FORM 10-K

WINDTREE THERAPEUTICS INC /DE/ - WINT

Filed: April 17, 2018 (period: December 31, 2017)

Annual report with a comprehensive overview of the company

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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, 2017

or

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

For the transition period from to

Commission file number 000-26422

WINDTREE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976-3622
(Address of principal executive offices)

(215) 488-9300

(Registrant's telephone number, including area code)

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 OTCQB® Market**
Series A Convertible Preferred Stock	

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES ☐ NO ☒

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2017 (based on the closing price for shares of the registrant's common stock as reported on The OTCQB® Market under the symbol WINT on that date was approximately $3.4 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 April 6, 2018, there were 3,769,088 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

In accordance with General Instruction G(3) to the Annual Report on Form 10-K, portions of the registrant's definitive proxy or information statement for its 2018 Annual Meeting of Stockholders or by amendment to this Annual Report on Form 10-K, to be filed with the Securities and Exchange Commission no later than 120 days, or April 30, 2018, after the registrant's fiscal year ended December 31, 2017, and to be delivered to stockholders in connection with the 2018 Annual Meeting of Stockholders, are herein incorporated by reference in Part III of this Form 10-K.

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, future milestones, goals and objectives, and our financial plans 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 expectations about the timing and anticipated outcomes of submitting regulatory filings in the United States and other markets for our products under development; our research and development programs, including planned development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant product candidates, our aerosol delivery system (ADS), which we are designing to aerosolize our KL4 surfactant; manufacturing plans for our drug products, active pharmaceutical ingredients (APIs), materials and ADS; and our plans regarding potential strategic alliances, collaboration agreements, including licensing opportunities, and other potential strategic transactions (including without limitation, by merger, acquisition or other corporate transaction).

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 such risks and uncertainties, which potentially could have a material adverse effect on our development programs, business and/or operations, include, but are not limited to the following:

Risks Related to Capital Resource Requirements

- as of April 15, 2018, we believe that we will have sufficient cash and cash equivalents to support our development activities and operations through May 2018. To execute our business plan beyond May 2018 and advance our AEROSURF® development program, we will require significant additional capital. 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;

- our phase 2b clinical trial did not meet its primary endpoint due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype device. That circumstance caused us to adjust our AEROSURF development plan to add an additional phase 2 clinical study. We have found it difficult to attract investors that are willing to provide the additional capital that we require and, as such, we have depended upon the support of our majority stockholder and licensee in the Asia Pacific markets while we seek to advance our AEROSURF development program and identify potential strategic transactions that might attract the interest of other investors;

- we plan to investigate the feasibility of potential strategic transactions and/or additional equity offerings; however, we believe that our ability to attract such investor interest and support is largely dependent upon our ability to successfully advance our device and clinical development programs in a timely manner and demonstrate meaningful progress towards our planned milestones, including completion of our NextGen ADS design verification activities with Battelle Memorial Institute and initiation of the planned AEROSURF bridge study; failure to demonstrate such progress could impair our ability to raise the additional capital we require;

- even if our development efforts are successful, we expect to incur continuing significant losses and will require significant additional capital to support our ongoing development, regulatory and business activities. In addition, our ability to raise such capital may be adversely impacted by future unforeseen adverse developments;

- our common stock has been quoted on the OTC Markets Group Inc.'s OTCQB® Market (OTCQB) tier since May 5, 2017, and has experienced, over time, lower trading volumes and reduced analyst interest. In addition, effective December 22, 2017, we implemented a share combination (1-for-20 reverse split) that had the effect of reducing the number of shares outstanding and further lowering our trading volumes. These conditions may make it more difficult to raise capital when needed. Our stockholders may find it more difficult to trade our securities on the OTCQB, and the value and liquidity of our common stock may be adversely affected, which could have a material adverse effect on our ability to raise the additional capital that we require. Moreover, even if we are successful in raising the required capital, any equity financings could result in substantial equity dilution of stockholders' interests;

- other factors may make it more difficult to conduct equity-based financings, including: we no longer are eligible to use a registration statement on Form S-3 to register our securities and will have to register shares that we issue through private placements using a long-form Form S-1; we no longer have access to an at-the-market equity sales program; and we have a complicated capital structure that includes common stock, convertible preferred stock and warrants to purchase common stock;

- if our AEROSURF development program is unduly delayed or should other complications arise, given our limited cash resources, we may be unable to implement the corrective actions that we might like, which potentially could adversely impact our planned development time lines and results. Under such circumstances, we may find it difficult to raise additional capital when needed to continue our development programs and support our operations;

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

- we have limited resources and may have difficulty effectively and timely modifying our business strategy as needed to respond to developments in our research and development activities, financial condition and in our business and industry;

