers of drug substances. However, to assure compliance with cGMP requirements, we have entered into Quality Agreements with all of our suppliers of APIs and related materials. If we do not maintain manufacturing and service relationships that are important to us and are not able to identify a replacement supplier or vendor or develop our own manufacturing capabilities, our ability to obtain regulatory approval for our products could be impaired or delayed and our costs could substantially increase. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. The process of changing a supplier could have an adverse impact on our current clinical development programs if supplies of drug substances, materials or excipients on hand are insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business.

We plan to rely on third parties to manufacture our lyophilized KL4 surfactant and manufacture and assemble our medical devices, which exposes us to risks that may affect our ability to maintain supplies of our clinical materials and ADSs and could potentially delay our research and development activities, as well as eventual regulatory approval and commercialization of our drug product candidates.

Our manufacturing strategy for AEROSURF includes manufacturing our lyophilized KL4 surfactant and our ADS using third-party CMOs. Technology transfers of our manufacturing process and our planned future reliance on CMOs exposes us, among other things, to the following risks:

- we may be unable to identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited and, after a product candidate is approved, the FDA must approve any transfer to a CMO. This approval could require one or more pre-approval inspections as well as a potentially lengthy qualification process. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. To qualify and receive regulatory approval for a new manufacturer could take as long as 2 years;
- we may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and thereafter manufacture our products in accordance with our plan;
- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our clinical and commercial needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements;
- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail timely to produce a sufficient supply to meet our commercial and/or clinical needs;
- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Body(ies), the Drug Enforcement Administration, and/or corresponding state agencies to ensure strict compliance with cGMP and/or QSR and other government regulations and corresponding international standards. Although we do not have control over the day-to-day operations of any CMO we may use, we are responsible for ensuring compliance with these regulations and standards, and the failure of a CMO to have a compliance status acceptable to the FDA or other regulatory authorities would delay approval of our product candidates;
- if we desire to make our drug products and/or devices available outside the U.S. for clinical or commercial purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and quality system regulations or standards of the various foreign regulators having jurisdiction over our activities abroad. Such failures (such as in-country quality testing) could result in not only a loss of approved supply to that country, but a total loss of a lot (or lots) of materials globally and could restrict our ability to execute our business strategies;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. Such an event could limit our ability to conduct technology transfers to alternate and successor manufacturers. We may be required to pay fees or other costs for access to such improvements; and
- we may have difficulty implementing changes or modifications to our manufacturing processes that may be required by the FDA or foreign regulator, if, for example, such changes would burden our CMO or otherwise disrupt operations, or our CMO could impose significant financial terms to implement any such change that could adversely affect our business. Failure to achieve such required changes or modifications could delay or prevent our gaining regulatory approval for our product candidates, or prevent us from continuing to market our approved products, which would have a material adverse effect on our business, financial condition and operations.

Each of the foregoing risks and others could delay our development programs and, if approved, commercial manufacturing plans, limit our ability to maintain continuity of supply for our approved products, delay or impair the approval, if any, of our product candidates by the FDA, or result in higher costs or deprive us of potential product revenues.

Manufacturing problems potentially could cause us to experience shortages of APIs, lyophilized KL4 **surfactant drug product, medical devices, and materials, or delay our preclinical or clinical development programs, which could have a material adverse effect on our business.**

The manufacture of pharmaceutical and medical device products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our CMOs or our materials and drug substances suppliers may experience manufacturing or quality control and assurance problems that could result in a failure to maintain compliance with cGMP and QSR requirements, or those of foreign regulators or notified bodies, which is necessary to continue manufacturing of our drug products, materials, drug substances, or medical devices. Other problems that may be encountered include:

- the need to make necessary modifications to maintain a qualified facility;
- difficulties with production and yields, including manufacturing and completing all required release testing on a timely basis to meet demand;
- quality control and assurance problems related to, among other things, in-process monitoring and controls, and release and stability testing of our drug product, or materials and drug substances;
- casualty damage to a facility; and
- shortages of qualified personnel.

Such a failure could result in product production and shipment delays or an inability to obtain materials or drug substance supplies.

We manufacture our lyophilized KL4 surfactant product candidate, our ADS and aerosol-conducting airway connector using CMOs. If manufacturing or quality control problems should arise at the facilities of a CMO or a manufacturer of our APIs and materials suppliers, such problems may in the particular circumstance require potentially complex, time-consuming and costly comprehensive investigations to determine the root causes of such problems and may require detailed and time-consuming remediation efforts, which can further delay a return to normal manufacturing and production activities. Any failure by our CMOs or by the manufacturing operations of any of our suppliers to comply with applicable regulatory manufacturing standards, including cGMP or QSR, or other FDA or similar foreign regulatory requirements could adversely affect our ability to manufacture our drug product and medical device candidates, which could have a material adverse effect on our ability to produce our drug and medical device products or obtain approval of our product candidates, and potentially adversely affect our research activities and our business and financial condition. A number of factors could cause interruptions in supply, including:

- equipment malfunctions or failures;
- lack of availability of raw materials or subcomponents,
- technology malfunctions;
- interruption of material availability;
- work stoppages or slowdowns;
- damage to or destruction of the facility;
- regional power shortages; and
- product tampering.

In connection with our drug product manufacturing activities, we own certain specialized manufacturing equipment installed at our CMO. However, we do not have fully-redundant systems and equipment to respond promptly in the event of a significant loss at a CMO's manufacturing operations. Under certain conditions, we may be unable to produce our drug product and medical devices at the required volumes or to appropriate standards, if at all. If we are unable to successfully maintain our manufacturing capabilities and at all times comply with cGMP and QSRs, it will adversely affect our development activities and clinical development programs.

For the development and, if approved, commercialization of AEROSURF, we will depend upon third parties to manufacture and assemble our ADS. If we are unable to identify qualified manufacturers and assemblers, our ability to implement our plans for the further development of AEROSURF and, if approved, commercialization of AEROSURF, will be adversely affected and both AEROSURF and our other aerosolized KL4 surfactant products could be severely impacted.

In connection with the development of AEROSURF, which is a combination drug/device product candidate that delivers aerosolized lyophilized KL4 surfactant, we plan to rely on CMOs to manufacture and assemble the ADS and all subcomponents of the ADS to support any preclinical experiments, our ongoing and planned clinical trials and, if approved, commercial activities. The ADS includes a durable device and disposable elements that are either manufactured or cleaned in an environmentally-controlled area. Each ADS is tested for conformance to designated product specifications during assembly must be quality control tested prior to release and monitored for conformance to designated product specifications.

We have worked with Battelle to develop a clinic-ready ADS to support our phase 2 clinical development program and currently are collaborating on design verification and validation of new version (NextGen) ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. As with many device development initiatives, there is a risk that, even if we are able to finalize specifications for a NextGen ADS that is suitable for use in our remaining AEROSURF development activities and, if approved, initial commercial activities, we may have difficulty identifying manufacturers that are able to consistently manufacture and assemble the subcomponents of our ADS to our specified standards. In addition, we may not be able to identify qualified additional or replacement manufacturers and assemblers to manufacture subcomponents and assemble the ADS and, if developed, later versions of the ADS, or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, regulatory manufacturing requirements. If we do not successfully identify and enter into agreements with manufacturers and assemblers that have the required expertise to produce our ADS, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL4 surfactant, including AEROSURF.

Risks Related to our Business and Strategy

We are continually evaluating our business strategy and may modify this strategy in light of developments in our business and other factors.

We continually evaluate our business strategy and plan to modify our strategy as necessary to achieve our objectives. The execution of a clinical development program is complex and involves the cooperation of many individuals and entities, including third parties that we may not be able to control, and requires the coordination of a number of elements, any one of which could involve delays or unforeseen events or circumstances that require adjustment or the development of alternative strategies. If we encounter such events or circumstances, we will change our strategy and plans if we believe that such a change will be in our best interest. There can be no assurance, whether or not we alter our strategy or plans for any reason, that we will be successful, or that we will secure regulatory approval for our products and execute any product launches effectively and on time, if at all, in all markets that we may identify. To respond to changing circumstances, we may also expand or alter our research and development activities from time to time, and allocate resources to work on development of different products or may pace, delay or halt the development of potential product programs. As a result of changes in our strategy, we may also change or refocus our existing drug development and manufacturing activities or our plans for commercialization of our products, if approved. These decisions could require changes in our facilities and personnel and restructuring various financial arrangements. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives.

We have limited resources, which could impair our ability to manage our diverse activities and accomplish our business objectives.

The demands on our management team have grown over time. Our development program for AEROSURF has progressed into phase 2b and we are planning for additional clinical development programs. Over time, our planned clinical trials are expected to enroll more patients, be conducted in a larger number of sites in the U.S., Canada, EU, Latin America, and Asia Pacific and will require more of our management resources to be successful. In addition to working on the AEROSURF development program, from time to time, we support studies of other potential KL4 surfactant pipeline products. To assist us with the development and, if approved, commercialization of our products, we have also devoted resources to identifying potential strategic partnerships, collaboration arrangements and similar transactions, in the U.S., EU, China and other potential markets. These activities have and will continue to place additional significant demands on our management and our financial and operational resources, and will require that we continue to develop and improve our financial, operational and other internal controls. From time to time, we will be required to make difficult decisions on how to best allocate our resources.

If we are successful in identifying potential strategic or collaboration partners, we will be required to dedicate management resources and implement controls to establish alliance structures, and potentially add a layer of complexity to our operations. We plan to identify potential strategic alliances and collaboration arrangements that would have the resources and capabilities to not only help develop our products but would also distribute our products either globally or in specific regions or countries. This expansion could further increase the challenges involved in implementing appropriate operational and financial systems, expanding manufacturing and production capacity, expanding infrastructure and capabilities, and providing adequate training and supervision to maintain high quality standards. We believe that the significant challenges associated with these potential activities will require us to recruit, train and integrate skilled management, scientific, medical and operations personnel; establish and effectively manage strategic partnerships and collaboration arrangements to support our development and commercialization activities; and provide for manufacturing, including analytical testing and distribution capabilities, for our products, and clinical capabilities for our products under development. Our inability to grow our business effectively and appropriately or otherwise adapt to these challenges would cause our business, financial condition and results of operations to suffer.

Risks Related to Strategic and Other Transactions

Our plan to use strategic alliances and collaboration arrangements to leverage partner capabilities may not be successful if we are unable to integrate their capabilities with our own or if our partners' capabilities do not meet our expectations.

As part of our strategy, we intend to continue to evaluate opportunities for strategic alliances and collaboration arrangements. For these efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. Among other things, technologies or know how to which we gain access may prove ineffective or unsafe. Ownership of these technologies or know-how may be disputed. The agreements that grant us access to such technologies may expire and may not be renewable or could be terminated if our partners or we do not meet our respective obligations. In addition, our partners may provide certain services for us, such as product development support or distribution or commercialization services. These agreements may be subject to differing interpretations and we and our partners may not agree on the appropriate interpretation or specific requirements. Among other things, our partners may prove difficult to work with, less effective than we originally expected or unable to satisfy their financial and other commitments to us. Failure of our partners to perform as needed could place us at a competitive disadvantage.

We may enter into strategic alliances or other collaboration arrangements, which could expose us to risks associated with the transfer of control to third parties and may require that we transfer rights to our products to our partners and collaborators. In addition, if such arrangements potentially provide for the marketing and sale of our products, if approved, including AEROSURF, we will be exposed to additional risks.

To support our AEROSURF development program and potentially the commercial introduction of AEROSURF, we seek to identify potential strategic partners who could provide local development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), although there can be no assurance that we will ultimately secure such an alliance on acceptable terms, if at all.

If we succeed in entering into one or more strategic alliances or other collaboration arrangements, our ability to execute our operating plan will depend upon numerous factors, including the performance of the strategic partners and collaborators with whom we may engage. Under these arrangements, our partners may control key decisions relating to the development and, if approved, commercialization of our products and may require that we transfer to them important rights to our products and/or product candidates. Such partner rights may limit our flexibility in considering development strategies and in commercializing our products. We may not be able to control the timing or resources that our partners devote to our arrangement. In addition, if we or our strategic alliance partners, distributors or collaborators breach or terminate our agreements or otherwise fail to perform their obligations under our distribution or commercialization arrangements to our satisfaction, we may not achieve our goals within the desired time, if at all, and projected sales and our revenues would suffer.

If a strategic alliance partner, distributor or collaborator were to enter into a business combination or other significant transaction, such transaction may adversely affect a partner or collaborator's willingness or ability to perform its obligations, which would adversely affect our business. We also may incur additional expense to terminate such arrangements and to identify and enter into arrangements with replacement distributors or collaborators. Moreover, we may have difficulty enforcing our rights in a foreign jurisdiction. Upon termination of any such agreements, we would need to identify other partners or collaborators or develop our own internal capabilities to develop and commercialize our products in markets outside the U.S., which could involve a significant investment and a potentially unacceptable delay. If we or our collaborators fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products in a competitive and timely manner and would have a material adverse effect on the commercialization of our products.

In entering into any collaboration arrangement, we also will need to consider whether such a collaboration could impair our ability to enter into other strategic transactions, including a potential merger or acquisition. As we seek regulatory approval for our aerosolized KL_4 surfactant in the EU, we have a collaboration with Laboratorios del Dr. Esteve, S.A. (Esteve) for certain of our drug product candidates in a territory consisting of Andorra, Greece, Italy, Portugal and Spain (the Esteve Territory) and will be dependent upon Esteve for marketing and distribution of our KL_4 surfactant products in the Esteve Territory. We may find it difficult to identify and enter into marketing and sales agreements for our KL_4 surfactant pipeline products on acceptable terms, if at all, in territories in the EU outside the Esteve Territory. If we identify potential collaborators for all or parts of the remainder of the EU, strategic differences could arise, which could result in disputes or otherwise impede the progress of our collaborations. Moreover, if a collaborator or its sublicensees does not meet their obligations, our arrangements may not be successful, and, as a result, we may not receive any revenues.

If one of our strategic partners or collaborators pursues a product that competes with our products, there could be a conflict of interest and we may not receive expected revenues or milestone or royalty payments.

Certain of our potential strategic partners and collaborators may be developing or marketing a variety of products, some with other partners. Partners or collaborators with whom we enter into distribution agreements may sell and market products that may indirectly compete with ours, or they may seek to develop, market or sell existing or alternative products or technologies or products targeted at the same diseases or conditions as the products that are the subject of an arrangement with us. Our strategic partners and collaborators may also develop products that are similar to or compete with products they are developing in collaboration with us. If these entities pursue other products instead of our products, we may not receive the anticipated revenues or milestone or royalty payments, or our efforts to distribute our products may be adversely affected, and it is likely that we would have no recourse against our partners or collaborators.

Risks Related to Healthcare Regulation, Quality and Safety

Issues with product quality could have an adverse effect on our business, subject us to regulatory actions and costly litigation and cause a loss of confidence in our products or us.

Our success depends upon our ability to develop quality products. Our future revenues will depend upon our ability to develop, maintain, and continuously improve our quality management system, including an objective and systematic process for monitoring and the evaluation of key process indicators. Quality and safety issues may occur with respect to any of our products. We are dependent upon third-party suppliers, manufacturers and service providers to support our development and commercialization activities. Third-party suppliers are required to comply with our quality standards. Failure of a third-party supplier to provide compliant raw materials or supplies could result in delays or other quality-related issues. A quality or safety issue could have an adverse effect on patients receiving our drug products and on our business, financial condition and results of operations and may result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in our current or future products or us, which may result in the loss of sales and difficulty in commercializing our products.

Adverse safety events or restrictions on use and safety warnings for our products can negatively affect our business, potential future product sales and stock price.

Adverse safety events involving our products under development and our marketed products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

If we enter into strategic alliances or collaboration arrangements, failure of a strategic partner or collaborator to maintain appropriate risk management and adverse event reporting controls exposes us to additional risk.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours or any public rumors about such events may give rise to claims against us and may also adversely affect our ability to market our products and conduct our clinical development programs.

Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Any failure to comply could adversely affect our business, financial condition and results of operations.

Our products and our operations are regulated by numerous government agencies, both inside and outside the U.S. Our drug product candidates and medical devices must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third-party providers must pass inspection and/or be approved or licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our post-marketing reporting, could result in warning or untitled letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. In addition, requirements of the FDA and other regulatory authorities may change and implementing any additional compliance requirements may increase our costs, or force us or our third-party providers to suspend production, which could result in a shortage of our approved product or delays in the commercial introduction of our new product candidates, if approved.

The Health Care Reform Law includes provisions, referred to as the federal "Open Payments" law (previously referred to as the "Sunshine Law"), that establish new reporting and disclosure requirements for pharmaceutical and medical device manufacturers. Under the law, pharmaceutical and device manufacturers are required to annually report various types of payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are to report data to the U.S. Centers for Medicare and Medicaid Services (CMS) on an annual basis, and the data are made publicly available via a CMS website. Inaccurate or incomplete reports may be subject to enforcement, and it is expected that data will be subject to significant public scrutiny. Like the federal Open Payments law, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state, or even go so far as to prohibit certain marketing related activities. Other states, such as California, Nevada, Massachusetts and Connecticut, require pharmaceutical and/or device companies to implement compliance programs or marketing codes. In others, it is possible that we will be subject to the state's reporting requirements and prohibitions. Compliance activities with respect to these measures could increase our costs and adversely affect business operations.

If AEROSURF is approved for commercial sale, we will be required to comply with not only the requirements of the FDA and potentially international regulators, but will also become subject to various federal, state and international laws regulating the sales, marketing, and distribution of healthcare-related products. These laws govern such activities as our relationships with healthcare providers, the promotion of our products, and pricing of prescription drug products and medical devices. The sales and marketing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, and other healthcare related laws, antitrust and other competition laws. The Department of Justice (DOJ) also has increased its focus on the enforcement of the U.S. Foreign Corrupt Practices Act (FCPA), particularly as it relates to the conduct of pharmaceutical companies. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers.

Of particular importance, federal and state anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. These laws can be complicated, are subject to frequent change and may be violated unknowingly. In addition, the absence of guidance for some of these laws and the very few court decisions addressing industry practices increase the likelihood that our practices could be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to the government (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. Many pharmaceutical, device, and other health care companies have been investigated and prosecuted for alleged violations of these laws. Sanctions under these laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi-million dollar fines to the government and agreed to abide by corporate integrity agreements, which often include significant and costly burdens. Under the federal False Claims Act and related state laws, private individuals may bring similar actions. In addition, an increasing number of state laws require manufacturers to report to the state certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

In addition, failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or collectively, HIPAA. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

We are continually evaluating our compliance programs, including policies, training and various forms of monitoring, designed to address the outlined above. However, no compliance program can mitigate risk in its entirety. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

The political and healthcare policy environment is becoming more challenging for pharmaceutical companies and medical device manufacturers and may adversely affect our business.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental challenges that could substantially affect our business and results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, are continuing to arise in many countries where we potentially may seek to do business, including the U.S. There is increasing pressure on pricing, reimbursement and demands for value-based data to gain access to patients and healthcare funds globally. This may increase the costs of development, risks of commercialization and overall value of the opportunity.

Given the increasing uncertainty in the healthcare and pharmaceutical industries, capital investment in our industry and our ability to attract capital investment is becoming more challenging. This trend, if continued, may restrict or impair our ability to gain necessary funding for continued development and, if approved, commercialization of our products.

Other Risks Affecting our Business

If our business development activities are unsuccessful, our business could suffer and our financial performance could be adversely affected.

As part of our long-term growth strategy, we engage in business development activities intended to identify strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar opportunities. Such opportunities may result in substantial investments in our business. Our success in developing products or expanding into new markets from such activities will depend on a number of factors, including our ability to find suitable opportunities for investment, alliance or acquisition; whether we are able to complete an investment, alliance or acquisition on terms that are satisfactory to us; the strength of our underlying technology, products and our ability to execute our business strategies; any intellectual property and litigation related to these products or technology; and our ability to successfully execute the investment, alliance or acquisition into our existing operations, including to fund our share of any in-process research and development projects. If we are unsuccessful in our business development activities, we may be unable to secure needed capital and expertise to support our development programs and our financial condition could be adversely affected.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to the cost or timing of clinical development programs, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions developed by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections and management's expectations in (or incorporated by reference in) this Annual Report on Form 10-K should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, which will likely result in significant legal and accounting expense and diversion of management resources, and current and potential stockholders may lose confidence in our financial reporting and the market price of our stock will likely decline.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

Any failure to maintain internal controls could adversely affect our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. If we do not file our financial statements on a timely basis as required by the SEC and Nasdaq, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We can give no assurance that material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, in the future our controls and procedures may no longer be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. Responding to inquiries from the SEC or Nasdaq, regardless of the outcome, are likely to consume a significant amount of our management resources and cause us to incur significant legal and accounting expense. Further, many companies that have restated their historical financial statements have experienced a decline in stock price and related stockholder lawsuits.

Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations affecting our activities, including in the jurisdictions in which we may sell our products, if approved, and a failure to comply with such regulations or prevail in litigation related to noncompliance could harm our business.