Risks related to Development Activities

- our AEROSURF development program activities, including to design, test, confirm and assemble the NextGen ADS, manufacture, test and release lyophilized KL4 surfactant and initiate, conduct and monitor clinical programs in clinical sites in multiple jurisdictions, could be adversely affected by unforeseen events and requirements or delayed, which potentially could have a material adverse effect on our development programs, business and operations;

- we are conducting the final phases of design verification for our NextGen ADS, which involves a series of tests to confirm that the device design conforms to expectations and that the device performs as intended; failure to achieve the desired outcomes could have a material, adverse effect on our ability to timely initiate our planned AEROSURF clinical trials;

- we participate in rigorous regulatory processes to potentially gain approval for any drug, medical device or combination drug/device product candidate, and FDA or other regulatory authorities may withhold or delay consideration of our applications, may not agree with us on matters raised during the review process, or may require us to conduct significant unanticipated activities to advance our product candidates; or 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;

- our efforts to gain regulatory approval in a timely manner for our drug and combination drug/device products in the U.S. and in international markets may be adversely affected by unforeseen developments and changed circumstances, including in the national or international political and regulatory environment which may make it more difficult to gain FDA or international regulatory approvals;

Risks Related to Strategic and Other Transactions

- 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, or 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;

- we believe that, even if our AEROSURF development efforts are successful, we also must seek to identify and pursue development of potential additional product candidates, including other KL4 surfactant product candidates, to potentially leverage our capabilities, maximize our resources, reduce our dependency upon a single product candidate, and attract the significant capital that we will require;

- our strategic alliances, collaboration agreements and other strategic transactions may be delayed, terminated or fail, which could prevent us from advancing our development programs in accordance with our plan;

Risks related to Manufacturing

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

- we have transferred the manufacturing process for our KL4 surfactant to our CMO, with elements of the final process validation pending. Such technology transfers and the related process validation may be time consuming and expensive and may experience problems, delays and setbacks;

- Our drug product must be produced in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, which are conducted by our own analytical laboratory, third-party laboratories, most of which are also single-source providers, and our CMO and which are expensive and could produce results that do not meet our specifications;

- we are engaged in a technology transfer of our manufacturing processes for our ADS to a device manufacturer and assembler, which is expected to produce ADSs and disposable components for use in our planned clinical programs. In executing the technology transfer, we may experience problems, delays and setbacks that could affect our time line for further development and clinical activities;

- our device manufacturer and assembler, with whom we expect to support further ADS development and manufacturing process enhancements, and manufacture and assemble our ADS for our continuing clinical programs and, if approved, commercial activities, may experience problems, delays and materials shortages;

- our CMOs and suppliers of our APIs may experience problems in manufacturing our drug product, APIs and medical device components from time to time; ultimately, if our products are approved, they may experience problems complying with the final drug and medical device approval specifications;

Other Risks Affecting our Business

- even if we secure regulatory approval for our products in one or more of the U.S. and international markets, competition, pricing and market valuations, as well as reimbursement and health care reform may adversely affect our ability to obtain reimbursement for our products at levels that provide an adequate return on investment; in addition, market conditions and other factors may make it difficult to gain access to certain markets and patient populations;

- we and our strategic partners or collaborators may be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel;
- 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;
- we may become involved in securities, product liability and other litigation and 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. In addition, 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, medical device or combination drug/device product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

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

Trademark Notice

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

WINDTREE THERAPEUTICS, INC.

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For the Fiscal Year Ended December 31, 2017

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 currently traded on The OTCQB® Venture Market (OTCQB) quotation system operated by The OTC Markets Group Inc., and 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 being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technologies 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. *See,* "Proprietary Platform – KL4 Surfactant and Aerosol Technologies – KL4 Surfactant Technology."

As of April 15, 2018, we believe that we will have sufficient cash and cash equivalents to support our development activities and business operations through May 2018. Our ability to advance our AEROSURF development plan is dependent upon our ability to secure additional capital both in the near and long-term through potential strategic transactions and/or private equity offerings.

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

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of respiratory distress syndrome (RDS) in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delays and death. 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 in the United States, and a significantly greater number globally, are given respiratory support after birth each year because they have or are at risk for RDS.

Surfactant therapy can be a life-saving treatment for RDS and is the primary therapy to address an underlying surfactant deficiency. Unfortunately, surfactants currently available in the U.S. are animal-derived and must be administered using invasive endotracheal intubation and mechanical ventilation, procedures that 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, bronchopulmonary dysplasia (BPD), chronic lung disease and increased risk of infection.

To avoid the risks associated with intubation and mechanical ventilation, more than half the premature infants in the U.S. and EU are initially treated with noninvasive respiratory support, such as nCPAP. Unfortunately, nCPAP does not address the underlying surfactant deficiency and consequently, many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require delayed surfactant therapy with invasive intubation (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.