Many of our activities, including the research, development, manufacture, sale and marketing of our products, are subject to extensive laws and regulation, including without limitation, health care "fraud and abuse" laws, such as the federal False Claims Act, the federal Anti-Kickback Statute, and other state and federal laws and regulations. We have developed and implemented a corporate compliance policy and oversight program based upon what we understand to be current industry best practices, but we cannot assure you that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such investigations, actions or lawsuits are instituted against us, and if we are not successful in defending or disposing of them without liability, such investigations, actions or lawsuits could result in the imposition of significant fines or other sanctions and could otherwise have a significant impact on our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about milestones and advances in development, market need and opportunity, drug products and related diseases. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear or responsive to the changing technological environment. There has been an emerging scrutiny and enforcement of investor relations communication by the FDA as well. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend ourselves or the public's legitimate interests in the face of political or market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Failure in our information technology systems could disrupt our operations and cause the loss of confidential information, customers and business opportunities.

In the ordinary course of our business, we and our third-party contractors maintain sensitive data on our and their respective networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our clinical trial participants and business partners. In particular, we rely on contract research organizations and other third parties to store and manage information from our clinical trials, including our AEROSURF phase 2 clinical development program. The secure maintenance of this sensitive information is critical to our business and reputation. Despite the implementation of security measures, our internal computer systems and those of our third-party contractors are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, we believe that companies and other entities and individuals have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access to systems and information. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems or those of our third-party contractors. For information stored with our third-party contractors, we rely upon, and the integrity and confidentiality of such information is dependent upon, the risk mitigation efforts such third-party contractors have in place. In the recent past, cyber-attacks have become more prevalent and much harder to detect and defend against. Our and our third-party contractors' respective network and storage applications may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. System failures, data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. System failures or accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. A data security breach could also lead to public exposure of personal information of our clinical trial patients and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate public disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

A catastrophic event at our Warrington, Pennsylvania facility or any of the facilities used by our third party-manufacturers would prevent us from producing our drug product candidates and/or medical devices.

All of our facilities are located our headquarters in Warrington, Pennsylvania. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. We depend upon third-party manufacturers to manufacture our lyophilized KL_4 surfactant, our AFECTAIR device and our ADS. We expect initially to manufacture each of these products at a single source facility. If a catastrophic event occurred at our headquarters facility or the facilities of any of our third-party manufacturers, such as a fire, flood or tornado, many of those products could not be produced until the manufacturing portion of such facility was restored and cleared by the FDA. With respect to the analytical laboratory at our headquarters facility, any interruption in release and ongoing stability testing could have an adverse impact on our inventories needed to support our ongoing clinical activities and, if approved, commercial activities. We have obtained insurance to protect against certain business interruption losses. However, there can be no assurance that any such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

If we cannot protect our intellectual property, other companies could use our technology in competitive products. Even if we obtain patents to protect our products, those patents may not be sufficiently broad or they may expire and others could then compete with us.

We seek patent protection for our drug and device products and product candidates to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability, and that of parties from whom we license technology, to successfully obtain patents, defend our patents, protect our trade secrets, and otherwise prevent others from infringing our proprietary rights.

The patent position of companies relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office (USPTO) has not adopted a consistent policy regarding the breadth of claims that is accorded in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not secure proprietary rights to products or processes that appear to be patentable.

The parties who licensed technologies to us and we have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the USPTO or foreign patent office issuing patents. In addition, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, even if the USPTO or foreign patent offices were to issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from third parties may not provide us any protection against competitors.

The patents that we hold have a limited life. We have licensed a series of patents for our KL4 surfactant technology from J&J and its wholly-owned subsidiary Ortho Pharmaceutical Corporation (Ortho Pharmaceutical), which are important, both individually and collectively, to our strategy of commercializing our KL4 surfactant products. These patents, which include KL4 surfactant composition of matter claims, KL4 peptide method of manufacture claims and relevant European patents, began to expire in November 2009, and will expire on various dates ending in 2017. In addition to the J&J patents, we have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the U.S. and in foreign countries. Certain of such patents related to lyophilized KL4 surfactant have issued in the U.S. and Europe and will expire in March 2033. For our aerosolized KL4 surfactant, we hold worldwide exclusive licenses from Philip Morris USA Inc. (PMUSA) and Philip Morris Products S.A. (PMPSA) to the proprietary aerosol technology for use with pulmonary surfactants together or in combination with other products for all respiratory diseases. Our exclusive license in the U.S. also extends to other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. The proprietary aerosol technology patents expire on various dates beginning in May 2016 and ending in 2033, or, in some cases, possibly later. We may not be able to develop enhanced or additional products or processes that will be patentable under patent law and, if we do enhance or develop additional products that we believe are patentable, additional patents may not be issued to us.

Our technology platform consists solely of our proprietary KL4 surfactant technology, our proprietary aerosol technology, and our novel aerosol-conducting airway connector.

Our technology platform is based on the scientific rationale of using our KL4 surfactant technology, our proprietary aerosol technology and our novel aerosol-conducting airway connector and related componentry to treat life-threatening respiratory disorders and to serve as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our drug product candidates and our combination drug-device products based on these technologies. Any material problems with our technology platforms could have a material adverse effect on our business.

Intellectual property rights of third parties could limit our ability to develop and market our products.

Our success also depends upon our ability to operate our business without infringing the patents or violating the proprietary rights of others. In certain cases, the USPTO keeps U.S. patent applications confidential while the applications are pending. As a result, we cannot determine in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from J&J, Ortho Pharmaceutical, PMUSA, PMPSA and The Scripps Institute. These agreements require us to make payments and satisfy performance obligations to maintain our rights under these licensing agreements. By their terms, all of these agreements last either throughout the life of the related patents or for a number of years after the first commercial sale of the relevant product. In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology. Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on agreements containing obligations regarding intellectual property, confidentiality and noncompetition provisions that could be breached and may be difficult to enforce.

Although we take what we believe to be reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of our confidential and proprietary information and trade secrets to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, improvements, discoveries and inventions of our employees, consultants, advisors and research collaborators while we employ them, such agreements can be difficult and costly to enforce. We generally seek to enter into these types of agreements with consultants, advisors and research collaborators; however, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. Such disputes often involve significant expense and yield unpredictable results.

Moreover, although all employees enter into agreements with us that include non-compete covenants, and our five senior executive officers have agreements that include broader non-competition covenants and provide for severance payments that are contingent upon the applicable employee’s refraining from competition with us, such non-compete provisions can be difficult and costly to monitor and enforce, such that, if any should resign, we may not be successful in enforcing our noncompetition agreements with them.

Despite the protective measures we employ, we still face the risk that:

- agreements may be breached;
- agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how may otherwise become known;
- our competitors may independently develop similar technology; or
- our competitors may independently discover our proprietary information and trade secrets.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we or our strategic partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We have over the years assembled a team of qualified personnel to advance the AEROSURF development program. In particular, we enhanced our clinical operations, regulatory affairs, quality control and assurance and administrative capabilities. We have competed and will continue to compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

We are highly dependent upon the members of our executive management team and our directors, as well as our consultants and collaborating scientists. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. A loss of any of our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have entered into employment agreements with five executive officers, including our President and Chief Executive Officer, our Senior Vice President and Chief Development Officer, our Senior Vice President and Chief Financial Officer, our Senior Vice President, General Counsel and Corporate Secretary, and our Senior Vice President, Human Resources. With the exception of our President and Chief Executive Officer whose agreement does not expire, the agreements of executive officers which otherwise would have expired on March 31, 2017 have been extended to March 2019 in accordance with their terms. In addition, retention agreements with four other officers and a key employee will expire on March 31, 2019. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

Our future success also will depend in part on the continued service of our key professional, scientific and management personnel and our ability to recruit and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense competition for qualified personnel and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies in many ways. We need to successfully introduce new products to achieve our strategic business objectives. The development and acquisition of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, and technology personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in developing products, preclinical testing and human clinical trials management, obtaining FDA approval and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in receiving FDA or foreign regulatory approval or commercializing products and obtaining patent protection before us. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our products in such markets.

For the sale of commercial products, we will compete against companies with greater marketing and manufacturing capabilities that may successfully develop and commercialize products that are more effective or less expensive than our products. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitive forces frequently and aggressively seek patent protection and licensing arrangements to collect royalties for technologies that they develop. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

The failure to prevail in litigation or the costs of litigation, including securities class actions, product liability claims and patent infringement claims, could harm our financial performance and business operations.

We are potentially susceptible to litigation. For example, as a public company, we may be subject to securities claims based on class actions, which generally seek unquantifiable damages and attorneys' fees and expenses. 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.

Our business activities, including development, manufacture and marketing of our drug products and medical devices also exposes us to liability risks. Using our drug product candidates or medical devices, including in clinical trials, may expose us to product liability claims. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts and medical device disclosures also may arise.

Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time.

We presently carry general liability, excess liability, products liability and property insurance coverage in amounts that are customary for companies in our industry of comparable size and level of activity. However, our insurance policies contain various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We may need to obtain additional product liability insurance coverage, including with locally-authorized insurers licensed in countries where we conduct our clinical trials, before initiating clinical trials; however, such insurance is expensive and may not be available when we need it. In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product, general liability or product liability claim, even if such claim is within the limits of our insurance coverage or meritless and/or unsuccessful, could adversely affect the availability or cost of insurance generally and our cash available for other purposes, such as research and development. In addition, such claims could result in:

- uninsured expenses related to defense or payment of substantial monetary awards to claimants;
- a decrease in demand for our drug product candidates;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our drug product candidates, if approved.

Moreover, the existence of a product liability claim could affect the market price of our common stock. In addition, as the USPTO keeps U.S. patent applications confidential in certain cases while the applications are pending, we cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are applied for and issued, the risk increases that our patents or patent applications for our KL4 surfactant product candidates or our medical device and combination drug/device products may give rise to a declaration of interference by the USPTO, or to administrative proceedings in foreign patent offices, or that our activities lead to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking to invalidate our patents, obtain substantial damages or enjoin us from conducting research and development activities.

Provisions of our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), our Amended and Restated By-Laws (By-Laws) and Delaware law could deter a change of our management and thereby discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation, our By-Laws and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third-party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. As a result, our Board of Directors could issue large blocks of preferred stock or authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, before the redemption of our common stock. Such provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. Moreover, our obligations to the holders of preferred stock could limit our ability to obtain additional financing or increase our borrowing costs, which could have an adverse effect on our financial condition. These preferential rights could also result in divergent interests between the holders of shares of preferred stock and holders of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We maintain our principal executive offices at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622, which consist of 30,506 square feet of space that we lease. In April 2016, as part of our effort to reduce cash outflows and conserve cash resources, we amended our lease to surrender 9,088 square feet to the landlord, reducing the size of our premises from 39,594 square feet to 30,506 square feet; reduced our proportionate share of the building expense; extended the term by four years from February 28, 2018 to February 28, 2022; adjusted the base rent as provided in the amendment; retained certain existing rights of first refusal and 5-year extension options; and received from the new landlord $80,000 to defray costs of moving and other costs related to reconfiguring the remaining premises.

At our leased premises, we maintain our corporate headquarters and operations, consisting of administration, research and drug and device development, clinical operations, regulatory affairs, and quality, as well as our analytical and technical support laboratory, which conducts release testing of all active pharmaceutical ingredients (APIs) as well as supportive research for our lyophilized and aerosolized KL4 surfactant and to identify and protect our intellectual property. We also maintain a controlled medical device development laboratory that is used by our development engineering team to conduct preclinical development activities for AEROSURF and our aerosol delivery technologies. We believe our current facilities are adequate for our needs in 2017.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions to which we are a party or of which our property is the subject 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. 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 or financial condition.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is traded on The Nasdaq Capital Market® (Nasdaq) under the symbol "WINT." As of March 23, 2017, we had 104 holders of record of shares of our common stock, and there were 9,439,365 shares of our common stock issued and outstanding.

The following table sets forth the quarterly sales price ranges of our common stock for the periods indicated, as reported by Nasdaq (adjusted for the 1-for-14 reverse stock split that was effective January 22, 2016).

	2016		2015	
	High	Low	High	Low
Period:				
First Quarter	$ 2.94	$ 1.58	$ 25.48	$ 15.89
Second Quarter	$ 3.86	$ 1.65	$ 20.72	$ 8.96
Third Quarter	$ 2.92	$ 1.76	$ 10.50	$ 3.50
Fourth Quarter	$ 3.24	$ 1.23	$ 7.53	$ 2.69

We have not paid dividends on our common stock and do not expect to declare and pay dividends on our common stock in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

INTRODUCTION

Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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" and "Risk Factors" sections of this Annual Report on Form 10-K 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 the Annual Report on Form 10-K.

Management's discussion and analysis of financial condition and results of operations (MD&A) is provided as a supplement to the accompanying 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 Consolidated Financial Statements for the year ending December 31, 2016 and notes thereto (Notes) included in this Annual Report on Form 10-K. *See*, "Item 8 – Financial Statements and Supplementary Data."

Our discussion is organized as follows:

- **Company Overview and Business Strategy:** this section provides a general description of our company and business plans.
- **Critical Accounting Policies:** this section contains a discussion of the accounting policies that we believe are important to our financial condition and results of operations and that require the exercise of judgment and use of estimates on the part of management in their application. In addition, all of our significant accounting policies, including the critical accounting policies and estimates, are discussed in Note 4 to the accompanying consolidated financial statements.
- **Results of Operations**: this section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations, including comparisons of the results for the years ended December 31, 2016 and 2015.
- **Liquidity and Capital Resources**: this section provides a discussion of our capital resources, future capital requirements, cash flows, potential sources of financing our activities, historical financing transactions, outstanding debt arrangements and commitments.

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 that are designed to deliver aerosolized KL4 surfactant without invasive procedures. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF® (lucinactant for inhalation), which is an investigational combination drug/device product that combines our KL4 surfactant with our novel drug delivery technologies. We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants born prior to 37 weeks gestational age who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. Unfortunately, current FDA-approved surfactants must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid the risks associated with surfactant administration, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP), and then, if they do poorly, receive delayed surfactant therapy.

By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will allow for earlier treatment of premature infants who currently receive delayed surfactant therapy, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure. By enabling administration of aerosolized KL4 surfactant to premature infants receiving nCPAP without invasive intubation and mechanical ventilation, we believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

The drug product component of the AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant 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. We ceased commercial and manufacturing activities for SURFAXIN in the first quarter of 2015 in order to focus our limited resources on advancing the AEROSURF clinical development program and our other aerosolized KL4 surfactant product candidates. In addition, we own worldwide exclusive rights to our aerosol delivery system (ADS), the medical device component of our AEROSURF product candidate. The ADS is designed to generate an aerosolized KL4 surfactant at consistent and reproducible volumes suitable to deliver therapeutic dosages in a reasonable period of time. We are currently developing a new version (NextGen) of ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities.

While we are focused primarily on AEROSURF, we believe that our aerosolized KL4 surfactant may be developed to address a broad range of serious respiratory conditions in children and adults. We have supported and plan in the future to support potential opportunities and third party preclinical studies to explore the utility of our KL4 surfactant to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI; as well as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance however, that we will secure any additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

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

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business – Company Overview" and "– Business Strategy," in this Annual Report on 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.

CRITICAL ACCOUNTING POLICIES

The following discussion and analysis of financial condition and results of operations are based upon our Consolidated Financial Statements, which have been prepared in conformity with U.S. generally accepted accounting principles (GAAP). Preparing financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, and information available from other outside sources, as appropriate. These estimates and assumptions are affected by the application of our accounting policies. Critical accounting policies and practices are both important to the portrayal of a company's financial condition and results of operations, and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Actual results could differ from such estimates due to changes in economic factors or other conditions that are outside the control of management. A summary of our significant accounting policies is described in Note 4 of the Consolidated Financial Statements contained in this Annual Report on Form 10-K. Of those policies, we believe that the following accounting policy is critical to aid our stockholders in fully understanding and evaluating our reported financial results.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities.

We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the years ended December 31, 2016 and 2015 was $39.5 million (or $4.74 basic net loss per share) and $55.2 million (or $7.98 basic net loss per share), respectively. Included in the net loss is (i) interest expense of $2.5 million and $4.6 million for 2016 and 2015, respectively; (ii) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million and $0.9 million for 2016 and 2015, respectively; and (iii) for 2016, a severance charge of $1.6 million.

The operating loss for the years ended December 31, 2016 and 2015 was $38.0 million and $39.8 million, respectively. The decrease in operating loss from 2015 to 2016 was due to a $0.7 million decrease in operating expenses and a $1.1 million increase in grant revenues.

Grant Revenue

We recognized grant revenue of $2.0 million and $1.0 million for the years ended December 31, 2016 and 2015, respectively.

Grant revenue for 2016 represents funds received and expended under three grants: (i) an initial award of $1.0 million under a Phase II Small Business Innovation Research Grant (SBIR) from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) valued at up to $2.6 million over three years to support the AEROSURF phase 2b clinical trial; (ii) the third and final $1.0 million tranche of a previously announced $3.0 million Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) to support continued development of our aerosolized KL_4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (Radiation Grant); and (iii) a $0.2 million fixed-price contract to support development of our aerosolized KL_4 surfactant to mitigate influenza-related lung injury.

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

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we account for such costs by category rather than by project. As many of our research and development activities form the foundation for the development of our KL_4 surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical development programs. We also account for research and development and report by major expense category as follows: (i) salaries and benefits, (ii) contracted services, (iii) raw materials, aerosol devices and supplies, (iv) rents and utilities, (v) depreciation, (vi) contract manufacturing, (vii) travel, (viii) stock-based compensation and (ix) other.

Research and development expenses by category for the years ended December 31, 2016 and 2015 are as follows:

(in thousands)	Years Ended December 31, 2016	2015
Product development and manufacturing	$ 10,172	$ 14,446
Clinical, medical and regulatory operations	7,230	7,125
Direct preclinical and clinical development programs	14,303	7,317
Total Research and Development Expenses	$ 31,705	$ 28,888

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.8 million and $1.1 million for 2016 and 2015, respectively.

For a description of the clinical development programs included in research and development expenses, *See*, "Item 1 – Business – Surfactant Therapy."

Product Development and Manufacturing

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

Product development and manufacturing expenses decreased $4.3 million from 2015 to 2016, due to (i) a decrease of $3.3 million in manufacturing and analytical testing costs following our decision to cease manufacturing and commercial activities for SURFAXIN and to close our manufacturing operations located in Totowa New Jersey (Totowa Facility) upon expiration of the lease on June 30, 2015, and (ii) our efforts in the second quarter of 2016 to conserve cash resources and implement other cost reduction initiatives.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses increased $0.1 million from 2015 to 2016 due to an increase in preclinical and clinical capabilities to support our AEROSURF development program, partially offset by a decrease in incentive compensation.

Direct Preclinical and Clinical Development Programs

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

Direct preclinical and clinical development programs expenses increased $7.0 million from 2015 to 2016 due to an increase in AEROSURF phase 2 clinical development program costs, including the initiation of additional clinical trial sites and the manufacture of additional clinic-ready ADSs.

Research and Development Expense by Major Expense Category

We also account for our research and development expense by major expense category as shown in the following table:

(in thousands)	Years Ended December 31, 2016	2015
Salaries & benefits	$ 7,426	$ 10,320
Contracted services	16,543	11,943
Raw materials, aerosol devices and supplies	3,350	2,010
Rents and utilities	812	1,225
Depreciation	231	476
Contract manufacturing	809	1,568
Travel	721	616
Stock-based compensation	614	642
Other	1,199	863
Allocation to batch production	-	(775)
	$ 31,705	$ 28,888

The decrease in salaries and benefits from 2015 to 2016 is due to our efforts in the second quarter of 2016 to conserve cash resources and implement other cost reduction initiatives, and the closure of our Totowa Facility in June 2015.

Contracted services include the cost of preclinical studies, clinical trial activities, certain components of our manufacturing operations, quality control and analytical stability and release testing of our drug product, consulting services, aerosol device design and engineering services, etc. The increase from 2015 to 2016 is due to AEROSURF clinical trial activities, including patient enrollment in the ongoing phase 2a clinical trial in premature infants 26 to 28 week gestational age and the phase 2b clinical trial in premature infants 28 to 32 week gestational age, manufacture of additional clinic-ready ADS to support ongoing clinical activities as well as development activities under our collaboration agreement with Battelle Memorial Institute (Battelle) for the further development of a NextGen ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities.

Raw materials, aerosol devices and supplies consist of purchases of our active pharmaceutical ingredients (APIs) for the manufacture of our KL_4 surfactant product candidates and supplies to support our manufacturing and analytical testing and development laboratories operations. Raw materials, aerosol devices and supplies purchases increased $1.3 million from 2015 to 2016 due to an increase in aerosol device purchases for use in our ongoing AEROSURF phase 2 clinical trials.

Rents and utilities are costs related to our leased corporate headquarters and laboratory facility, and our former manufacturing operations. The decrease from 2015 to 2016 is due to the closure of our Totowa Facility in June 2015 following the cessation of commercial activities for SURFAXIN, and, in May 2016, under an amendment to our facility lease, a reduction of 9,088 square feet in the size of our leased premises at our corporate offices in Warrington, PA, and related adjustments to the base rent, our proportionate share of building expense, and utilities. The foregoing actions were implemented as part of an ongoing effort to reduce cash outflows and allocate our limited resources to advancing the AEROSURF clinical development program and our aerosolized KL_4 surfactant pipeline.

Contract manufacturing represents costs related to the technology transfer of our liquid and lyophilized KL_4 surfactant manufacturing processes to a CMO and manufacture of a sufficient supply of lyophilized KL_4 surfactant to support the planned AEROSURF phase 2 clinical development program. The decrease from 2015 to 2016 is related to adjustments that we made to the ongoing technology transfer of our lyophilized surfactant manufacturing process to a new facility at our CMO to conserve our cash resources and better align the manufacture of our clinical drug supply with our expected revised clinical time line.

The category “Other” consists primarily of ongoing research and development costs such as insurance, taxes, education and training and software licenses.

Allocation to batch production represents manufacturing, quality and analytical testing costs related to SURFAXIN batch production for commercial supply, medical affairs programs and other development activities.

Research and Development Projects

A substantial portion of our cumulative losses to date relate to investments in our research and development projects, for which we incurred $60.6 million in expenses for the two-year period ended December 31, 2016. Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are unknowns that may significantly affect cost projections and timelines. In view of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost of development of any of our product candidates are highly uncertain and cannot be estimated with any degree of certainty. In addition to the risks and uncertainties affecting our research and development projects discussed in this MD&A (see, “Item 1A – Risk Factors”), other risks could arise that we may not foresee that could affect our ability to estimate projections and timelines.

Our research and development programs have been focused initially on the management of RDS in premature infants. Our lead program, AEROSURF for the treatment of RDS in premature infants, involves the following projects (i) manufacturing development for our lyophilized KL_4 surfactant, initially for use in our AEROSURF clinical development program and, if AEROSURF is approved, commercial activities; (ii) the development and manufacture of a clinic-ready ADS to support our AEROSURF phase 2 clinical development program, and further development and manufacture of a new version (NextGen) of ADS under the collaboration agreement with Battelle potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities; and (iii) AEROSURF phase 2 clinical development program activities and preparatory work for the planned phase 3 clinical trial. Through the first quarter of 2015, we pursued the development, manufacture and commercialization of SURFAXIN liquid instillate for the prevention of RDS in premature infants at high risk for RDS, which was approved by the FDA in March 2012 and introduced commercially in early 2013. However, in April 2015, we determined to cease our manufacturing and commercial activities for SURFAXIN and focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL_4 surfactant pipeline.

For our AEROSURF clinical development program, we are presently enrolling a phase 2a clinical trial in premature infants 26 to 28 week gestational age and a phase 2b clinical trial in premature infants 28 to 32 week gestational age. Our key activities, including the potential timing and anticipated milestones, are discussed in “Item 1 – Business – Business Strategy.” We are also planning and preparing for potential additional development activities for AEROSURF, including a planned phase 3 clinical trial. To that end, we expect to make additional investments in scientific and clinical development capabilities, including advancing the manufacturing development activities at our CMO for our lyophilized KL_4 surfactant; continuing development of our NextGen ADS under our collaboration agreement with Battelle; and continuation of the ongoing phase 2 clinical trials, as well as preparation and potential initiation of the planned phase 3 clinical trial.

As discussed under Business Strategy, we believe that our aerosolized KL_4 surfactant, alone or in combination with other pharmaceutical compounds, may be an effective intervention for people at risk for, or with, manifestations of, acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, in the future we may explore other opportunities to apply KL_4 surfactant therapies to treat conditions such as chronic sinusitis, complications of certain major surgeries, and mechanical ventilator-induced lung injury (often referred to as VILI), severe acute respiratory syndrome (SARS), pneumonia and sepsis. However, there can be no assurance that we will secure the additional capital needed, through government-funded grant programs or otherwise, to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

Ultimately, if we do not successfully develop and gain marketing approval for our drug product candidates, in the U.S. or elsewhere, 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)	Years Ended December 31, 2016	2015
Selling, General and Administrative Expenses	$ 8,373	$ 11,004

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

Selling, general and administrative expenses include non-cash charges associated with stock-based compensation and depreciation of $0.8 million and $1.1 million for the years ended December 31, 2016 and 2015, respectively.

Selling, general and administrative expenses decreased $2.6 million from 2015 to 2016 due to our ceasing sales and marketing activities in connection with our decision in April 2015 to cease commercial and manufacturing activities for SURFAXIN, and focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL_4 surfactant pipeline. This decrease was partially offset by $1.4 million of severance charges during the first and second quarters of 2016 (*see*, " **–** Note 4 **–** Summary of Significant Accounting Policies").

We plan to continue investments in protecting our existing intellectual property, and in pursuing potential additional intellectual property rights, including patents, trademarks, and trade secrets, and regulatory exclusivity designations, such as potential orphan drug, new drug product exclusivities, Fast Track, breakthrough therapy, accelerated approval and priority review. *See*, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Years Ended December 31, 2016	2015
Change in Fair Value of Common Stock Warrant Liability	$ 223	$ 851

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 Topic 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 an appropriate valuation pricing model depending 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 fair value of common stock warrant liability."

The form of warrant agreement for the registered five-year warrants that we issued in the February 2011 public offering (2011 Warrants) contains anti-dilutive provisions that adjust the exercise price if we issue 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 2011 Warrants. Although by their express terms, these warrants are 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, at estimated fair value determined using a trinomial pricing model.

Changes in our common stock warrant liability are primarily related to changes in our common stock share price during the periods. The change for the year ended December 31, 2016 represents the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

Other Income / (Expense)

(in thousands)	Years Ended December 31, 2016	2015
Loss on debt extinguishment	$ -	$ (11,758)
Interest income	18	4
Interest expense	(2,518)	(4,583)
Other income	823	150
Other expense, net	$ (1,677)	$ (16,187)

The 2015 restructuring of a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield) (Deerfield) (*see*, " – Note 9 – Long-term Debt") qualified as an extinguishment of debt in accordance with ASC 470, *Debt-Modifications and Extinguishments*, and as a result, in 2015, we incurred an $11.8 million non-cash loss on debt extinguishment for the year ended December 31, 2015 consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which included $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part 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.

Interest expense primarily consists of interest expense associated with the Deerfield Loan (*see*, "– Liquidity and Capital Resources – Deerfield Loan").

Other income 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)	Years Ended December 31, 2016	2015
Amortization of prepaid interest expense	$ 1,710	$ 971
Cash interest expense	450	1,451
Non-cash amortization of debt discount	-	1,287
Debt discount write-off	-	707
Amortization of debt costs	-	12
Write-off of debt costs	-	66
Total interest expense	$ 2,160	$ 4,494

Amortization of prepaid interest expense represents non-cash amortization of $5 million of Series A Units and Series B units that Deerfield purchased in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Notes. Cash interest expense represents interest at an annual rate of 8.25% and 8.75%, respectively, in 2016 and 2015 on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants prior to the second amendment to the Deerfield Loan. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2016, we had cash and cash equivalents of $5.6 million, current liabilities of $13.4 million 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 debt is payable in two equal installments in February 2018 (subject to a potential one-year deferral if we have achieved a market capitalization of $250 million) and February 2019.

In February 2017, we completed a private placement offering for which we received net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration (*see*, "– Private Placement Offering"). In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings under our at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) resulting in net proceeds to us of $0.9 million (*see*, At-the-Market Program – Stifel ATM Program). Before any additional financings, including under our ATM Program or in connection with potential strategic transactions, we believe that we have sufficient cash resources available to support our development activities, business operations and debt service obligations through the planned completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 2017.

We expect to continue to incur significant losses and require significant additional capital to advance our AEROSURF clinical development program, support our operations and meet our debt service obligations beyond mid-year 2017, and we do not have sufficient existing cash and cash equivalents for at least the next year following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to raise additional capital through the following: (i) all or a combination of strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through public or private equity offerings (including pursuant to the ATM Program with Stifel). If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date that the financial statements are issued. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other restrictions (discussed below) and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to limit or cease our development activities and consider other means of creating value for our stockholders, such as licensing development and/or commercialization of products that we otherwise might plan to develop ourselves. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

We believe that our ability to fund our activities in the near term will be highly dependent upon whether our phase 2b clinical trial is deemed a success and we achieve results that are sufficiently positive to support a strategic transaction and/or equity financing. Our clinical trials are subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the trial in mid-year 2017 as planned, or at all. If our clinical trial should be further delayed for any reason, we likely would be compelled to end the phase 2b clinical trial earlier than planned, which may potentially have a negative impact on the results of the trial. Even if we are able to complete the phase 2b trial as planned, if the results of our clinical trial are inconclusive, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or safety profile, we may be unable to secure the additional capital that we will require to continue our development activities and operations, which could have a material adverse effect on our business.

Moreover, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) our 2014 Universal Shelf on Form S-3 will expire June 12, 2017 and our ability to file a replacement shelf registration statement may depend in large part on whether our common stock continues to be listed on The NASDAQ Stock Market ("Nasdaq"), (ii) since the market value of our common stock held by non-affiliated persons (public float) is less than $75 million, Form S-3 includes a "limited offering" rule that limits the size of primary securities offerings that we may conduct in any 12-month period to no more than one third of our public float calculated based on a closing price of our common stock within 60 days of a transaction. Transactions under our ATM Program are subject to this limitation, (iii) in May 2016, we received a deficiency notice from Nasdaq that we are no longer in compliance with the minimum stockholders' equity listing requirement. In January 2017, a Nasdaq Hearings Panel granted us a further extension through May 15, 2017, subject to certain conditions, to regain compliance with the Nasdaq listing requirements (*see*, "Nasdaq Deficiency Notice," below). If we fail to regain compliance during this extension period, our common stock may be delisted from Nasdaq and the value and liquidity of our common stock may be adversely affected, (iv) our stockholders may not approve, as required under Nasdaq listing rules, a strategic transaction recommended by our Board that is valued at a discount to the then-current market value of our common stock and involves the issuance of greater than 20% of our outstanding common stock, (v) our stockholders may not approve a potential stockholder proposal to increase the number of shares of common stock authorized under our Certificate of Incorporation, which could impair our ability in the future to conduct equity financings or enter into certain strategic transactions; (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (vii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions on our ability to conduct primary offerings on Form S-3, to be in a position to raise more than one third the value of our public float, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL_4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. We recently announced that we have been awarded a Phase II Small Business Innovation Research Grant (SBIR) grant valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF phase 2b clinical trial in premature infants 28 to 32 week gestational age. In 2016, we received and expended $0.9 million of this award. We have also received grants that supported medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In June 2016, we announced the results of a study funded by the NIH that KL_4 surfactant could potentially be an effective medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (pneumonopathy) due to exposure from a nuclear accident or act of terrorism. In addition, in February 2017 we announced the results of a study funded by the NIH that KL_4 surfactant could be a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

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

As of December 31, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance. Upon exercise of the pre-funded warrants, we would issue shares to the holders and receive no additional proceeds. In addition, as of December 31, 2016, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 40.7 million shares of common stock and 5 million shares of preferred stock available for issuance and not otherwise reserved.

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

Nasdaq Deficiency Notice

On May 19, 2016, we received a notification letter from the Staff of the Listings Qualifications Department of Nasdaq (Staff) notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, we reported stockholders' deficit of $5.0 million. The Staff noted that, as of May 19, 2016, we also did not meet either of the alternative compliance standards under Nasdaq Listing Rule 5550(b) of (i) a market value of listed securities of at least $35 million, or (ii) net income of $500,000 from continuing operations. Nasdaq granted us an extension to regain compliance until November 15, 2016. We did not regain compliance by that date, and the Staff issued a written delisting notification that our common stock would be delisted. At that time, we filed an appeal and received a hearing with the Nasdaq Hearings Panel on January 12, 2017. The Nasdaq Hearings Panel determined to allow us continued listing on Nasdaq until May 15, 2017, while we work to regain compliance with all applicable criteria for continued listing on Nasdaq. During the extension, we are required to provide the Panel interim reports of our progress toward regaining compliance. If we fail to demonstrate a reasonable likelihood of regaining compliance on or before May 15, 2017, the Panel will issue a final delist determination and our stock will be delisted from trading on Nasdaq. We submitted our first status report on February 17, 2017. Any further appeal at that time would not stay the delisting of our stock from Nasdaq.

As of December 31, 2016, we had stockholders' deficit of $28.8 million and a market value of listed securities of $10.9 million, and as of March 23, 2017, we remained out of compliance with the Nasdaq Listing Rules. There can be no assurance that we will be able to regain compliance with either the minimum stockholders' equity rule or the minimum value of listed securities rule within the extension period, or at all.

Cash Flows

As of December 31, 2016 and 2015, we had cash and cash equivalents of $5.6 million and $38.7 million, respectively. Net cash outflows for 2016 consisted of $33.6 million used for ongoing operating activities and $0.3 million for investing activities offset by cash inflows for 2016 of $0.7 million for financing activities.

Operating Activities

Net cash used in operating activities was $33.6 million and $33.5 million for the years ended December 31, 2016 and 2015, 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 was $0.3 million and $0.2 million for the years ended December 31, 2016 and 2015, respectively, and represents capital expenditures, partially offset by proceeds from sale of property and equipment.

Financing Activities

Net cash provided by financing activities was $0.7 million and $27.7 million for the years ended December 31, 2016 and 2015, respectively, summarized as follows:

	Years Ended December 31,	
(in thousands)	**2016**	**2015**
Issuance of securities, net of expenses	$ 709	$ 32,629
Exercise of common stock warrants and options	-	136
Principal payments on long-term debt	-	(5,000)
Repayment of equipment loans	-	(62)
Cash flows from financing activities, net	$ 709	$ 27,703

The following sections provide a more detailed discussion of our cash flows from available financing facilities and activities.

Financings Pursuant to Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of equity offerings. In May 2014, we filed a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) with the SEC that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of December 31, 2016, after reserves for outstanding unexercised warrants and amounts remaining available under our ATM Program, approximately $139.8 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

Registered Public Offerings

On July 22, 2015, we completed a registered public offering of 1,791,667 Series A units and 3,000,000 Series B units each at a price per unit of $8.40, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 625,000 Series A units at a price per unit of $8.40 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see*, " – Note 9 – Long-term Debt"). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $9.80 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $8.40 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $9.80 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes. The offering was made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

Private Placement Offering

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units for net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration in the form of a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of (i) one share of Series A Convertible Preferred Stock; and (ii) 1,000 Series A-1 Warrants to purchase one share of Common Stock at an exercise price equal to $1.37.

Warrants

During the year ended December 31, 2015, holders of the 2011 Warrants exercised warrants to purchase 51,193 shares of our common stock at an exercise price of $2.66 per share, resulting in proceeds to us of $0.1 million. No warrants were exercised during the year ended December 31, 2016.

At-the-Market Program (ATM Program)

Stifel ATM Program

On February 11, 2013, we entered into an At-the-Market Equity Sales Agreement (ATM Agreement) with 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 over a three-year period up to a maximum of $25,000,000 of shares of our common stock (ATM Program). On February 11, 2016, we amended the ATM Agreement to extend the term three years until February 11, 2019. We are not required to sell any shares at any time during the term of the ATM Program.

If we issue a sale notice to Stifel, we may designate the minimum price per share at which shares may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell the shares by any method deemed to be an “at-the-market” equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers’ transactions on The Nasdaq Capital Market®, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. Either party may suspend the offering under the ATM Agreement by notice to the other party. 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 agreed to pay Stifel a commission equal to 3.0% of the gross sales price of any shares sold pursuant to the ATM Agreement. With the exception of expenses related to the shares, Stifel will be responsible for all of its own costs and expenses incurred in connection with the offering.

During the year ended December 31, 2016, we completed offerings of our common stock under our ATM Program of 360,263 shares, resulting in aggregate gross and net proceeds to us of approximately $0.7 million. In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings of our common stock under the ATM Program of 710,788 shares, resulting in aggregate gross and net proceeds to us of approximately $0.9 million.

As of December 31, 2016, approximately $22.3 million remained available under the ATM Program, subject to certain current limitations under our 2014 Universal Shelf as described in Note 3 – Liquidity Risks and Management’s Plans.

Long-term Debt

Long-term debt consists solely of amounts due under a $25 million loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	Years Ended December 31, 2016	2015
Deerfield Loan	$ 25,000	$ 25,000

Under the terms of the Deerfield loan agreement, Deerfield made two advances, the first upon execution of the agreement in February 2013 in the amount of $10 million, and the second upon the first commercial sale of SURFAXIN in December 2013 in the amount of $20 million. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement also contains customary terms and conditions, representations and warranties and affirmative and negative covenants, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets, but it does not require us to meet minimum financial and revenue performance covenants. In addition, all amounts outstanding under the Deerfield Loan may become immediately due and payable upon (i) an “Event of Default,” as defined in the Deerfield Loan agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of our assets (a Major Transaction).

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 0.2 million shares of our common stock at an exercise price of $39.34 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 0.3 million shares of our common stock at an exercise price of $39.34 per share (together with the warrants issued in connection with the execution of the agreement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price will be, and have been, adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock. The Deerfield Warrants will expire on the sixth anniversary of the Deerfield Loan agreement, February 13, 2019, and contain limitations on the ability of a holder to exercise the Deerfield Warrants if after such exercise, the holder would beneficially own more than 9.985% of the total number of shares of our common stock then issued and outstanding. The Deerfield Warrants may be exercised in whole or in part either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Deerfield Warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the Deerfield Warrants or that portion of the Deerfield Warrants for cash in an amount equal to the Black-Scholes value (as defined in the Deerfield Warrants) of the Deerfield Warrants or that portion of the Deerfield Warrants redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the Deerfield Warrants and receive therefor that number of shares of common stock that equals the Black-Scholes value of the Deerfield Warrants or that portion of the Deerfield Warrants exercised. Prior to a holder exercising the Deerfield Warrants for shares in such transactions, the Company may elect to terminate the Deerfield Warrants or that portion of the Deerfield Warrants being exercised and pay the holder cash in an amount equal to the Black-Scholes value of the Deerfield Warrants.

We initially recorded the loan as long-term debt at its face value of $30.0 million less debt discounts and issuance costs consisting of (i) $11.7 million fair value of the Deerfield Warrants issued upon the First Disbursement and the Second Disbursement (0.5 million warrants in total), and (ii) a $450,000 transaction fee. The discount was being accreted to the $30 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 and have been classified as equity.

On July 9, 2015, we entered into an amendment to our Deerfield Loan agreement and related notes (Deerfield Notes) to better align our Deerfield Loan principal repayment obligations with anticipated milestones under our clinical development program for AEROSURF. Under the terms of the amendment, (i) upon execution, we prepaid in cash $2.5 million of the principal amounts outstanding, (ii) on July 22, 2015, upon the occurrence of the July 2015 public offering, we prepaid in cash an additional $2.5 million of the principal amounts outstanding, (iii) the principal installment originally due in February 2017 was eliminated and (iv) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million. We also paid Deerfield’s expenses (including reasonable counsel fees and expenses) incurred in connection with the amendment. Under the Deerfield Loan agreement, the $12.5 million principal installment due in February 2018 may be deferred one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement.

On July 22, 2015, we entered into a second amendment to our Deerfield Loan agreement and Deerfield Notes, pursuant to which (a) upon closing the July 2015 public offering on July 22, 2015, we prepaid in cash $2.5 million of the principal amounts outstanding, as contemplated by the first amendment, and (b) Deerfield purchased and accepted $5 million Series A and Series B units offered in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. In addition, (i) we paid in cash when due on September 30, 2015, all accrued and unpaid interest under the Deerfield Notes for the period from June 30, 2015 to July 22, 2015 at the original rate of 8.75%; (ii) Deerfield agreed to apply the $5 million prepaid interest accruing from and after July 23, 2015, as and when such payments are due and payable, as follows; first, to interest accruing on the $12.5 million principal installment due on February 13, 2019, and second, to interest accruing on the $12.5 million principal installment due on February 13, 2018, until fully allocated, which is scheduled to occur at the end of the second quarter of 2016; (iii) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Notes will accrue at a rate of 8.25% per annum; and (iv) no credit will be given with respect to prepaid interest on principal under the Deerfield Notes that is prepaid, in whole or in part, except for a prepayment at our election or a prepayment required under the Deerfield Loan agreement in connection with a Major Transaction that qualifies as a "Qualified Major Transaction." A "Qualified Major Transaction" means a change of control transaction (as defined in the Deerfield Warrants), in which (i) we are not the surviving entity and (ii) our common stock valuation (as defined in the Deerfield Warrants) immediately prior to the change of control transaction equals or exceeds $100 million. In addition, we paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the second amendment.

The restructuring of the Deerfield Loan was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and in 2015, as a result, we incurred an $11.8 million non-cash loss on debt extinguishment for the year ended December 31, 2015 consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which includes $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part 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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2016 or 2015, or during the periods then ended.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See, Index to Consolidated Financial Statements on Page F-1 attached hereto.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

(a) 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), do 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 Annual Report on Form 10-K. 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.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated 2013 Framework. Based on our assessment, our management believes that our internal control over financial reporting is effective based on those criteria, as of December 31, 2016.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

(c) Changes in internal controls

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 December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors of the Company

The following table sets forth the names of the persons serving on our Board of Directors (the "Board"). Our stockholders elect the directors to serve until the next annual meeting of stockholders and, if applicable, until their successors are duly elected and qualified.

Name	Position with the Company
John R. Leone	Chairman of the Board
Craig Fraser	Director, President and Chief Executive Officer
Joseph M. Mahady	Director
Bruce A. Peacock	Director
Marvin E. Rosenthale, Ph.D.	Director

John R. Leone, age 69**,** has served as a member of our Board of Directors since November 2012 and was elected Chairman in January 2013. He serves as a member of the Board's Compensation Committee and the Nomination and Governance Committee. With over 30 years of experience, Mr. Leone has built an outstanding track record in pharmaceutical operations, commercial portfolio management, and financing life science companies. His commercial experience includes significant domestic and international executive management roles and direct responsibility for the commercial launch of numerous pharmaceutical products.

Mr. Leone is currently an Operating Partner at Madryn Asset Management, an investment platform focused on providing capital to healthcare companies. Madryn Asset Management was spun out from Visium Asset Management where Mr. Leone was a Partner from May 2013 to January 2017. Prior to joining Visium, Mr. Leone was a Partner at Paul Capital Healthcare, a private equity firm that manages one of the largest dedicated healthcare funds globally (2007 to 2013). Previously, Mr. Leone served as President and Chief Executive Officer at Cambrex Corporation, and as Senior Vice President and Chief Operating Officer of U.S. Commercial Operations at Aventis Pharmaceuticals. While at Aventis, he played a key role in spearheading the successful integration of its predecessor companies, Rhone-Poulenc Rorer and Hoechst Marion Roussel, and had responsibility for all commercial business units, including oncology, metabolism, cardiovascular, dermatology, respiratory and anti-infective. Mr. Leone also served on the Board of Directors at ViroPharma Incorporated from January 2006 until its acquisition in March 2014. Mr. Leone received his B.S. degree in Engineering from the U.S. Military Academy at West Point and his M.B.A. from the University of Colorado.

Craig Fraser, age 52, has served as President and Chief Executive Officer and a member of the Board since February 1, 2016. He brings over 28 years of experience as a leader in both product development and commercial operations and in building biopharmaceutical and device businesses for startups as well as larger companies. Prior to joining us, Mr. Fraser held executive positions at several biopharmaceutical companies, including Aegerion Pharmaceuticals as Chief Operating Officer (July 2014 to August 2015) and as President, International & Global Manufacturing and Supply (October 2011 to July 2014); as Vice President of Global Disease Areas at Pfizer (October 2009 to October 2011) and Vice President and Global Business Manager at Wyeth Pharmaceuticals (December 2007 to November 2009). Previously, Mr. Fraser served as Vice President, Sales & Marketing and Commercial Operations and as Vice President, Global Strategic Marketing at Johnson & Johnson; and as Gastroenterology Franchise Lead, National Sales Director – Immunology and Acute Cardiovasculars, and Marketing Director – Cardiovasculars and Diagnostics at Centocor. Mr. Fraser is a veteran of both the U.S. Marine Corps and the U.S. Army. Mr. Fraser does not serve on any other public company boards. Mr. Fraser received his B.S. degree in Public Administration from Slippery Rock University of Pennsylvania.

Joseph M. Mahady, age 64, has served as a member of our Board since January 2013. He also serves as Chairman of the Board's Compensation Committee and a member of the Audit Committee. Mr. Mahady has extensive strategic and operational experience in the biopharmaceutical industry. He has broad international commercial experience, having served in a direct leadership role in more than 30 product launches, and has a successful record of developing profitable businesses based on transformational technologies in both the U.S. and international markets.

Mr. Mahady held significant leadership positions during his 30-year career with Wyeth Corporation, including as President, Wyeth Pharmaceuticals (2008 – 2009), and Senior Vice President, Wyeth Corporation (2002 – 2009), with responsibility to direct the worldwide operations of that company's $20 billion global pharmaceutical business. He retired from Wyeth in 2009. Since his retirement, Mr. Mahady served as Chairman of Lumara Health (formerly KV Pharmaceuticals) and as a member of the boards of directors of Albemarle, EKR Therapeutics and Strongbridge Biopharma. Mr. Mahady received his B.S. degree in Pharmacy from St. John's University College of Pharmacy and his M.B.A. in Pharmaceutical Studies from Fairleigh Dickinson University.

Bruce A. Peacock, age 65, has served as a member of our Board since September 2010. He also serves as Chairman of the Board's Audit Committee and is a member of the Compensation and the Nomination and Governance Committees. Mr. Peacock brings to our Board extensive biotech and pharmaceutical experience, including financial expertise in debt, equity capital and alliance transactions. He also has significant experience in drug development, having led the effort to gain regulatory approval for several drug candidates in the United States and in other major markets worldwide. Mr. Peacock also has had responsibility for marketing, commercial and manufacturing operations.

Mr. Peacock has served as a Venture Partner with SV Life Sciences Advisers LLC since 2006. From August 2013 to September 2014, Mr. Peacock served as Chief Financial and Business Officer of Ophthotech Corporation, having served as Chief Business Officer since September 2010. Previously, he served as President and Chief Executive Officer of Alba Therapeutics; Chief Executive Officer and Director of The Little Clinic, a medical care services company; President and Chief Executive Officer and a Director of Adolor Corporation, a publicly-held biotechnology company; President, Chief Executive Officer and a Director of Orthovita Inc., a publicly-held orthopaedic biomaterials company; Executive Vice President, Chief Operating Officer and a Director of Cephalon Inc.; and Chief Financial Officer of Centocor Inc. Mr. Peacock serves as Co-Chairman of the Board of Alba Therapeutics and as a member of the boards of directors of the following publicly held biopharmaceutical companies: since September 2014, Dicerna Pharmaceuticals, Inc.; and since July 2014, Ocular Therapeutix. Mr. Peacock previously served as a member of the Board of Directors of AGTC Genetic Technologies Corporation (March 2015 - August 2016). Since 2012, Mr. Peacock has served as a member of the board of directors of Invisible Sentinel, Inc., since 2015, PanOptica, Inc. and, since 2016 CARMA Therapeutics, all three privately-owned companies. Mr. Peacock earned a bachelor's degree in Business Administration from Villanova University and is a certified public accountant.

Marvin E. Rosenthale, Ph.D., age 83, has served as a member of our Board since 1998. He also serves as Chairman of the Board's Nomination and Governance Committee and is a member of the Audit Committee. Dr. Rosenthale brings to our Board more than 50 years of management and executive experience in the pharmaceutical industry. In addition, since 1998, he has served as a member of the board of directors of nine pharmaceutical companies, which provides him a broad perspective of the customs, practices and strategic priorities of pharmaceutical companies in today's challenging competitive and financial markets.

Prior to his retirement in 1999, Dr. Rosenthale served as President and Chief Executive Officer of Allergan Ligand Retinoid Therapeutics, Inc., having joined as Vice President in 1993. Previously, over a period of 16 years, Dr. Rosenthale served in a variety of executive positions at Johnson & Johnson, including Vice President, Drug Discovery Worldwide, at R.W. Johnson Pharmaceutical Research Institute, and director of the divisions of pharmacology and biological research and Executive Director of Drug Discovery Research at Ortho Pharmaceutical. Dr. Rosenthale also served in various positions with Wyeth Laboratories. Dr. Rosenthale has served on the boards of directors of NuRx Pharmaceuticals Inc. (2008-2010) and Radiant Pharmaceuticals Corp. (formerly AMDL, Inc., 2000-2006). Dr. Rosenthale received a Ph.D. in pharmacology from Hahnemann Medical College, a M.Sc. in pharmacology from Philadelphia College of Pharmacy & Science and a B.Sc. in pharmacy from the Philadelphia College of Pharmacy & Science.

Executive Officers and Key Officers and Employee

The following table sets forth the names and positions of our executive officers and leaders of important functional groups. The Board approves the election of officers annually and such officers serve until the meeting of the Board following the next annual meeting of the stockholders and, if applicable, until their successors are duly elected and qualified:

Name	Position with the Company
Craig Fraser	President and Chief Executive Officer
Steven G. Simonson, M.D.	Senior Vice President and Chief Development Officer
John A. Tattory	Senior Vice President and Chief Financial Officer
Mary B. Templeton, Esq.	Senior Vice President, General Counsel and Corporate Secretary
Kathryn A. Cole	Senior Vice President, Human Resources
George Cox	Vice President, Technical Operations
Lawrence A. Weinstein	Vice President, Medical Device Development
Ronald Dundore, Ph.D.	Executive Director, Regulatory Affairs and Quality

Mr. Fraser's biographical information appears above.

Steven G. Simonson, M.D., age 58, was appointed our Senior Vice President and Chief Development Officer in October 2014, having served as our Vice President, Clinical Development, since joining the Company in May of 2014. Dr. Simonson brings over 25 years of medical practice and pharmaceutical industry clinical trial experience with a significant background in pulmonary critical care and developing respiratory drugs to the Company, including preclinical, first time into man and phases 1-4, and IND, NDA and sNDA experience. Dr. Simonson spent 15 years at AstraZeneca Pharmaceuticals in areas of medical and clinical leadership primarily in the pulmonary and infection therapeutic areas. He has been involved in or led several successful IND and NDA filings including the Pulmicort® Turbuhaler® M3 NDA, which was approved for treatment of asthma. He spent the next two years as Vice President of Clinical Development at Agennix, Inc., a biopharmaceutical company primarily focused in oncology and sepsis, leading programs including studies of talactoferrin in necrotizing enterocolitis, the second most common cause of morbidity in premature neonates. Most recently, Dr. Simonson was an Executive Director in the Molecule Development Group at Covance, a biopharmaceutical development services company, where he applied his experience to developing clinical development programs for small and mid-size biotech and pharmaceutical companies. Dr. Simonson completed training in internal medicine followed by a fellowship in pulmonary and critical care medicine at Duke University Medical Center. He then held several faculty appointments at Duke in the departments of Anesthesiology and Medicine, including the divisions of Pulmonary and Critical Care Medicine. He is a Fellow of the American College of Chest Physicians, and author or co-author of multiple peer reviewed publications, abstracts, posters and chapters. Dr. Simonson received his medical degree from the Medical College of Wisconsin, and his Masters of Health Sciences degree in Biometry from the Duke University School of Medicine.

John A. Tattory, age 51, was appointed our Senior Vice President and Chief Financial Officer in March 2014, having previously served as our Vice President, Finance and Chief Accounting Officer (March 2013 - March 2014), and our Vice President, Finance, and Controller and the designated principal accounting officer (July 2010 - March 2013), and Vice President, Finance (January 2008 – July 2010). He brings more than 25 years of financial management and leadership experience, including directing U.S. and international financial operations, strategic transactions, licensing and collaboration arrangements, and equity and debt financings. Prior to joining us, Mr. Tattory held financial management positions at Tyco International, where he served as Director, Financial Planning & Analysis for Tyco Flow Control, an operating unit that included the majority of business operations in international markets; and Bristol-Myers Squibb (BMS), where he held financial roles of increasing responsibility, most recently as Finance Director, U.S. Primary Care, with responsibility for the financial matters of various BMS pharmaceutical businesses, including international operations. Previously, Mr. Tattory served as an Audit Manager with Ernst & Young LLP. Mr. Tattory is a certified public accountant (CPA) and holds a B.S. degree in Commerce from Rider University.

Mary B. Templeton, Esq., age 70, has served as Senior Vice President, General Counsel and Corporate Secretary since September 2011, having previously served as Senior Vice President and Deputy General Counsel since joining us in March 2006. Ms. Templeton brings to us more than 35 years of legal and senior management experience. Prior to joining us, Ms. Templeton held senior executive positions in the financial services industry, including as Senior Vice President and General Counsel of The Charles Schwab Corporation and as Senior Vice President and General Counsel of The Sequor Group Inc. (securities subsidiaries of Security Pacific Corporation) and was in private practice in Philadelphia and New York. Previously, at Charles Schwab & Co., Ms. Templeton led development of the first mutual fund marketplace, and, at Bradford Trust Company (New York), the first for-profit clearing corporation registered with the SEC. Ms. Templeton received a B.A. degree from Chatham University, where she is a member of the Board of Trustees, and a J.D. with High Honors from Rutgers Law School, where she was Editor-in-Chief of the Law Journal. She is a member of the Bar Associations of Pennsylvania and New York.

Kathryn A. Cole, age 51, has served as our Senior Vice President, Human Resources, since January 2006. Ms. Cole brings more than 20 years of extensive Human Resources experience, mostly in the life sciences industry, managing change and aligning human resources strategies with business objectives to ensure a focused, results-driven organization. Prior to joining us, Ms. Cole served as Vice President, Human Resources for Savient Pharmaceuticals Inc., in addition to other human resource management positions of increasing responsibility for Cytogen Corporation, EpiGenesis Pharmaceuticals, and the Prudential Insurance Company of America. Ms. Cole received her undergraduate degree in Communication from Douglass College and her M.S. degree in Industrial Relations and Human Resources from the Rutgers University School of Management and Labor Relations.

George Cox, age 65, currently serves as Vice President, Manufacturing & Supply Chain, having served as Vice President, Supply Chain, since April 2008. Mr. Cox brings more than 30 years of technical operations and supply chain experience, including directing multi-facility manufacturing in the United States and Europe and the establishment of agreements with various Contract Manufacturing Organizations to insure the supply continuity for both drug and medical device products. Prior to joining us, Mr. Cox served as Senior Director, Supply Chain with Auxilium Pharmaceuticals, where he implemented the organizational strategy to support the growth of the commercial and clinical operations. Mr. Cox has held executive technical operations positions at MedImmune, where he was instrumental in obtaining significant government contracts for the pandemic flu vaccine and the launch of their nasal seasonal flu vaccine, and Rhone-Polenc Rorer Pharmaceuticals, and also spent significant time in the financial arena including as plant controller for Proctor-Silex. Mr. Cox received a B.S. in Accounting from Villanova University.

Lawrence A. Weinstein, age 54, was appointed our Vice President, Medical Device Development, in May 2014. He brings over 30 years of respiratory medical device experience with significant direct experience working with capillary-based technologies, new product development, as well as operational and quality assurance activities. Mr. Weinstein was also involved in the successful launch of several respiratory products. Prior to joining the Company, Mr. Weinstein served as President and Chief Operating Officer for ALR Technologies (July 2010 – May 2014), President of Hydrate, Inc. and Senior Vice President of Operations for PRE Holding (2007 – June 2010), and Vice President of Product Technology at PARI (2003 2007). Previously, Mr. Weinstein served as Director of Technology for DHD Healthcare as well as several roles of increasing responsibility with Cordis Corporation. Mr. Weinstein is a named inventor on over 20 U.S. patents. He is the author or co-author of over 20 published articles, abstracts and posters in aerosol drug delivery and respiratory humidification. Mr. Weinstein received his M.B.A. and a M.S. degree in Industrial Engineering from the University of Miami.

Ronald L. Dundore, Ph.D., age 62, has served as our Executive Director of Regulatory Affairs and Quality since July 2016, having previously served as Executive Director of Regulatory Affairs since joining us in November 2015. He has over 25 years of pharmaceutical industry experience in all phases of drug development from preclinical research and development through post-approval activities. Prior to joining us, Dr. Dundore held various positions in industry and government; Principal Consultant at PAREXEL International (June 2013-November 2015), Vice President of US Regulatory Affairs at Pharmaxis (May 2012-June 2013), Vice President of Regulatory and Quality Affairs at InfaCare Pharmaceutical Corp. (September 2006-May 2012), Director of Regulatory Affairs at AstraZeneca, Associate Director of Regulatory Affairs at Rhone-Poulenc Rorer/Aventis, Senior Regulatory Specialist at Zeneca, Pharmacology and Toxicology Reviewer at FDA, and Principal Research Investigator at Sterling-Winthrop Pharmaceuticals. Dr. Dundore received a B.S. in Biology and a Ph.D. in Pharmacology from The Pennsylvania State University and was a Research Fellow in the Departments of Internal Medicine and Pharmacology, University of Iowa College of Medicine.

Family Relationships

There are no family relationships among our directors or executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), requires our directors, officers (including a person performing a principal policy-making function) and persons who beneficially own more than 10% of a registered class of our equity securities (collectively, “Reporting Persons”) to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Reporting Persons are required by SEC regulations to furnish us with copies of all filings they make under Section 16(a) and we are required to identify those Reporting Persons who failed to make such filings timely. Based solely on a review of the copies of any such filings made available to us and written representations from our officers and directors, we believe that all Reporting Persons complied with the filing requirements under Section 16(a) of the Exchange Act during the year ended December 31, 2016.

Procedures for Recommending Nominees to our Board

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board since we described those procedures in our proxy statement for our 2016 Annual Meeting of Stockholders, which we filed with the SEC on May 24, 2016.

Audit Committee

The Audit Committee of the Board is a standing committee of our Board and currently consists of Bruce A. Peacock, Joseph M. Mahady and Marvin E. Rosenthale, Ph.D. The primary purpose of the Audit Committee is to assist the Board of Directors in fulfilling its oversight responsibilities relating to our accounting, reporting and financial practices, and our compliance with the all related legal and regulatory requirements, including oversight of:

- the maintenance by management of the reliability and integrity of the Company's accounting policies, financial reporting and disclosure practices, and tax compliance;
- the establishment and maintenance by management of processes to assure that an adequate system of internal control is functioning within the Company; and
- the establishment and maintenance by management of processes to assure compliance by the Company with all applicable laws, regulations and Company policy.

In addition, the Audit Committee is responsible for, among other things, the appointment, compensation and oversight of the work of any registered public accounting firm engaged (including resolution of disagreements between management and the auditor regarding financial reporting), reviewing the range and cost of audit and non-audit services performed by our independent accountants, reviewing the adequacy of our systems of internal control, and reviewing all related party transactions. In discharging its role, the Audit Committee is empowered to investigate any matter brought to its attention and has full access to all of our books, records, facilities and personnel. The Audit Committee also has the power to retain such legal, accounting and other advisors as it deems necessary to carry out its duties.

The Board has adopted a written Audit Committee Charter. The composition and responsibilities of the Audit Committee and the attributes of its members, as reflected in its Charter, are intended to be in accordance with applicable listing requirements of The Nasdaq Capital Market ("Nasdaq") and the rules of the SEC for corporate audit committees. All members of our Audit Committee are "independent" as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules and the financial sophistication requirements of the SEC rules and Nasdaq Listing Rule 5605(c)(2)(A). The Board has determined that Bruce A. Peacock is an "audit committee financial expert" as defined under SEC rules. *See,* Mr. Peacock's biographical information in "Directors of the Company," above.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the Code of Business Conduct and Ethics on our Internet website at "http://www.windtreetx.com" under the "Company" tab in the Corporate Governance section. We intend to make all required disclosures on our website concerning any amendments to, or waivers from, our Code of Business Conduct and Ethics with respect to our executive officers and directors. Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

Named Executive Officers

The following table summarizes, for the years 2016 and 2015, the compensation of (1) each individual who served as our principal executive officer at any time during 2016 and (2) the two most highly-compensated executive officers (other than the principal executive officer) who were serving as executive officers on December 31, 2016 ranked by their total compensation for the fiscal year ended December 31, 2016, to whom we collectively refer herein as our "Named Executive Officers."

To improve readability, the following columns have been removed from the table as there is no reportable information with respect to these items: "Stock Award," "Non-Equity Incentive Plan Compensation" and "Nonqualified Deferred Compensation Earnings."

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Award ($)(1)	All Other Compensation ($)(2)	Total ($)
Craig Fraser						
President and Chief Executive Officer	2016	$ 381,017	$ -	$ 376,564	$ 6,237	$ 763,818
Steven G. Simonson, M.D.						
Senior Vice President and	2016	329,167	-	87,567	12,000	428,734
Chief Development Officer	2015	315,000	100,000	242,633	18,001	675,634
John A. Tattory						
Senior Vice President,	2016	288,150	-	67,559	8,100	363,809
Chief Financial Officer and Treasurer	2015	265,850	77,000	132,345	10,875	486,070
John G. Cooper						
Former President and	2016	34,849	-	225,417	667,513(4)	927,779
Chief Executive Officer (3)	2015	400,000	150,000	308,805	18,001	876,806

(1) Represents the grant date fair value of the stock options computed in accordance with Accounting Standards Codification (ASC) Topic 718 "Stock Compensation" (ASC Topic 718). The assumptions that we utilized are described in Note 11, Stock Options and Stock-based Employee Compensation, to our consolidated financial statements for the year ended December 31, 2016. The amounts reported in this column have not been paid to, nor realized by, the Named Executive Officer. In connection with his hiring on February 1, 2016, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 204,863 shares of our common stock, representing 2.5% of our outstanding shares, at an exercise price of $2.33 per share, which was the closing price on February 2, 2016 and the price next determined after approval of the grant. The Compensation Committee approved grants to Dr. Simonson and Mr. Tattory on February 2, 2016 for 35,714 and 23,214 shares, respectively, each with an exercise price of $2.33. The Compensation Committee approved grants to Mr. Fraser, Dr. Simonson and Mr. Tattory on July 28, 2016 for 40,000, 25,000 and 25,000 shares, respectively, each with an exercise price of $1.77. The Compensation Committee approved grants to Dr. Simonson, Mr. Tattory and Mr. Cooper, on March 27, 2015 for 19,643, 10,714 and 25,000 shares, respectively, each with an exercise price of $16.38. All options vest in three equal annual installments beginning with the first year anniversary of the date of grant. All options have a term of 10 years.

Also, in accordance with Mr. Cooper's executive employment agreement, upon termination of his employment, his Executive Equity Awards continue to vest for a period of 18 months, and will be exercisable for a period of 36 months after the date of termination. An additional incremental fair value was computed as of January 31, 2016 for Mr. Cooper, reflecting the modification of the award for the required service period.

(2) The reported amount reflects the Company match under the Company's 401(k) Plan, except for Mr. Cooper in 2016 (See Note (4) below). During 2016 and 2015, as applicable, the aggregate perquisites and other personal benefits afforded to each Named Executive Officer was less than $10,000, calculated as the incremental cost of providing such benefits to each Named Executive Officer, in accordance with SEC disclosure rules. This amount does not include the cost of medical and health benefits, as such benefits are available to all of our employees. See also, "- Retirement Benefits," and "- Executive Employment Agreements."

(3) Mr. Cooper resigned his position effective January 31, 2016.

(4) The reported amount reflects amounts paid to Mr. Cooper in accordance with his Executive Employment Agreement - Severance ($550,000); Accrued Vacation ($117,513).

Outstanding Equity Awards at Fiscal Year-End 2016

The following table shows the number of shares covered by exercisable and unexercisable options held by the Named Executive Officers on December 31, 2016. To improve readability, the following columns have been removed from the table as there is no reportable information with respect to these items: “Option Awards – Equity Incentive Plan Awards: No. of Securities Underlying Unexercised Unearned Options,” “Stock Awards: Number of Shares or Units of Stock That Have Not Vested,” and “– Market Value of Shares or Units of Stock That Have Not Vested.”

Named Executive Officer	Option Awards			
	No. of Securities Underlying Unexercised Options -Exercisable	No. of Securities Underlying Unexercised Options -Unexercisable	Option Exercise Price ($)*	Option Expiration Date
Craig Fraser		204,863(1)	$ 2.33	2/2/26
		40,000(2)	1.77	7/28/26
Steven G. Simonson, M.D.	6,191	2,380(3)	23.80	5/19/24
	6,549	13,094(4)	16.38	3/27/25
		35,714(5)	2.33	2/2/26
		25,000(2)	1.77	7/28/26
John A. Tattory	357		378.00	1/28/18
	238		405.30	9/16/18
	95		254.10	12/12/18
	5,357		25.62	10/7/21
	2,857		37.94	5/4/22
	5,715		33.04	3/26/23
	4,287	2,142(6)	36.12	3/6/24
	3,573	7,141(4)	16.38	3/27/25
		23,214(5)	2.33	2/2/26
		25,000(2)	1.77	7/28/26
John G. Cooper	762		686.70	6/21/17
	714		548.10	12/11/17
	1,270		405.30	12/12/18
	635		254.10	12/12/18
	17,857		25.62	2/1/19
	9,286		37.94	2/1/19
	25,000		33.04	2/1/19
	4,762	2,381(7)	36.12	2/1/19
	8,335	16,665(8)	16.38	2/1/19

* Adjusted where applicable to reflect the 1-for-15 reverse stock split effective December 28, 2010 and the 1-for-14 reverse stock split effective January 22, 2016.

(1) In connection with the hiring of Mr. Fraser on February 1, 2016, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 204,863 shares of our common stock, representing 2.5% of our outstanding shares. These options vest in equal installments on the first three anniversaries of the February 1, 2016 grant date, assuming that the officer continues to be employed with the company through each vesting date. These options expire on the tenth anniversary of the grant date.

(2) These options vest and become exercisable in equal installments on the first three anniversaries of the July 28, 2016 grant date, assuming that the officer continues to be employed with the company through each vesting date. These options expire on the tenth anniversary of the grant date.

(3) Represents unvested portion of option award that began vesting as follows: 1,429 vested on the May 29, 2014 grant date and thereafter the remaining options began vesting in three equal annual installments on the first anniversary of the May 19, 2014 grant date. The unvested portion will vest on the third anniversary of the May 29, 2014 grant date, assuming that the officer continues to be employed with the company through that vesting date. These options expire on the tenth anniversary of the grant date.

(4) Represents the unvested portion of the option award that began vesting in three equal annual installments on the first anniversary of the March 27, 2015 grant date. The unvested portion will vest in two equal installments on the second and third anniversaries of the March 27, 2015 grant date, assuming that the officer continues to be employed with the company through each vesting date. These options expire on the tenth anniversary of the grant date.

(5) These options vest and become exercisable in equal installments on the first three anniversaries of the February 2, 2016 grant date, assuming that the officer continues to be employed with the company through each vesting date. These options expire on the tenth anniversary of the grant date.

(6) Represents the unvested portion of the option award that began vesting in three equal annual installments on the first anniversary of the March 6, 2014 grant date. The unvested portion will vest in two equal installments on the second and third anniversaries of the March 6, 2014 grant date, assuming that the officer continues to be employed with the company through each vesting date. These options expire on the tenth anniversary of the grant date.

(7) Under his employment agreement with us, Mr. Cooper's options continue to vest through August 1, 2017, a period of 18 months after the February 1, 2016 executive employment agreement termination date. Mr. Cooper's options are exercisable until the earlier of the expiration of their term or February 1, 2019, a period of 36 months after the February 1, 2016 executive employment agreement termination date. The unvested portion will vest on the third anniversary of the March 6, 2014 grant date.

(8) Under his employment agreement with us, Mr. Cooper's options continue to vest through August 1, 2017, a period of 18 months after the February 1, 2016 executive employment agreement termination date. Mr. Cooper's options are exercisable until the earlier of the expiration of their term or February 1, 2019, a period of 36 months after the February 1, 2016 executive employment agreement termination date. One half of the unvested portion will vest on the second anniversary of the March 27, 2015 grant date. The remaining one half will not vest due to the terms of the executive employment agreement.

Retirement Benefits

During 2016, none of our Named Executive Officers participated in any plan that provides for the payment of retirement benefits, or benefits that will be paid primarily following retirement, other than our 401(k) savings plan ("401(k) Plan"). Under the 401(k) Plan, eligible employees (as defined in the 401(k) Plan) may elect to make pre-tax deferrals or Roth deferrals up to the maximum amount allowed by law (which was limited for this purpose in 2016 to $18,000). The 401(k) Plan also permits (i) rollover contributions and (ii) catch up contributions by employees age 50 and over (which was limited for this purpose in 2016 to $6,000). Under the 401(k), we may make matching contributions, which equaled 50% of an employee's deferred compensation in 2016, and 75% of an employee's deferred compensation in 2015. We satisfy our commitment to make a quarterly match on regular contributions and a year-end match on all catch up contributions in the form of shares of our common stock determined by reference to the lower of (i) the average closing price of shares of our common stock on all trading days in the applicable quarter, or (ii) the closing price of our common stock on the last trading day of the quarter.

Participant contributions are fully vested when made. Employer contributions in the form of shares generally vest in full over the first three years of service (as defined in the 401(k) Plan), with 34% vesting upon the anniversary of the first year of service, 33% vesting upon the anniversary of the second year of service, and 33% vesting upon the anniversary of the third year of service; provided, that a participant may not dispose of any shares of our common stock representing the employer contribution until all shares are fully vested at the end of the third year of service. The 401(k) Plan does not permit the acquisition or holding of employer securities, other than the shares of our common stock credited to participant accounts to satisfy the employer match. The 401(k) Plan contains standard provisions covering breaks in service, payment of expenses out of plan assets, hardship distributions, and distributions upon termination of employment, including retirement.

The 401(k) Plan is intended to be a qualified plan under the rules and regulations of the Internal Revenue Service. We act as Plan Administrator, the trustee and custodian of plan assets is The Charles Schwab Trust Company and the third party administrator is Sentinel Benefits & Financial Group. As Plan Administrator, and with the assistance of Sentinel Benefits & Financial Group, we determine the list of funds that will be made available to participants, who then direct the investment of their participant account balances among those funds. In addition, participants may elect to place their entire plan assets (other than shares of our common stock from the employer match that are not vested) in a self-directed brokerage account with Charles Schwab & Co., Inc.

Appointment of President and Chief Executive Officer

Effective on February 1, 2016, our Board appointed Craig Fraser to serve as our President and Chief Executive Officer. The Board also appointed Mr. Fraser to serve as a member of the Board, effective immediately. (See, "Part III – Item 10 – Directors, Executive Officers and Corporate Governance – Directors of the Company." At the time of his appointments, Mr. Fraser was not a related person to us and there was no transaction or other arrangement involving us under which Mr. Fraser or any of his related persons has or will have a direct or indirect material interest. He has no family relationship with any of our other directors or executive officers.

In connection with his hiring, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 204,863 shares of our common stock, representing 2.5% of our outstanding shares, at an exercise price of $2.33 per share, which was the closing price on February 2, 2016 and the price next determined after approval of the grant. These options will vest in three equal installments on the next three anniversary dates of the grant, provided that Mr. Fraser remains employed with us throughout the period. The option has a term of 10 years. Although issued outside the Company's 2011 Long-Term Incentive Plan (the 2011 Plan), the option is subject to terms and conditions that are generally consistent with the 2011 Plan and the form of option agreement in effect thereunder.

Executive Employment Agreements

On March 26, 2013, the Compensation Committee approved a form of executive employment agreement (the "Executive Agreements") for senior executive officers. These agreements had an initial term expiring on March 31, 2015. In December 2014, we entered into amendments to the Executive Agreements to eliminate automatic acceleration of outstanding equity awards upon a change in control and to extend the term of the agreements two years through March 31, 2017. The following describes the key terms of the Executive Agreements, including for Messrs. Fraser and Tattory and Dr. Simonson, as in effect on December 31, 2016.

- The Executive Agreements were effective February 1, 2016 for Mr. Fraser, April 1, 2014 for Mr. Tattory and December 19, 2014 for Dr. Simonson. Mr. Fraser's agreement is effective until terminated. For Mr. Tattory and Dr. Simonson, beginning on April 1, 2017, the Compensation Committee or an executive may determine not to renew an agreement and provide notice of non-renewal to the other party at least 90 days prior to the expiration date. Since no such notice was provided, the term of the Executive Agreements has automatically been extended for two additional years, until March 31, 2019. The Executive Agreements include a 12-month post-employment noncompetition agreement, an 18-month non-solicitation agreement, and provide for confidentiality and the assignment to us of all intellectual property. Mr. Fraser's base salary on the effective date of his agreement was $415,000. Effective in February 2016, the base salaries of Mr. Tattory and Dr. Simonson were increased to $290,000, and $330,000, respectively. Effective March 1, 2017, the base salaries of Messrs. Fraser and Tattory and Dr. Simonson were increased to $427,450, $318,375 and $339,075, respectively. Each executive has a target annual bonus ("Annual Bonus Amount"), which is a percent of base salary and is awarded at the discretion of the Compensation Committee. The Annual Bonus Amount for Mr. Fraser is 50%, and for each of Mr. Tattory and Dr. Simonson, 30%, of such individual's base salary.

- Upon termination by us without Cause or by the executive for Good Reason (in each case as defined in the Executive Agreements), in addition to any amounts or benefits that are due under any of our vested plans or other policy, and on the condition that the executive enters into a separation agreement containing a final and effective plenary release of claims in a form acceptable to us, each executive will be entitled to: (i) a pro rata bonus equal to a percentage of the executive's Annual Bonus Amount determined by dividing the total actual bonuses paid to other contract executives for the year in which the termination occurs by the aggregate of such other contract executives' total target bonuses for that year, and further prorated for the number of days the executive was employed in the year of termination, payable at the time that other contract executives are paid bonuses with respect to the year of termination; (ii) a severance amount equal to the sum of the executive's base salary then in effect (determined without regard to any reduction constituting Good Reason) and the Annual Bonus Amount, payable in equal installments from the date of termination to the date that is 12 months after the date of termination (the "Severance Period"); and (iii) all vested stock options, restricted stock grants and other similar equity awards held by the executive ("Executive Equity Awards") shall continue to be exercisable during the Severance Period. In addition, during the Severance Period, if the executive elects to continue medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), we will continue to pay our costs of the executive's and his or her dependents' benefits as in effect on the date of termination as such benefits are provided to active employees. If COBRA coverage is unavailable, we will reimburse the executive an amount which, after taxes, is sufficient to purchase medical and dental coverage substantially equivalent to that which the executive and his dependents were receiving immediately prior to the date of termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under our plans, and provided further, that our obligation to provide benefits will cease or be reduced to the extent that a subsequent employer provides substantially similar coverage. All of our obligations to an executive shall cease if at any time during the Severance Period the executive engages in a material breach of the Executive Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach.

- Upon termination in connection with a Change of Control (as defined in the Executive Agreements), in addition to the benefits that arise upon a Change of Control (discussed below) and any benefits that are due to an executive under any vested plans or other policies, the executive shall be entitled to: (i) a pro rata bonus equal to the executive's Annual Bonus Amount and prorated for the number of days the executive was employed in the year of termination, payable in a lump sum within 10 days after the date of termination; (ii) a severance amount equal to 1.5 times the sum of the executive's base salary then in effect (determined without regard to any reduction constituting Good Reason) and the Annual Bonus Amount, payable in a lump sum within 10 days after the date of termination except in certain circumstances; and (iii) all Executive Equity Awards shall accelerate and become fully vested and any restrictions under restricted stock agreements will be lifted. In addition, if the executive elects to continue medical benefits through COBRA, for a period of 18 months, we will continue to pay our costs of the executive's benefits as in effect on the date of termination as such benefits are provided to active employees. If COBRA coverage is unavailable, we will reimburse the executive an amount which, after taxes, is sufficient to purchase coverage that is substantially equivalent to the coverage available to comparable active employees on the date of termination, reduced by the amount that would be paid by comparable active employees, provided that our obligation to provide benefits shall cease or be reduced to the extent that a subsequent employer provides substantially similar coverage. All of our obligations to an executive shall cease if at any time during the Severance Period the executive engages in a material breach of the Executive Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach. If the foregoing payments shall be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties with respect to such excise tax, they will automatically be reduced to the extent and in the manner provided in the Executive Agreements.

- Upon a Change of Control and assuming the executive remains employed, (i) the term of the Executive Agreements (if shorter) shall be automatically extended until the second anniversary of the date of the Change of Control; and (ii) during the remaining term of the Executive Agreements (as extended), and provided that an executive is employed on the last day of a fiscal year ending in that period, the executive will be entitled to an annual bonus at least equal to the Annual Bonus Amount, payable no later than March 15 in the next succeeding fiscal year.

Executive Separation Agreements

Effective February 1, 2016, we and John G. Cooper, our then President and Chief Executive Officer, terminated his Executive Agreement dated April 1, 2013, as amended December 29, 2014. Under the terms of his Executive Agreement, Mr. Cooper is entitled to receive the benefits outlined above under the caption "Executive Employment Agreements" with respect to benefits in connection with a termination without Cause except as follows: (i) Mr. Cooper's severance amount equals 1.5 times the sum of his base salary then in effect (determined without regard to any reduction constituting Good Reason) and the Annual Bonus Amount; and, (ii) all Executive Equity Awards continue to vest through August 1, 2017, and are exercisable through February 1, 2019. In addition, Mr. Cooper agreed to cooperate in the transition of his duties and responsibilities as may be reasonably requested by the Company, and cooperate in other matters in which his cooperation may be reasonably requested for up to 10 hours per month during the Severance Period. The Company has agreed, with certain exceptions, to pay Mr. Cooper an hourly rate of $300 per hour for his time incurred in excess of 10 hours per month during the Severance Period. Since the date of termination through March 23, 2017, the Company has not requested Mr. Cooper's services related to any matters.

Director Compensation

Each of our non-employee directors receives cash compensation for his services. Directors who are also employees are not compensated separately for serving on the Board or any of its committees. On June 9, 2015, the Compensation Committee and Board approved cash compensation for non-employee directors as follows: (i) $8,750 per quarter for all directors other than the Chairman of the Board, and $15,000 per quarter for the Chairman of the Board; (ii) $3,750 per quarter for the director who served as Chairman of the Audit Committee; (iii) $2,500 per quarter for the director who served as Chairman of the Compensation Committee; (iv) $1,875 per quarter for the director who served as Chairman of the Nomination and Governance Committee; (v) $1,750 per quarter for each director who served as a non-Chairman member of the Audit Committee; (vi) $1,250 per quarter for each director who served as a non-Chairman member of the Compensation Committee; and (vii) $1,000 per quarter for each director who served as a non-Chairman member of the Nomination and Governance Committee. In addition, in order to better align the interests of our Board with our stockholders, the Compensation Committee considers and recommends to the Board long-term equity compensation. On August 4, 2016, in addition to approving retainers for the following year in the amounts authorized under the June 9, 2015 resolutions, the Compensation Committee approved an award to each non-employee director of options to purchase our common stock and restricted stock units as set forth in the table below. These awards, which were issued pursuant to our 2011 Plan, were approved after due consideration of the practices of other similarly situated biotechnology companies in providing equity compensation to their non-employee directors. The foregoing annual compensation amounts and equity awards will remain in effect until superseded. The Compensation Committee plans to conduct a review of peer company director compensation practices periodically, including before considering changes to our director compensation policy and amounts in the future.

The following chart summarizes the cash and non-cash compensation paid to our non-employee directors during the year ended December 31, 2016. To improve readability, the following columns have been removed from the table, as there is no reportable information with respect to these items: “Non-Equity Incentive Compensation” and “Change in Pension Value and Nonqualified Deferred Compensation Earnings.”

Name	Fees Earned or Paid in Cash	Stock Awards (1)	Option Awards (2)	Total
John R. Leone	$ 69,000	$ 8,000	$ 18,960	$ 95,960
Joseph M. Mahady	52,000	8,000	18,960	78,960
Bruce A. Peacock	59,000	8,000	18,960	85,960
Marvin E. Rosenthal, Ph.D.	49,500	8,000	18,960	76,460

(1) Represents the grant date fair value of the stock award, equivalent to the closing stock price on the grant date, computed in accordance with Accounting Standards Codification (ASC) Topic 718. On August 4, 2016, the Compensation Committee approved stock awards for each director of 4,348 restricted stock units. All restricted stock units awarded in 2016 vest in full on the first anniversary of the grant.

(2) Represents the grant date fair value of the stock options computed in accordance with ASC Topic 718 "Stock Compensation" (ASC Topic 718). The assumptions that we utilized are described in Note 11 - Stock Options and Stock-based Employee Compensation, to our consolidated financial statements for the year ended December 31, 2016. The amounts reported in this column have not been paid to, nor realized by, the Director. On August 4, 2016, the Compensation Committee approved grants for each director of options to purchase 15,000 shares with an exercise price of $1.84. These options vest in full on the first anniversary of the grant. All options have a term of 10 years.

In addition to the items included in the foregoing chart, directors are entitled to reimbursements for their travel, lodging and other expenses incurred in connection with attendance at meetings of the Board, Board committee meetings and related activities.

Pursuant to our charter documents, we indemnify our directors to the maximum extent permissible under the General Corporation Law of the State of Delaware. In addition, we have entered into indemnity agreements with our officers and directors that provide, among other things, that we will indemnify them, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings to which he or she is or may be made a party by reason of his or her position as a director, officer, or other agent of ours, and otherwise to the fullest extent permitted under the General Corporation Law of the State of Delaware and our Amended and Restated By-Laws (“By-Laws”). These agreements were updated and re-executed in January 2016.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

The following table describes as of December 31, 2016 the number of shares of our common stock issuable upon exercise of outstanding options. Except as described in footnote 3 to the table, there are no equity incentive plans not approved by security holders (other than our 401(k) Plan under which the company match is made in shares of our common stock), that line of the table has been omitted.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b) (4)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders				
2011 Long-Term Incentive Plan	941,892	$	11.91	1,042,313
2007 Long-Term Incentive Plan (1)	12,338	$	384.72	-
Amended and Restated 1998 Stock Incentive Plan (2)	506	$	652.50	-
Equity compensation plans not approved by security holders				
Inducement Grant (3)	204,863	$	2.33	-
Total	1,159,599	$	14.46	1,042,313

(1) The 2007 Plan terminated on the effective date of the 2011 Plan. All shares that were available under the 2007 Plan, including any that are expired forfeited or otherwise returnable to the 2007 Plan are transferred to and become available for grant under the 2011 Plan. All awards granted under the 2007 Plan continue to be governed by the terms of the 2007 Plan and the award agreements.

(2) The 1998 Plan expired on the effective date of the 2007 Plan. All awards granted under the 1998 Plan continue to be governed by the terms of the 1998 Plan and the award agreements.

(3) In connection with the hiring of Mr. Fraser on February 1, 2016, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 204,863 shares of our common stock, representing 2.5% of our outstanding shares.

(4) The Weighted-Average Exercise Price of Outstanding Options has been adjusted where applicable to reflect the 1-for-15 reverse stock split effective December 28, 2010 and the 1-for-14 reverse stock split effective January 22, 2016.

Security Ownership of Certain Beneficial Owners

The following table sets forth information regarding the beneficial ownership of our common stock (i) unless otherwise noted, as of March 23, 2017, by each current director and each executive officer set forth in the table below (each a “Named Executive Officer”) as of that date, (ii) as of March 23, 2017, by all directors and executive officers as a group, and (iii) as of the date noted in each related footnote, by the entities known by us to be the beneficial owners of more than five percent of the outstanding shares of our common stock.

Name and Address of Beneficial Owner (1)	Common Stock	Common Stock Equivalents (2)	Total Beneficial Ownership	Percentage of Class Beneficially Owned (1)
Non-Executive Directors				
John R. Leone	11,250	18,356	29,606	*
Joseph M. Mahady	6,211	22,356	28,567	*
Bruce A. Peacock	6,211	24,690	30,901	*
Marvin E. Rosenthale, Ph.D. (3)	8,669	8,071	16,740	*
Named Executive Officers				
Craig Fraser	11,193	75,288	86,481	*
Steven G. Simonson, M.D.	13,308	36,572	49,880	*
John A. Tattory	10,270	35,929	46,199	*
Former Officer				
John G. Cooper (4)	11,421	79,334	90,755	*
Executive Officers and Directors as a group (8 persons) (5)	**83,519**	**248,072**	**331,591**	**3.42%**
5% Security Holders				
Name and Address				
Alyeska Investment Group, L.P. (6)	464,768	680,571	1,145,339	9.99%
77 West Wacker Drive, 7th Floor				
Chicago, IL 60601				
Broadfin Capital, LLC (7)	854,409	2,907,762	3,762,171	9.99%
300 Park Avenue, 25th Floor				
New York, New York 10022				
Deerfield Management Company, L.P. (8)	-	1,095,239	1,095,239	9.99%
780 3rd Avenue, 37th Floor				
New York, NY 10017				
Hudson Bay Master Fund Ltd. (9)	-	669,000	669,000	6.62%
777 Third Avenue, 30th Floor				
New York, NY 10017				
Lee's Pharmaceutical Holdings Ltd. (10)	-	1,338,000	1,338,000	9.99%
Unit 110-111, Bio-Informatics Centre				
No. 2 Science Park Avenue, Hong Kong Science Park				
Shatin, Hong Kong				

(1) Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended ("Exchange Act") and includes voting and investment power with respect to shares of common stock. Shares of common stock, and shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days after March 23, 2017 held by each person or group named above are deemed outstanding for computing the percentage ownership of the person or group holding any options or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person or group. As of March 23, 2017, there were 9,439,365 shares of common stock issued and outstanding. The address of each individual person is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.

(2) Except where noted, Common Stock Equivalents include shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days after March 23, 2017 held by each person or group named above.

(3) Total beneficial ownership shown in the table includes 595 shares held by his spouse as to which Dr. Rosenthale disclaims beneficial ownership.

(4) Mr. Cooper resigned his position effective January 31, 2016.

(5) This information does not include securities held by Mr. Cooper, who is no longer an officer.

(6) This information is based on a Schedule 13G filed with the SEC on February 14, 2017 with respect to 643,339 shares of the 1,145,339 common stock beneficially owned by each of the following persons: (i) Alyeska Investment Group, L.P., (ii) Alyeska Investment Group, LLC, (iii) Alyeska Fund 2 GP, LLC, and (iv) Anand Parekh. The 1,145,339 common stock beneficially owned included Common Stock Equivalents consisting of warrants to purchase 178,571 shares of our common stock, as reported on the Schedule 13G, issued as part of the July 2015 public offering, and 503 Convertible Preferred Shares, convertible into 503,000 shares of our common stock that was part of the February 2017 securities purchase agreement. The form of both the July 2015 public offering and the February 2017 securities purchase agreement restricts the exercise or conversion of such securities to the extent that, upon exercise or conversion, the number of shares then beneficially owned by the holder and its affiliates and any other person or entities with which such holder would constitute a group under §13(d) of the Exchange Act would exceed 9.99% of the total number of shares then outstanding (the "Ownership Cap"). Notwithstanding the number of shares reported above, the reporting person is unable to exercise such warrants to the extent that after such exercise the Ownership Cap would be exceeded.

(7) This information is based on a Schedule 13G filed with the SEC on February 10, 2017 with respect to 854,409 shares of common stock beneficially owned by each of the following persons: (i) Broadfin Capital, LLC, (ii) Broadfin Healthcare Master Fund, Ltd., and (iii) Kevin Kotler. In addition, in connection with the July 2015 public offering and the February 2017 Securities Purchase Agreement, we issued Common Stock Equivalents consisting of warrants to purchase 1,904,762 shares of our common stock and 1,003 Convertible Preferred Shares, convertible into 1,003,000 shares of our common stock, respectively. The form of both the July 2015 public offering and the February 2017 securities purchase agreement restricts the exercise or conversion of such securities to the extent that, upon exercise or conversion, the number of shares then beneficially owned by the holder and its affiliates and any other person or entities with which such holder would constitute a group under §13(d) of the Exchange Act would exceed 9.99% of the total number of shares then outstanding (the "Ownership Cap"). Notwithstanding the number of shares reported above, the reporting person is unable to exercise such warrants to the extent that after such exercise the Ownership Cap would be exceeded.

(8) This information is based on a Schedule 13G filed with the SEC on February 14, 2017, by (i) Deerfield Mgmt, L.P., general partner of the entities identified in clauses (iv) through (vii) with respect to securities beneficially owned by such entities, (ii) Deerfield Management Company, L.P., an investment advisor for the entities identified in clauses (iv) through (vii) with respect to securities beneficially owned by such entities, (iii) James E. Flynn, (iv) Deerfield Special Situations Fund, L.P., (v) Deerfield Special Situations International Master Fund, L.P., (vi) Deerfield Private Design Fund II, L.P., and (vii) Deerfield Private Design International II, L.P. The Common Stock Equivalents listed above consist of warrants to purchase 1,095,239 shares of our common stock that contain a provision restricting the exercise or conversion of such securities to the extent that, upon exercise or conversion, the number of shares then beneficially owned by the holder and its affiliates and any other person or entities with which such holder would constitute a group under §13(d) of the Exchange Act would exceed 9.985% or 9.99% (depending on the warrant) of the total number of shares then outstanding (the "Ownership Cap"). Notwithstanding the number of shares reported, the reporting person disclaims beneficial ownership of the shares of common stock issuable upon exercise of such warrants to the extent that upon such exercise the number of shares beneficially owned by all reporting persons hereunder, in the aggregate, would exceed the Ownership Cap.

(9) The 669,000 common stock beneficially owned is for Common Stock Equivalents consisting of 669 Convertible Preferred Shares, convertible into 669,000 shares of our common stock that was part of the February 2017 Securities Purchase Agreement, the form of which restricts the exercise or conversion of such securities to the extent that, upon exercise or conversion, the number of shares then beneficially owned by the holder and its affiliates and any other person or entities with which such holder would constitute a group under §13(d) of the Exchange Act would exceed 9.99% of the total number of shares then outstanding (the "Ownership Cap"). The reporting person is unable to exercise such warrants to the extent that after such exercise the Ownership Cap would be exceeded.

(10) The 1,338,000 common stock beneficially owned is for Common Stock Equivalents consisting of 1,338 Convertible Preferred Shares, convertible into 1,338,000 shares of our common stock that was part of the February 2017 Securities Purchase Agreement, the form of which restricts the exercise or conversion of such securities to the extent that, upon exercise or conversion, the number of shares then beneficially owned by the holder and its affiliates and any other person or entities with which such holder would constitute a group under §13(d) of the Exchange Act would exceed 9.99% of the total number of shares then outstanding (the "Ownership Cap"). The reporting person is unable to exercise such warrants to the extent that after such exercise the Ownership Cap would be exceeded.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions between the Company and Related Parties

There were no reportable transactions between us and any person that is a related party to us since the beginning of our fiscal year ended December 31, 2015 through December 31, 2016, and none are currently proposed. Any proposed transaction between us and any related party that involves an amount in excess of the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years must be submitted to, and reviewed and approved by, the Audit Committee of the Board. The Audit Committee will make its determination based on the particular circumstances of the proposed transaction, including whether the proposed transaction is in our best interest and does not involve an expense in excess of that which would likely be incurred in an arms' length transaction. In reviewing such transactions, the Audit Committee refers to our written corporate policies related to conflicts of interest and related party transactions.

Director Independence

The Board presently consists of five members, one of whom also serves as our Chief Executive Officer. Presently, Messrs. Leone, Mahady and Peacock and Dr. Rosenthale are deemed to be "independent" directors within the meaning of the rules of the SEC and the Nasdaq listing requirements. Each director who serves on a standing committee, including the Compensation Committee, the Nomination and Governance Committee and the Audit Committee, is considered to be "independent" within the meaning of the SEC rules and the Nasdaq listing requirements.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees, Audit-Related Fees, Non-Audit Fees, Tax Fees and Other Fees

The following table sets forth all fees paid or accrued by us for professional services rendered by Ernst & Young LLP, our independent registered public accounting firm, during the years ended December 31, 2016 and 2015:

Fee Category:	Fiscal 2016	% of Total	Fiscal 2015	% of Total
Audit Fees	$ 350,000	77%	$ 375,000	77%
Audit-Related Fees	75,000	16%	75,000	15%
Tax Fees	30,000	7%	40,000	8%
Total Fees	$ 455,000	100%	$ 490,000	100%

Audit Fees are fees for: the audit of our annual consolidated financial statements and the review of the consolidated financial statements included in our quarterly reports on Form 10-Q.

Audit-Related Fees are fees for services related to registration statements and other offering memoranda and accounting consultation.

Tax Fees consisted of tax compliance/preparation and other tax services. No portion of these Tax Fees is related to financial information or operational system design or implementation services.

The Audit Committee has considered whether the provision of all other services by Ernst & Young LLP is compatible with maintaining the independence of Ernst & Young LLP and has concluded that Ernst & Young LLP is independent.

Pre-Approval Policies

The Audit Committee pre-approves specified audit and non-audit services prior to the engagement of our independent registered public accounting firm. With respect to other audit and non-audit services, the Chairman of the Audit Committee has the authority to approve any additional audit services and permissible non-audit services, provided the Chairman informs the Audit Committee of such approval at its next regularly scheduled meeting. Our Chief Financial Officer monitors the performance of all services rendered by our independent auditors, determines whether such services are within the list of pre-approved services and informs the Audit Committee on a timely basis of any such services.

On an ongoing basis, our Chief Financial Officer, together with our independent registered public accounting firm, is responsible to submit to the Audit Committee all requests for approval of services that require a specific pre-approval. The Audit Committee reviews these requests and advises management and the independent registered public accounting firm if the Audit Committee pre-approves the engagement of the independent auditors for such projects and services. On a periodic basis, management reports to the Audit Committee the actual spending for such projects and services compared to the approved amounts. The Audit Committee may delegate the ability to pre-approve audit and permitted non-audit services to a sub-committee of the Audit Committee, provided that any such pre-approvals are reported at the next Audit Committee meeting.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

The consolidated financial statements required to be filed in this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements on page F-1 hereof.

Exhibits are listed on the Index to Exhibits at the end of this Annual Report on Form 10-K. The exhibits required to be filed pursuant to Item 601 of Regulation S-K, which are listed on the Index in response to this Item, are incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY.

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 31, 2017

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Name & Title**	**Date**
/s/ Craig Fraser	Craig Fraser Director, President, and Chief Executive Officer (Principal Executive)	March 31, 2017
/s/ John Tattory	John Tattory Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2017
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	March 31, 2017
/s/ Joseph M. Mahady	Joseph M. Mahady Director	March 31, 2017
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 31, 2017
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 31, 2017

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K.

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation of Windtree Therapeutics, Inc. (Windtree) filed on April 18, 2016	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 18, 2016.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended, filed on June 23, 2016	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 23, 2016.
3.3	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of Windtree, dated February 15, 2017	Incorporated by reference to Exhibit 3.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
3.4	Amended and Restated By-Laws of Windtree, as amended effective April 19, 2016	Incorporated by reference to Exhibit 3.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 18, 2016.
4.1	Form of Warrant dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Windtree and Deerfield	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.2	Form of Warrant dated December 3, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) on December 3, 2013 under a Facility Agreement dated as of February 13, 2012 between Windtree and Deerfield	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 6, 2013.
4.3	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Windtree and Battelle Memorial Institute	Incorporated by reference to Exhibit 4.11 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
4.4	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Windtree and Battelle Memorial Institute	Incorporated by reference to Exhibit 4.12 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
4.5	Form of Series A Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.6	Form of Pre-Funded Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.7	Form of Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.

Exhibit No.	Description	Method of Filing
4.8	Form of Series A-1 Warrant dated February 13, 2017	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
10.1+	Sublicense Agreement, dated as of October 28, 1996, between Johnson & Johnson, Ortho Pharmaceutical Corporation and Acute Therapeutics, Inc.	Incorporated by reference to Exhibit 10.6 to Windtree's Registration Statement on Form SB-2/A, as filed with the SEC on April 18, 1997 (Commission File Number 333-19375).
10.2+	Amended and Restated License Agreement by and between Windtree and Philip Morris USA Inc., d/b/a/ Chrysalis Technologies, dated March 28, 2008	Incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.3+	License Agreement by and between Windtree and Philip Morris Products S.A., dated March 28, 2008	Incorporated by reference to Exhibit 10.5 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.4+	Amended and Restated Sublicense and Collaboration Agreement made as of December 3, 2004, between Windtree and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.28 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.5+	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Windtree and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.29 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.6*	Windtree's 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.
10.7*	Form of 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.
10.8*	Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Appendix II to Windtree's Definitive Proxy Statement on Form DEF 14A, as filed with the SEC on August 15, 2011 (Commission File Number 000-26422).
10.9*	Form of Employee Option Agreement under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012.
10.10*	Form of Non-Employee Director Option Agreement under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012.

Exhibit No.	Description	Method of Filing
10.11*	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.11 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015.
10.12*	Windtree's Amended and Restated 2011 Long-Term Incentive Plan effective as of January 22, 2016	Incorporated by reference to Exhibit 10.12 in the Original Filing.
10.13*	Employment Agreement by and between the Company and Craig Fraser dated as of February 1, 2016.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016.
10.14*	Inducement Stock Option Award Agreement dated February 1, 2016 between Craig Fraser and Windtree under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016.
10.15*	Employment Agreement dated as of December 19, 2014, by and between Windtree and Steven G. Simonson, M.D.	Incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015.
10.16*	Amendment dated December 29, 2014 to Employment Agreement dated as of December 19, 2014, effective as of April 1, 2015, by and between Windtree and Steven G. Simonson, M.D.	Incorporated by reference to Exhibit 10.5 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015.
10.17*	Employment Agreement dated as of March 21, 2014, by and between Windtree and John A. Tattory	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 12, 2014.
10.18*	Amendment dated December 29, 2014 to Employment Agreement dated as of March 21, 2014, by and between Windtree and John A. Tattory	Incorporated by reference to Exhibit 10.19 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015.
10.19	Form of Indemnification Agreement between the Company and its named executive officers and directors.	Incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016
10.20	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Windtree	Incorporated by reference to Exhibits 10.1 and 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.21	Second Amendment to Lease Agreement, dated January 3, 2013 by and between TR Stone Manor Corp. and Windtree	Incorporated by reference to Exhibits 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 8, 2013.
10.22	Fourth Amendment to Lease Agreement, dated April 29, 2016, by and between PH Stone Manor LP and Windtree	Incorporated by reference to Exhibits 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 31, 2016.

Exhibit No.	Description	Method of Filing
10.23+	Master Services Agreement dated October 24, 2013 between Windtree and DSM Pharmaceuticals, Inc. (now known as Patheon Manufacturing Services LLC)	Incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 12, 2013.
10.24+	Supply Agreement dated as of December 22, 2010 between by and between Corden Pharma (formerly Genzyme Pharmaceuticals LLC, now known as Corden Pharma) and Windtree	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 29, 2010.
10.25+	Collaboration Agreement made as of October 10, 2014, by and between Windtree and Battelle Memorial Institute	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
10.26	Amendment dated as of August 4, 2015 to Collaboration Agreement dated as of October 14, 2014 between Windtree and Battelle Memorial Institute.	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on August 10, 2015.
10.27	Second Amendment to Collaboration Agreement between Windtree and Battelle Memorial Institute dated March 31, 2016.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 5, 2016.
10.28+	Facility Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.29	Amendment dated July 9, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 9, 2015.
10.30	Second Amendment dated July 22, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 24, 2015.
10.31	Registration Rights Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.32	Security Agreement dated as of February 13, 2013, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.33	At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Windtree and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 13, 2013.
10.34	Amendment No. 1 dated February 11, 2016, to the At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Windtree and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 16, 2016.

Exhibit No.	Description	Method of Filing
10.35	Security Purchase Agreement dated as of February 13, 2017 between Windtree and selected investors	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
10.36	Registration Rights Agreement dated as of February 13, 2017 between Windtree and selected investors	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017.
21.1	Subsidiaries of Windtree	Filed herewith.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm	Filed herewith.
31.1	Certification of Chief Executive Officer and 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. Annual Report on Form 10-K for the year ended December 31, 2016, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2016 and December 31, 2015, (ii) Statements of Operations for the years ended December 31, 2016 and December 31, 2015, (iii) Statements of Changes in Equity for the years ended December 31, 2016 and December 31, 2015, (iv) Statements of Cash Flows for the years ended December 31, 2016 and December 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.

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

*A management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report pursuant to Item 15(b) of Form 10-K.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Contents Page

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Windtree Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Windtree Therapeutics, Inc. (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Windtree Therapeutics, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst and Young LLP

Philadelphia, Pennsylvania
March 31, 2017

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,588	$ 38,722
Prepaid interest, current portion	1,094	1,710
Prepaid expenses and other current assets	512	362
Total current assets	7,194	40,794
Property and equipment, net	1,054	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	1,226	2,319
Total assets	$ 9,699	$ 44,377
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,813	$ 369
Collaboration payable	3,967	3,281
Accrued expenses	7,611	7,195
Common stock warrant liability	-	223
Total current liabilities	13,391	11,068
Long-term debt	25,000	25,000
Other liabilities	138	43
Total liabilities	38,529	36,111
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, $0.001 par value; 60,000,000 and 36,000,000 shares authorized at December 31, 2016 and 2015, respectively; 8,725,069 and 8,196,011 shares issued at December 31, 2016 and 2015, respectively; 8,723,577 and 8,194,519 shares outstanding at December 31, 2016 and 2015, respectively	9	8
Additional paid-in capital	592,883	590,490
Accumulated deficit	(618,668)	(579,178)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity	(28,830)	8,266
Total liabilities & stockholders' equity	$ 9,699	$ 44,377

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31, 2016	2015
Revenues:		
Product sales	$ -	$ 7
Grant Revenue	2,042	980
	2,042	987
Expenses:		
Cost of product sales	-	929
Research and Development	31,705	28,888
Selling, general and administrative	8,373	11,004
	40,078	40,821
Operating loss	(38,036)	(39,834)
Change in fair value of common stock warrant liability	223	851
Other income / (expense):		
Loss on debt extinguishment	-	(11,758)
Interest income	18	4
Interest expense	(2,518)	(4,583)
Other income	823	150
Other expense, net	(1,677)	(16,187)
Net loss	$ (39,490)	$ (55,170)
Net loss per common share		
Basic and diluted	$ (4.74)	$ (7.98)
Weighted average number of common shares outstanding		
Basic and diluted	8,328	6,967

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
(in thousands)

	Common Stock				Treasury Stock		
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Shares	Amount	Total
Balance - December 31, 2014	**6,115**	**$ 6**	**$ 546,255**	**$ (524,008)**	**(1)**	**$ (3,054)**	**$ 19,199**
Net Loss	-	-	-	(55,170)	-	-	(55,170)
Issuance of common stock, July 2015 financing	1,792	2	37,626	-	-	-	37,628
Issuance of common stock, 401(k) Plan employer match	94	-	539	-	-	-	539
Issuance of common stock warrants	-	-	4,053	-	-	-	4,053
Exercise of common stock warrants	194	-	320	-	-	-	320
Stock-based compensation expense	1	-	1,697	-	-	-	1,697
Balance - December 31, 2015	**8,196**	**$ 8**	**$ 590,490**	**$ (579,178)**	**(1)**	**$ (3,054)**	**$ 8,266**
Net Loss	-	-	-	(39,490)	-	-	(39,490)
Issuance of common stock, ATM financing	360	1	708	-	-	-	709
Issuance of common stock, 401(k) Plan employer match	169	-	274	-	-	-	274
Stock-based compensation expense	-	-	1,411	-	-	-	1,411
Balance - December 31, 2016	**8,725**	**$ 9**	**$ 592,883**	**$ (618,668)**	**(1)**	**$ (3,054)**	**$ (28,830)**

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2016	2015
Cash flows from operating activities:		
Net loss	$ (39,490)	$ (55,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	255	712
Change in provision for excess inventory	-	(174)
Stock-based compensation and 401(k) plan employer match	1,685	2,235
Fair value adjustment of common stock warrants	(223)	(851)
Amortization of discount of long-term debt	-	1,287
Loss on debt extinguishment	-	11,758
Debt discount write-off	-	707
Amortization of prepaid interest	1,709	971
(Loss) / gain on sale or disposal of equipment	(16)	84
Changes in:		
Inventory	-	201
Prepaid expenses and other current assets	(150)	459
Accounts payable	1,444	19
Collaboration payable	686	3,012
Accrued expenses	387	1,348
Deferred revenue	-	(43)
Other assets	-	67
Other liabilities	124	(126)
Net cash used in operating activities	(33,589)	(33,504)
Cash flows from investing activities:		
Purchase of property and equipment	(281)	(458)
Proceeds from sale of property and equipment	27	270
Net cash used in investing activities	(254)	(188)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	709	32,629
Proceeds from exercise of common stock warrants	-	136
Principal payments on long-term debt	-	(5,000)
Repayment of equipment loans	-	(62)
Net cash provided by / financing activities	709	27,703
Net decrease in cash and cash equivalents	(33,134)	(5,989)
Cash and cash equivalents - beginning of year	38,722	44,711
Cash and cash equivalents - end of year	$ 5,588	$ 38,722
Supplementary disclosure of cash flows information:		
Interest paid	$ 280	$ 1,468

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

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 that are designed to deliver aerosolized KL_4 surfactant without invasive procedures. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF® (lucinactant for inhalation), which is an investigational combination drug/device product that combines our KL_4 surfactant with our novel drug delivery technologies. We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants born prior to 37 weeks gestational age who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. Unfortunately, current FDA-approved surfactants must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid the risks associated with surfactant administration, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP), and then, if they do poorly, receive delayed surfactant therapy.

By enabling delivery of our aerosolized KL_4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will allow for earlier treatment of premature infants who currently receive delayed surfactant therapy, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure. By enabling administration of aerosolized KL_4 surfactant to premature infants receiving nCPAP without invasive intubation and mechanical ventilation, we believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

The drug product component of the AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL_4 surfactant 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. We ceased commercial and manufacturing activities for SURFAXIN in the first quarter of 2015 in order to focus our limited resources on advancing the AEROSURF clinical development program and our other aerosolized KL_4 surfactant product candidates. In addition, we own worldwide exclusive rights to our aerosol delivery system (ADS), the medical device component of our AEROSURF product candidate. The ADS is designed to generate an aerosolized KL_4 surfactant at consistent and reproducible volumes suitable to deliver therapeutic dosages in a reasonable period of time. We are currently developing a new version (NextGen) of ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities.

While we are focused primarily on AEROSURF, we believe that our aerosolized KL_4 surfactant may be developed to address a broad range of serious respiratory conditions in children and adults. We have supported and plan in the future to support potential opportunities and third party preclinical studies to explore the utility of our KL_4 surfactant to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI; as well as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance however, that we will secure any additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business – Company Overview" and "– Business Strategy," in this Annual Report on 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 KL_4 pipeline programs.

Note 2 – Basis of Presentation

The accompanying consolidated financial statements reflect a 1-for-14 reverse split of our common stock and a change in the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended, that was approved by our Board of Directors and stockholders and made effective on January 22, 2016. All share and per share information date herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split and reduction in authorized shares.

Note 3 – Liquidity Risks and Management's Plans

As of December 31, 2016, we had cash and cash equivalents of $5.6 million, current liabilities of $13.4 million 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 debt is payable in two equal installments in February 2018 (subject to a potential one-year deferral if we have achieved a market capitalization of $250 million) and February 2019.

In February 2017, we completed a private placement offering for which we received net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration (*See,* " – Note 17 – Subsequent Events"). In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings under our at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) resulting in net proceeds to us of $0.9 million (*see,* "Note 10 – Stockholders' Equity – At-the-Market Program"). Before any additional financings, including under our ATM Program or in connection with potential strategic transactions, we believe that we have sufficient cash resources available to support our development activities, business operations and debt service obligations through the planned completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 2017.

We expect to continue to incur significant losses and require significant additional capital to advance our AEROSURF clinical development program, support our operations and meet our debt service obligations beyond mid-year 2017, and we do not have sufficient existing cash and cash equivalents for at least the next year following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to raise additional capital through the following: (i) all or a combination of strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through public or private equity offerings (including pursuant to the ATM Program with Stifel). If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date that the financial statements are issued. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other restrictions (discussed below) and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to limit or cease our development activities and consider other means of creating value for our stockholders, such as licensing development and/or commercialization of products that we otherwise might plan to develop ourselves. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

We believe that our ability to fund our activities in the near term will be highly dependent upon whether our phase 2b clinical trial is deemed a success and we achieve results that are sufficiently positive to support a strategic transaction and/or equity financing. Our clinical trials are subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the trial in mid-year 2017 as planned, or at all. If our clinical trial should be further delayed for any reason, we likely would be compelled to end the phase 2b clinical trial earlier than planned, which may potentially have a negative impact on the results of the trial. Even if we are able to complete the phase 2b trial as planned, if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require to continue our development activities and operations, which could have a material adverse effect on our business.

Moreover, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) our 2014 Universal Shelf on Form S-3 will expire June 12, 2017 and our ability to file a replacement shelf registration statement may depend in large part on whether our common stock continues to be listed on The NASDAQ Stock Market ("Nasdaq"), (ii) since the market value of our common stock held by non-affiliated persons (public float) is less than $75 million, Form S-3 includes a "limited offering" rule that limits the size of primary securities offerings that we may conduct in any 12-month period to no more than one third of our public float calculated based on a closing price of our common stock within 60 days of a transaction. Transactions under our ATM Program are subject to this limitation, (iii) in May 2016, we received a deficiency notice from Nasdaq that we are no longer in compliance with the minimum stockholders' equity listing requirement. In January 2017, a Nasdaq Hearings Panel granted us a further extension through May 15, 2017, subject to certain conditions, to regain compliance with the Nasdaq listing requirements (*see*, "Nasdaq Deficiency Notice," below). If we fail to regain compliance during this extension period, our common stock may be delisted from Nasdaq and the value and liquidity of our common stock may be adversely affected, (iv) our stockholders may not approve, as required under Nasdaq listing rules, a strategic transaction recommended by our Board that is valued at a discount to the then-current market value of our common stock and involves the issuance of greater than 20% of our outstanding common stock, (v) our stockholders may not approve a potential stockholder proposal to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, which could impair our ability in the future to conduct equity financings or enter into certain strategic transactions; (vi) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings, and (vii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions on our ability to conduct primary offerings on Form S-3, to be in a position to raise more than one third the value of our public float, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL$_4$ surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. We recently announced that we have been awarded a Phase II Small Business Innovation Research Grant (SBIR) grant valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF® phase 2b clinical trial in premature infants 28 to 32 week gestational age. In 2016, we received and expended $0.9 million of this award. We also have received grants that have supported medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In June 2016, we announced the results of a study funded by the NIH that KL$_4$ surfactant could potentially be an effective medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (pneumonopathy) due to exposure from a nuclear accident or act of terrorism. In addition, in February 2017 we announced the results of a study funded by the NIH that KL$_4$ surfactant could be a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

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

As of December 31, 2016, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance. Upon exercise of the pre-funded warrants, we would issue shares to the holders and receive no additional proceeds. In addition, as of December 31, 2016, there were 60 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 40.7 million shares of common stock and 5 million shares of preferred stock available for issuance and not otherwise reserved.

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

Nasdaq Deficiency Notice

On May 19, 2016, we received a notification letter from the Staff of the Listings Qualifications Department of Nasdaq (Staff) notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, we reported stockholders' deficit of $5.0 million. The Staff noted that, as of May 19, 2016, we also did not meet either of the alternative compliance standards under Nasdaq Listing Rule 5550(b) of (i) a market value of listed securities of at least $35 million, or (ii) net income of $500,000 from continuing operations. Nasdaq granted us an extension to regain compliance until November 15, 2016. We did not regain compliance by that date, and the Staff issued a written delisting notification that our common stock would be delisted. At that time, we filed an appeal and received a hearing with the Nasdaq Hearings Panel on January 12, 2017. The Nasdaq Hearings Panel determined to allow us continued listing on Nasdaq until May 15, 2017, while we work to regain compliance with all applicable criteria for continued listing on Nasdaq. During the extension, we are required to provide the Panel interim reports of our progress toward regaining compliance. If we fail to demonstrate a reasonable likelihood of regaining compliance on or before May 15, 2017, the Panel will issue a final delist determination and our stock will be delisted from trading on Nasdaq. We submitted our first status report on February 17, 2017. Any further appeal at that time would not stay the delisting of our stock from Nasdaq.

As of December 31, 2016, we had stockholders' deficit of $28.8 million and a market value of listed securities of $10.9 million, and as of March 23, 2017, we remained out of compliance with the Nasdaq Listing Rules. There can be no assurance that we will be able to regain compliance with either the minimum stockholders' equity rule or the minimum value of listed securities rule within the extension period, or at all.

Note 4 – Accounting Policies and Recent Accounting Pronouncements

The consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the U. S.

Consolidation

The consolidated financial statements include all of the accounts of Windtree Therapeutics, Inc. and its inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.). All intercompany transactions and balances have been eliminated in consolidation.

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.

Cash and cash equivalents

Cash and cash equivalents are held in U.S. banks and consist of liquid investments and money market funds with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents and restricted cash. The fair values of our cash equivalents are based on quoted market prices. The carrying amount of cash equivalents is equal to their respective fair values at December 31, 2016 and 2015, respectively. Warrants classified as liabilities are recorded at their fair market value. Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which we believe approximates fair value.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

Restricted cash

Restricted cash consists of a certificate of deposit held by our bank as collateral for a letter of credit in the same notional amount held by our landlord (as amended April 29, 2016) to secure our obligations under our Lease Agreement dated May 26, 2004 for our headquarters location in Warrington, Pennsylvania (*See*, " – Note 13 – Commitments," for further discussion on our leases).

Long-lived assets

Our long-lived assets, primarily consisting of equipment, are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When the undiscounted cash flows of an asset are less than its carrying value, an impairment is recorded and the asset is written down to estimated value. No impairment was recorded during the years ended December 31, 2016 and 2015 as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable. In the second quarter of 2015, we closed the Totowa Facility and sold manufacturing equipment for total cash proceeds of $0.3 million, resulting in a $0.1 million loss from the sale and disposal of these assets.

Grant revenue

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

Research and development

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 development programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred in accordance with Accounting Standards Codification (ASC) Topic 730, *Research and Development*.

Stock-based compensation

Stock-based compensation is accounted for under the fair value recognition provisions of ASC Topic 718, *Stock Compensation* (ASC Topic 718). *See*, " – Note 11 – Stock Options and Stock-based Employee Compensation," for a detailed description of our recognition of stock-based compensation expense. The fair value of stock option grants is recognized evenly over the vesting period of the options or over the period between the grant date and the time the option becomes non-forfeitable by the employee, whichever is shorter.

Warrant accounting

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 Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. We classify derivative warrant liabilities on the consolidated balance sheet as current liabilities, which are revalued at each balance sheet date subsequent to the initial issuance. Depending on the terms of a warrant agreement, we use applicable valuation pricing models to value the related derivative warrant liabilities. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in fair value of common stock warrant liability." *See*, " – Note 8 – Common Stock Warrant Liability," for a detailed description of our accounting for derivative warrant liabilities.

Collaborative arrangements

We account for collaborative arrangements in accordance with applicable accounting guidance provided in ASC Topic 808, *Collaborative Arrangements*. *See*, " – Note 12 – Collaboration, Licensing and Research Funding Agreements – Battelle Memorial Institute," for a description of our accounting for the Battelle collaboration Agreement.

Income taxes

We account for income taxes in accordance with ASC Topic 740, *Accounting for Income Taxes*, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities.

We use a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Because we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

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 years ended December 31, 2016 and 2015, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 9.4 million and 9.1 million shares, respectively. As of December 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 ASC Topic 260, *Earnings per Share*, when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of these warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of warrants classified as derivative liabilities. For the year ended December 31, 2016 and 2015, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive.

The table below provides information pertaining to the calculation of diluted net loss per common share for the periods presented:

(in thousands)	December 31, 2016	2015
Numerator:		
Net loss as reported	$ (39,490)	$ (55,170)
Less: income from change in fair value of warrant liability	(223)	(851)
Numerator for diluted net loss per common share	$ (39,713)	$ (56,021)
Denominator:		
Basic weighted average common shares outstanding	8,328	6,967
Dilutive common shares from assumed warrant exercises	-	-
Diluted weighted average common shares outstanding	8,328	6,967

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

Concentration of Suppliers

We currently obtain the active pharmaceutical ingredients (APIs) of our KL4 surfactant drug products from single-source suppliers. In addition, we rely on a number of third-party institutions and laboratories that perform various studies as well as quality control release and stability testing and other activities related to our KL4 surfactant development and manufacturing activities. At the present time, several of these laboratories are single-source providers. The loss of one or more of our single-source suppliers or testing laboratories could have a material adverse effect upon our operations.

Business segments

We currently operate in one business segment, which is the research and development of products focused on surfactant therapies for respiratory disorders and diseases, and the manufacture and commercial sales of approved products. We are managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. We do not operate separate lines of business with respect to our product candidates.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in the annual period ending December 31, 2017, including interim periods within that annual period. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. We have adopted ASU 2014-15 effective December 31, 2016. Management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of the accompanying financial statements. *See*, " – Note 3 – Liquidity Risks and Management's Plans.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 482)*. This ASU requires lessees to put most leases on their balance sheets but recognize expenses in the income statement in a manner similar to current accounting standards. The ASU is effective for the annual period ending December 31, 2019 and interim periods thereafter. Early adoption is permitted. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. We are currently evaluating the effect that ASU 2016-02 may have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)*. This update addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. The standard is effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. We are currently evaluating the effect that ASU 2016-09 may have on our consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The new standard requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. The standard is effective for annual periods beginning after December 15, 2017 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. The guidance should be applied using a retrospective transition method to each period presented. We are currently evaluating the effect that ASU 2016-18 may have on our consolidated financial statements and related disclosures.

Note 5 – Fair Value Measurements

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

Assets and liabilities measured at fair value on a recurring basis are categorized in the table below as of December 31, 2016 and 2015:

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

(in thousands)	Fair Value December 31, 2015	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 38,722	$ 38,722	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 38,947	$ 38,947	$ -	$ -
Liabilities:				
Common stock warrants	$ 223	$ -	$ -	$ 223

The following table summarizes changes in the fair value of common stock warrant liability measured on a recurring basis using Level 3 inputs for 2015. For 2016, the change in fair value of common stock warrant liability represents the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

(in thousands)	
Balance at January 1, 2015	**$ 1,258**
Exercise of warrants[(1)]	(184)
Change in fair value of common stock warrant liability	(851)
Balance at December 31, 2015	**$ 223**
Change in fair value of common stock warrant liability	(223)
Balance at December 31, 2016	**$ -**

[(1)]See " – Note 8 – Common Stock Warrant Liability"

The significant unobservable inputs 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	December 31, 2016	2015
Historical volatility	-	159%
Expected term (in years)	-	0.2
Risk-free interest rate	-	0.15%

Fair Value of Long-Term Debt

At December 31, 2016, the estimated fair value of the Deerfield Loan (*see*, " - Note 9, “Long-term Debt”) was $21.4 million compared to a 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 – Property and Equipment

Property and equipment comprises the following:

(in thousands)	December 31, 2016	2015
Manufacturing, laboratory & office equipment	$ 4,940	$ 6,290
Furniture & fixtures	615	778
Leasehold improvements	2,459	2,437
Subtotal	8,014	9,505
Accumulated depreciation and amortization	(6,960)	(8,466)
Property and equipment, net	$ 1,054	$ 1,039

Depreciation expense on property and equipment for the years ended December 31, 2016 and 2015 was $0.3 million and $0.7 million, respectively.

Note 7 – Collaboration Payable and Accrued Expenses

Collaboration payable represents amounts due to Battelle under a collaboration agreement related to the development of a new version of our ADS (*See*, Note 12 – Collaboration, Licensing and Research Funding Agreements). Under the terms of the agreement, collaboration invoices have 12-month terms and begin accruing interest at 12% per annum after 90 days from the date of invoice issuance. As of December 31, 2016, collaboration payable was $4.0 million, including $0.3 million of accrued interest. As of December 31, 2015, collaboration payable was $3.3 million, including $0.1 million of accrued interest.

Accrued expenses comprise the following:

(in thousands)	December 31, 2016	2015
Salaries, bonus & benefits	$ 1,309	$ 2,387
Research and development	5,174	2,867
Manufacturing operations	454	1,097
Professional fees	305	326
Other	369	518
Total accrued expenses	$ 7,611	$ 7,195

Note 8 – Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC Topic 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 and 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.

No warrants were exercised during the year ended December 31, 2016.

During the year ended December, 31, 2015, holders of the 2011 Warrants exercised warrants to purchase 51,193 shares of our common stock at an exercise price of $2.66 per share, resulting in proceeds to us of $0.1 million.

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

Note 9 – Long-term Debt

Long-term debt consists solely of amounts due under a loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

	Years Ended December 31,	
(in thousands)	**2016**	**2015**
Deerfield Loan	$ 25,000	$ 25,000

Under the terms of the Deerfield loan agreement, Deerfield made two advances, the first upon execution of the agreement in February 2013 in the amount of $10 million, and the second upon the first commercial sale of SURFAXIN in December 2013 in the amount of $20 million. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement also contains customary terms and conditions, representations and warranties and affirmative and negative covenants, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets, but it does not require us to meet minimum financial and revenue performance covenants. In addition, all amounts outstanding under the Deerfield Loan may become immediately due and payable upon (i) an "Event of Default," as defined in the Deerfield Loan agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of our assets (a Major Transaction).

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 0.2 million shares of our common stock at an exercise price of $39.34 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 0.3 million shares of our common stock at an exercise price of $39.34 per share (together with the warrants issued in connection with the execution of the agreement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price will be, and have been, adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock. The Deerfield Warrants will expire on the sixth anniversary of the Deerfield Loan agreement, February 13, 2019, and contain limitations on the ability of a holder to exercise the Deerfield Warrants if after such exercise, the holder would beneficially own more than 9.985% of the total number of shares of our common stock then issued and outstanding. The Deerfield Warrants may be exercised in whole or in part either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Deerfield Warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the Deerfield Warrants or that portion of the Deerfield Warrants for cash in an amount equal to the Black-Scholes value (as defined in the Deerfield Warrants) of the Deerfield Warrants or that portion of the Deerfield Warrants redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the Deerfield Warrants and receive therefor that number of shares of common stock that equals the Black-Scholes value of the Deerfield Warrants or that portion of the Deerfield Warrants exercised. Prior to a holder exercising the Deerfield Warrants for shares in such transactions, the Company may elect to terminate the Deerfield Warrants or that portion of the Deerfield Warrants being exercised and pay the holder cash in an amount equal to the Black-Scholes value of the Deerfield Warrants.

We initially recorded the loan as long-term debt at its face value of $30.0 million less debt discounts and issuance costs consisting of (i) $11.7 million fair value of the Deerfield Warrants issued upon the first advance and the second advance (0.5 million warrants in total), and (ii) a $450,000 transaction fee. The discount was being accreted to the $30 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 and have been classified as equity.

The fair value of the Deerfield Warrants at issuance was calculated using the Black-Scholes option-pricing model. The significant Level 3 unobservable inputs used in valuing the Deerfield Warrants are the historical volatility of our common stock market price, expected term of the warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would have resulted in a significantly higher or lower fair value measurement.

Significant Unobservable Input Assumptions of Level 3 Valuations			
Historical volatility		101%	
Expected term (in years)	5.2	–	6.0
Risk-free interest rate	1.2%	–	1.5%

On July 9, 2015, we entered into an amendment to our Deerfield Loan agreement and related notes (Deerfield Notes) to better align our Deerfield Loan principal repayment obligations with anticipated milestones under our clinical development program for AEROSURF. Under the terms of the amendment, (i) upon execution, we prepaid in cash $2.5 million of the principal amounts outstanding, (ii) on July 22, 2015, upon the occurrence of the July 2015 public offering, we prepaid in cash an additional $2.5 million of the principal amounts outstanding, (iii) the principal installment originally due in February 2017 was eliminated and (iv) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million. We also paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the amendment. Under the Deerfield Loan agreement, the $12.5 million principal installment due in February 2018 may be deferred one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement.

On July 22, 2015, we entered into a second amendment to our Deerfield Loan agreement and Deerfield Notes, pursuant to which (a) upon closing the July 2015 public offering on July 22, 2015, we prepaid in cash $2.5 million of the principal amounts outstanding, as contemplated by the first amendment, and (b) Deerfield purchased and accepted $5 million Series A and Series B units offered in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. In addition, (i) we paid in cash when due on September 30, 2015, all accrued and unpaid interest under the Deerfield Notes for the period from June 30, 2015 to July 22, 2015 at the original rate of 8.75%; (ii) Deerfield agreed to apply the $5 million prepaid interest accruing from and after July 23, 2015, as and when such payments are due and payable, as follows; first, to interest accruing on the $12.5 million principal installment due on February 13, 2019, and second, to interest accruing on the $12.5 million principal installment due on February 13, 2018, until fully allocated, which is scheduled to occur at the end of the second quarter of 2016; (iii) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Notes will accrue at a rate of 8.25% per annum; and (iv) no credit will be given with respect to prepaid interest on principal under the Deerfield Notes that is prepaid, in whole or in part, except for a prepayment at our election or a prepayment required under the Deerfield Loan agreement in connection with a Major Transaction that qualifies as a "Qualified Major Transaction." A "Qualified Major Transaction" means a change of control transaction (as defined in the Deerfield Warrants), in which (i) we are not the surviving entity and (ii) our common stock valuation (as defined in the Deerfield Warrants) immediately prior to the change of control transaction equals or exceeds $100 million. In addition, we paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the second amendment.

The restructuring of the Deerfield Loan was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and as a result, we incurred an $11.8 million non-cash loss on debt extinguishment for the year ended December 31, 2015 consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which includes $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part 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.

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

	Years Ended December 31,	
(in thousands)	**2016**	**2015**
Amortization of prepaid interest expense	$ 1,710	$ 971
Cash interest expense	450	1,451
Non-cash amortization of debt discount	-	1,287
Debt discount write-off	-	707
Amortization of debt costs	-	12
Write-off of debt costs	-	66
Total interest expense	$ 2,160	$ 4,494

Amortization of prepaid interest expense represents non-cash amortization of $5 million of Series A Units and Series B units that Deerfield purchased in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Notes. Cash interest expense represents interest at an annual rate of 8.25% and 8.75%, respectively, in 2016 and 2015 on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants prior to the second amendment to the Deerfield Loan. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan.

Note 10 – Stockholders' Equity

Registered Public Offerings

On July 22, 2015, we completed a registered public offering of 1,791,667 Series A units and 3,000,000 Series B units each at a price per unit of $8.40, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 625,000 Series A units at a price per unit of $8.40 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see*, " – Note 9 – Long-term Debt"). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $9.80 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $8.40 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $9.80 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes. The offering was made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

At-the-Market Program (ATM Program)

Stifel ATM Program

On February 11, 2013, we entered into an At-the-Market Equity Sales Agreement (ATM Agreement) 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 over a three-year period up to a maximum of $25,000,000 of shares of our common stock (ATM Program). We are not required to sell any shares at any time during the term of the ATM Program.

If we issue a sale notice to Stifel, we may designate the minimum price per share at which shares may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell the shares by any method deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers' transactions on The Nasdaq Capital Market®, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. Either party may suspend the offering under the ATM Agreement by notice to the other party.

The ATM Agreement, as amended on February 11, 2016, will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2019 or (3) the termination of the ATM Agreement in accordance with its terms. Either party may terminate the ATM Agreement at any time upon written notification to the other party in accordance with the ATM Agreement, and upon such termination, the offering will terminate.

We agreed to pay Stifel a commission equal to 3.0% of the gross sales price of any shares sold pursuant to the ATM Agreement. With the exception of expenses related to the shares, Stifel will be responsible for all of its own costs and expenses incurred in connection with the offering.

During the year ended December 31, 2016, we completed offerings of our common stock under our ATM Program of 360,263 shares, resulting in aggregate gross and net proceeds to us of approximately $0.7 million. In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings under our ATM Program, resulting in aggregate gross and net proceeds to us of approximately $0.9 million.

As of December 31, 2016, approximately $22.3 million remained available under the ATM Program, subject to certain current limitations under our 2014 Universal Shelf as described in Note 3 – Liquidity Risks and Management's Plans.

401(k) Plan Employer Match

We have a voluntary 401(k) savings plan (401(k) Plan) covering eligible employees that allows for periodic discretionary company matches equal to a percentage of each participant's contributions (up to the maximum deduction allowed, including "catch up" amounts). We currently provide for the company match by issuing shares of common stock that are registered pursuant to a registration statement on Form S-8 filed with the U.S. Securities and Exchange Commission (SEC). For the years ended December 31, 2016 and 2015, the match resulted in the issuance of 168,753 and 94,114 shares of common stock, respectively. Expenses associated with the 401(k) match for the years ended December 31, 2016 and 2015 were $0.3 million and $0.5 million, respectively.

Common Shares Reserved for Future Issuance

Common shares reserved for potential future issuance upon exercise of warrants

The chart below summarizes shares of our common stock reserved for future issuance upon the exercise of warrants:

(in thousands, except price per share data)	December 31, 2016	December 31, 2015	Exercise Price	Expiration Date
Battelle - 2014 collaboration agreement [(1)]	107	107	$ 70.00	10/10/2024
Investors - July 2015 financing	4,792	4,792	$ 9.80	7/22/2022
Investors - July 2015 financing (prefunded)	2,857	2,857	$ -	7/22/2022
Deerfield - 2013 loan	500	500	$ 39.34	2/13/2019
Former employee	-	2	$ 44.80	3/18/2016
Investors - February 2011 financing	-	274	$ 2.66	2/22/2016
Total	8,256	8,532		

(1) *See*, " – Note 12 – Collaboration, Licensing and Research Funding Agreements" for further details on the Battelle collaboration agreement

Common shares reserved for potential future issuance upon exercise of stock options or granting of additional equity incentive awards

On January 21, 2016, at a Special Meeting of Stockholders, our stockholders authorized the issuance of an additional 1.1 million shares under the 2011 Long-Term Incentive Plan, which shares were registered on Form S-8 on January 27, 2016. As of December 31, 2016 and 2015, we had 1.0 million and 0.4 million shares, respectively, available for potential future issuance under the 2011 Long-Term Incentive Plan (the 2011 Plan).

Common shares reserved for potential future issuance under our 401(k) Plan

As of December 31, 2016 and 2015, we had 167,372 and 4,567 common shares, respectively, reserved for potential future issuance under the 401(k) Plan. On March 8, 2016, the Board of Directors approved the issuance of 300,000 shares of common stock that may be issued pursuant to our 401(k) Plan. These shares were registered on Form S-8 on March 29, 2016. On October 27, 2015 the Board of Directors approved the issuance of 78,571 shares of common stock that may be issued pursuant to our 401(k) Plan. These shares were registered on Form S-8 on January 6, 2016.

Note 11 – Stock Options and Stock-based Employee Compensation

Long-Term Incentive Plans

We have the 2011 Plan that provides for the grant of long-term equity and cash incentive compensation awards and replaced a 2007 Long-Term Incentive Plan (the 2007 Plan). Awards outstanding under the 2007 and an earlier 1998 Plan (expired) will continue to be governed by the terms of the plans and award agreements under which they were granted.

Under the 2011 Plan, we may grant awards for up to 2.0 million shares of our common stock. Additionally, any shares returnable to the 2007 Plan as a result of cancellations, expirations and forfeitures will be returned to, and become available for issuance under, the 2011 Plan. Shares returnable to the 1998 Plan as a result of cancellations, expirations and forfeitures will not become available for issuance under the 1998 Plan or the 2011 Plan. Awards under the Plan may include stock options, stock appreciation rights (SARs), restricted stock awards (RSAs), restricted stock units, other performance and stock-based awards, and dividend equivalents.

An administrative committee (the Committee – currently the Compensation Committee of the Board of Directors) or Committee delegates may determine the types, the number of shares covered by, and the terms and conditions of, such awards. Eligible participants may include any of our employees, directors, advisors or consultants.

Stock options and restricted stock units (RSUs) outstanding and available for future issuance are as follows:

(in thousands)	December 31, 2016	2015
Stock Options and RSUs Outstanding		
2011 Plan	942	493
2007 Plan	12	17
1998 Plan	1	12
Non-Plan	205	-
Total Outstanding	1,160	522
Available for Future Grants under 2011 Plan	1,042	420

No SARs, RSAs, other performance and stock-based awards, or dividend equivalents have been granted under the 2011 Plan. Although individual grants may vary, option awards generally are exercisable upon vesting, vest in a series of three successive, equal installments beginning with the first anniversary of the grant date, and have a 10-year term. Non-Plan stock options outstanding are in connection with the hiring of our Chief Executive Officer, Mr. Fraser, on February 1, 2016. Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) and this inducement grant is exercisable upon vesting, vests in a series of three successive, equal installments beginning with the first anniversary of the grant date, and has a 10-year term.

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2016	517	$ 51.35	
Granted	773	2.10	
Forfeited or expired	(148)	77.14	
Outstanding at December 31, 2016	1,142	$ 14.66	8.0
Vested and exercisable at December 31, 2016	301	$ 44.04	5.1
Vested and expected to vest at December 31, 2016	1,037	$ 14.81	8.0

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1 2016	5	$ 6.72
Awarded	17	1.84
Vested	(5)	6.72
Unvested at December 31, 2016	17	$ 1.84

Based upon application of the Black-Scholes option-pricing formula described below, the weighted-average grant-date fair value of options granted during the years ended December 31, 2016 and 2015 was $1.39 and $10.48, respectively. The weighted-average grant-date fair value of RSUs granted during the years ended December 31, 2016 and 2015 was $1.84 and $6.72, respectively. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2016 are each $0.

Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2016 and 2015 of $1.4 million and $1.7 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2016	2015
Research and development	$ 614	$ 642
Selling, general and administrative	809	1,054
Total	$ 1,423	$ 1,696

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the historical volatility of our common stock and other factors. We also use historical data and other factors to estimate option exercises, employee terminations and forfeiture rates. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

	December 31, 2016	2015
Weighted average expected volatility	78%	83%
Weighted average expected term (years)	5.7	5.5
Weighted average risk-free interest rate	1.39%	1.50%
Expected dividends	-	-

The total fair value of the underlying shares of the options vested during 2016 and 2015 equals $1.9 million and $2.7 million, respectively. As of December 31, 2016, there was $1.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the 2011 Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.9 years.

Note 12 – Collaboration, Licensing and Research Funding Agreements

Collaboration Agreement

Battelle Memorial Institute

In October 2014, we entered into a collaboration agreement with Battelle providing for the development of a new version (NextGen) of our ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. Under our agreement, we and Battelle are executing a development plan to design, develop, and complete the testing, verification, and documentation of the NextGen ADS, with a sharing of development costs. These costs are recognized in research and development expense as incurred and were $2.9 million and $3.1 million for the years ended December 31, 2016 and 2015, respectively.

In connection with the collaboration agreement, we issued to Battelle two warrants to purchase shares of our common stock, each having an exercise price of $70.00 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 71,429 shares of our common stock, exercisable upon successful completion by Battelle of development activities described above (Initial Warrant), and (ii) a warrant to purchase up to 35,714 shares of our common stock (Additional Warrant; and together with the Initial Warrant, the Battelle Warrants), exercisable if and only if Battelle successfully completes the development activities no later than November 15, 2016, which date was adjusted, and may be further adjusted, as provided in the Collaboration Agreement. We and Battelle have agreed to execute a registration rights agreement, which has not been executed, providing for the registration of the resale of shares underlying the Battelle Warrants. The Battelle Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Battelle Warrants may be exercised on a cashless basis. The Battelle Warrants were issued pursuant to an exemption from registration contained in Regulation D, Rule 506. The Battelle Warrants are accounted for as equity instruments under the applicable accounting guidance of ASC Topic 815.

If Battelle successfully completes their activities under the agreement, we have agreed to pay Battelle royalties equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of $25 million.

Licensing and Research Funding Agreements

Philip Morris USA Inc. and Philip Morris Products S.A.

Under license agreements with Philip Morris USA Inc. (PMUSA) and Philip Morris Products S.A. (PMPSA), we hold exclusive worldwide licenses to the ADS technology for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, the Exclusive Field), and an exclusive license in the U.S. for use with certain non-surfactant drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. We generally are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field (as defined in the license agreements) in the territories, including sales of aerosol devices and related components that are not based on the capillary aerosolization technology (unless we exercise our right to terminate the license with respect to a specific indication). We also agreed to pay minimum royalties quarterly beginning in 2014, but are entitled to a reduction of future royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned in prior periods. We paid the minimum royalty for 2015 of $400,000 related to these license agreements. For 2016, we paid the minimum royalty of $250,000 to PMUSA and paid $62,500 to PMPSA with the remaining $187,500 deferred until July 2017.

Johnson & Johnson and Ortho Pharmaceutical Corporation

We, Johnson & Johnson (J&J) and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, are parties to a license agreement granting to us an exclusive worldwide license to the J&J proprietary KL4 surfactant technology. Under the license agreement, we are obligated to pay fees of up to $2.5 million in the aggregate upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for certain designated products. We have paid $950,000 to date for milestones that have been achieved including a $500,000 milestone payment in 2012 that became due as a result of the FDA's approval of SURFAXIN. In addition, we are required to make royalty payments at different rates, depending upon type of revenue and country, in amounts in the range of a high single-digit percent of net sales (as defined in the license agreement) of licensed products sold by us or sublicensees, or, if greater, a percentage of royalty income from sublicensees in the low double digits.

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of a broad portfolio of potential KL4 surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Antonio Esteve, Ph.D., a principal of Esteve, served as a member of our Board of Directors from May 2002 until January 2013. Esteve will pay us a transfer price on sales of our KL4 surfactant products. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the territory. Esteve is obligated to make stipulated cash payments to us upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to phase 3 clinical trials for the covered products by conducting and funding development performed in the territory. As part of a 2004 restructuring in which Esteve returned certain rights to us in certain territories (Former Esteve Territories), we agreed to pay Esteve 10% of any cash up front and milestone fees (up to a maximum aggregate of $20 million) that we receive in connection with any strategic collaborations for the development and/or commercialization of certain of our KL4 surfactant products in the Former Esteve Territories.

Note 13 –Commitments

Operating Leases

Our operating leases consist primarily of facility leases for our operations in Pennsylvania and New Jersey.

We maintain our corporate headquarters and operations in Warrington, Pennsylvania. The facility serves as the main operating facility for drug and device development, regulatory, analytical technical services, research and development, and administration. In April 2016, the lease was amended to (i) reduce the leased space from 39,594 square feet to 30,506 square feet and (ii) extend the term an additional four years through February 2022. The total aggregate base rental payments remaining under the extended portion of the lease are approximately $3.9 million.

Until June 30, 2015, we leased approximately 21,000 square feet of space for our manufacturing operations in Totowa, New Jersey (Totowa Facility), at an annual rent of $525,000. The lease for this facility, which was used to manufacture SURFAXIN drug product, expired on June 30, 2015.

Rent expense under these leases was $0.8 million and $1.0 million for the years ended December 31, 2016 and 2015, respectively.

Note 14 –Litigation

We are not aware of any pending or threatened 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.

Note 15 –Income Taxes

Since our inception, we have never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to our recorded tax benefit for the years ended December 31, 2016 and 2015 is as follows:

(in thousands)	December 31, 2016	2015
Income tax benefit, statutory rates	$ 13,426	$ 18,758
State taxes on income, net of Federal benefit	2,599	3,760
Research and development tax credit	1,305	1,047
Employee related	(1,215)	(340)
Interest related	890	-
Warrant valuation related	76	289
Income tax benefit, statutory rates	17,081	23,514
Valuation allowance	(17,081)	(23,514)
Income tax benefit, net	$ -	$ -

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2016 and 2015, are as follows:

(in thousands)	December 31, 2016	2015
Long-term deferred assets:		
Net operating loss carryforwards (Federal and state)	$ 234,825	$ 218,203
Research and development tax credit	15,700	13,917
Compensation expense on stock	2,157	2,776
Charitable contribution carryforward	6	6
Other accrued	342	469
Depreciation	460	482
Total long-term deferred tax assets	253,490	235,853
Valuation allowance	(253,490)	(235,853)
Deferred tax assets, net	$ -	$ -

We are in a net deferred tax asset position at December 31, 2016 and 2015 before the consideration of a valuation allowance. Because we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured. It is our policy to classify interest and penalties recognized on uncertain tax positions as a component of income tax expense. There was neither interest nor penalties accrued as of December 31, 2016 or 2015, nor were any incurred in 2016 or 2015.

At December 31, 2016 and 2015, we had available carryforward net operating losses for Federal tax purposes of $581.4 million and $540.2 million, respectively, and a research and development tax credit carryforward of $15.7 million and $13.9 million, respectively. The Federal net operating loss and research and development tax credit carryforwards will continue to expire through 2036.

At December 31, 2016, we had available carryforward Federal and State net operating losses of $5.2 million and $0.4 million, respectively, related to stock-based compensation, the tax effect of which will result in a credit to equity as opposed to income tax expense, to the extent these losses are utilized in the future.

At December 31, 2016 and 2015, we had available carryforward losses of approximately $570.3 million and $527.1 million, respectively, for state tax purposes. Of the $570.3 million state tax carryforward losses, $544.8 million is associated with the state of Pennsylvania, with the remainder associated with the other 6 states within which we have established tax nexus.

Utilization of net operating loss (NOL) and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. There also could be additional ownership changes in the future, which may result in additional limitations in the utilization of the carryforward NOLs and credits.

A full valuation allowance has been provided against our deferred tax assets and, if a future assessment requires an adjustment, an adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Note 16 –Selected Quarterly Financial Data (Unaudited)

The following tables contain unaudited statement of operations information for each quarter of 2016 and 2015. The operating results for any quarter are not necessarily indicative of results for any future period.

2016 Quarters Ended:

(in thousands, except per share data)	**Mar. 31**	**June 30**	**Sept. 30**	**Dec. 31**	**Total Year**
Revenues:					
Product sales	$ -	$ -	$ -	$ -	$ -
Grant Revenue	75	106	961	900	2,042
Total revenues	75	106	961	900	2,042
Expenses:					
Cost of product sales	-	-	-	-	-
Research and Development	10,360	8,316	7,081	5,948	31,705
Selling, general and administrative	3,657	1,783	1,613	1,320	8,373
Total expenses	14,017	10,099	8,694	7,268	40,078
Operating loss	(13,942)	(9,993)	(7,733)	(6,368)	(38,036)
Change in fair value of common stock warrant liability	223	-	-	-	223
Other expense, net	(182)	(631)	(630)	(234)	(1,677)
Net loss	$ (13,901)	$ (10,624)	$ (8,363)	$ (6,602)	$ (39,490)
Net loss per common share - basic	$ (1.70)	$ (1.29)	$ (1.00)	$ (0.77)	$ (4.74)
Net loss per common share - diluted	$ (1.70)	$ (1.29)	$ (1.00)	$ (0.77)	$ (4.74)
Weighted average number of common shares outstanding - basic	8,191	8,238	8,355	8,523	8,328
Weighted average number of common shares outstanding - diluted	8,191	8,238	8,355	8,523	8,328

2015 Quarters Ended:

(in thousands, except per share data)	**Mar. 31**	**June 30**	**Sept. 30**	**Dec. 31**	**Total Year**
Revenues:					
Product sales	$ 7	$ -	$ -	$ -	$ 7
Grant Revenue	184	75	66	655	980
Total revenues	191	75	66	655	987
Expenses:					
Cost of product sales	929	-	-	-	929
Research and Development	7,082	7,129	6,452	8,225	28,888
Selling, general and administrative	3,353	3,383	2,057	2,211	11,004
Total expenses	11,364	10,512	8,509	10,436	40,821
Operating loss	(11,173)	(10,437)	(8,443)	(9,781)	(39,834)
Change in fair value of common stock warrant liability	(31)	469	139	274	851
Other expense, net	(975)	(1,358)	(13,252)	(602)	(16,187)
Net loss	$ (12,179)	$ (11,326)	$ (21,556)	$ (10,109)	$ (55,170)
Net loss per common share - basic	$ (1.96)	$ (1.82)	$ (2.80)	$ (1.26)	$ (7.98)
Net loss per common share - diluted	$ (1.96)	$ (1.82)	$ (2.80)	$ (1.26)	$ (7.98)
Weighted average number of common shares outstanding - basic	6,114	6,125	7,550	8,050	6,967
Weighted average number of common shares outstanding - diluted	6,114	6,125	7,550	8,050	6,967

Note 17 Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2016 through the date we issued these financial statements. During this period, we noted a subsequent event as described below:

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units for net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of (i) one share of Series A Convertible Preferred Stock; and (ii) 1,000 Series A-1 Warrants to purchase one share of Common Stock at an exercise price equal to $1.37.

Exhibit 21.1

Subsidiaries of Registrant: 1. Discovery Laboratories, Inc., formerly known as Acute Therapeutics, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-86105, Form S-3 No. 333-35206, Form S-3 No. 333-72614, Form S-3 No. 333-82596, Form S-3 No. 333-101666, Form S-3 No. 333-107836, Form S-3 No. 333-111360, Form S-3 No. 333-118595, Form S-3 No. 333-121297, Form S-3 No. 333-122887, Form S-3 No. 333-128929, Form S-3 No. 333-133786, Form S-3 No. 333-139173, Form S-3 No. 333-156237, Form S-3 No. 333-187934, Form S-3 No. 333-193490, and 333-196420) of Windtree Therapeutics, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-180497, Form S-8 No. 333-184277 Form S-8 No. 333-189966, Form S-8 No. 333-197139, and S-8 No. 333-209141) pertaining to the Windtree Therapeutics, Inc. 2011 Long-Term Incentive Plan

(3) Registration Statement (Form S-8 No. 333-148028) pertaining to the Windtree Therapeutics, Inc. 2007 Long-Term Incentive Plan

(4) Registration Statement (Form S-8 No. 333-33900, Form S-8 No. 333-55900, Form S-8 No. 333-67422. Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-116268, Form S-8 No. 333-127790, Form S-8 No. 333-138476, Form S-8 No. 333-208879, Form S-3 No. 333-209141 and Form S-8 No. 210464) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Windtree Therapeutics, Inc.

(5) Registration Statement (Form S-8 No. 333-59945) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Windtree Therapeutics, Inc., the 1996 Stock Option/Stock Issuance Plan of Windtree Therapeutics, Inc., and the 1996 Stock Option/ Stock Issuance Plan of Acute Therapeutics, Inc.

(6) Registration Statement (Form S-8 No. 333-110412, Form S-8 No. 333-137643, Form S-8 No. 333-156443, Form S-8 No. 333-164470, Form S-8 No. 333-165809, Form S-8 No. 333-169662, Form S-8 No. 333-173259, Form S-8 No.333-180497, Form S-8 No. 333-187486, Form S-8 No. 333-191502, Form S-8 No. 333-197139, Form S-8 No. 333-201478, Form S-8 No. 333-208879, and S-8 No. 333-209141) pertaining to the 401(k) Plan of Windtree Therapeutics, Inc.

of our report dated March 31, 2017, with respect to the consolidated financial statements of Windtree Therapeutics, Inc. and subsidiary included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 31, 2017

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

1. I have reviewed this Annual Report on Form 10-K of Windtree Therapeutics, Inc.;

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

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 31, 2017

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

Exhibit 31.1

CERTIFICATIONS

I, John Tattory, certify that:

1. I have reviewed this Annual Report on Form 10-K of Windtree Therapeutics, Inc.;

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

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 31, 2017

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

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Windtree Therapeutics, Inc. (the "Company") hereby certifies that our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 ("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: March 31, 2017

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

/s/ John A. Tattory
John A. Tattory
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company 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.