AEROSURF is designed to deliver aerosolized KL4 surfactant noninvasively and potentially may meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, has the potential to address a serious unmet medical need by enabling earlier KL4 surfactant therapy for infants receiving nCPAP alone, reducing the number of premature infants who are subjected to invasive surfactant administration, and potentially providing transformative clinical and pharmacoeconomic benefits. FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

While we are focused primarily on AEROSURF, we are also assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant is the drug component in AEROSURF and may potentially provide benefits related to use, such as longer shelf life, reduced cold-chain requirements and lower viscosity. *See*, "– Business Strategy and Updates - Other KL4 Surfactant Development Initiatives – Lyophilized KL4 Surfactant."

Beyond RDS

In the future, we plan potentially to develop a pipeline of KL4 surfactant products to address serious critical care respiratory conditions in children and adults. In that regard, we have received support, and plan to seek additional support, from the National Institutes of Health (NIH) and other government funding sources to explore with recognized educational and research institutions the utility of our KL4 surfactant to address a variety of respiratory conditions.

We believe that our aerosolized KL4 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 KL4 surfactant therapies and our aerosol delivery technology to facilitate the delivery of other drugs into the lung and to use KL4 surfactant to treat conditions such as 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

AEROSURF Clinical and Device Development Update

We are focused primarily on the management of RDS in premature infants. In November 2013, we filed an investigational new drug application (IND) with FDA and initiated a phase 2 clinical development program for AEROSURF for the treatment of RDS in premature infants. Our efforts to advance the AEROSURF development program are grounded in our earlier work, including a significant pivotal phase 3 clinical trial, for SURFAXIN®, the liquid instillate dosage form of our KL4 surfactant, which was approved by FDA in 2012. [1] To date, we have completed three AEROSURF phase 2 clinical trials assessing the safety and tolerability of AEROSURF and demonstrating evidence of a beneficial treatment effect when the treatment is delivered as intended in all 3 trials. We have also advanced the development of a proprietary aerosol delivery system (ADS) and manufactured a sufficient number of ADS prototypes to support our nonclinical research and our clinical programs. This work was supported in part by collaborations with Battelle Memorial Institute (Battelle) dating back to 2012. We are currently working with Battelle to complete design verification procedures for a next generation (NextGen) ADS that is expected to replace the prototype device that we have used to date in our phase 2 clinical trials. The following sections summarize our plans for 2018 and our progress over the last three years.

Focus for 2018 – NextGen ADS

In 2018, we plan to focus on a number of initiatives potentially to advance our AEROSURF development program, including a project with Battelle to complete development of the NextGen ADS, which combines the same aerosolization technology used during the phase 2 clinical program, but with improved ergonomics, interface, controls, and dose monitoring in a modular design. Design verification activities are underway. In this process, we have assessed the design of the NextGen ADS and implemented changes potentially to mitigate the risks of device-related treatment interruptions experienced in the prototype device used in the phase 2b clinical trial. *See*, "– AEROSURF Phase 2b Clinical Trial." We believe that the NextGen ADS, which is being developed to be easier and faster to use, may support enhanced clinical outcomes by potentially allowing for reduced time to initial administration of our KL4 surfactant and reduced time intervals between doses, if required. *See*, "– Proprietary Platform – KL4 Surfactant and Aerosol Technologies – Aerosol Technologies – Aerosol Delivery System (ADS)."

Focus for 2018 – AEROSURF Bridge Study

To clinically verify the design and confirm the performance of the NextGen ADS, including with respect to the device-related treatment interruptions experienced in the phase 2b clinical trial, we are planning to conduct a device bridging clinical study with the following objectives: (i) to gain in-clinic experience with the NextGen ADS, (ii) to confirm whether our device development objectives have been met, and (iii) to generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial, which was adversely affected by device-related treatment interruptions. Our plans include a multicenter, randomized, controlled study with masked treatment assignment in approximately 70 premature infants that is designed to assess safety and tolerability of administering aerosolized KL4 surfactant administered to premature infants 26 to 32 week gestational age receiving nCPAP in one dose group (50 minutes) with up to 4 repeat doses (administered with a minimum of 20 minutes between doses) compared to infants receiving nCPAP alone. In addition to assessing safety and tolerability, the key objectives of this trial include assessing nCPAP failure rates at 72 hours and 28 days and the performance of the NextGen ADS. We plan to conduct this trial in 20 to 25 of our higher-performing clinical sites, predominantly in the U.S. This trial will not be powered to establish statistical significance. We anticipate that this trial will start in the fourth quarter of 2018.

[1] SURFAXIN, the first synthetic, peptide-containing surfactant based on our KL4 surfactant technology, was approved by FDA in March 2012. SURFAXIN is administered intratracheally using methods similar to currently available surfactants. We ceased SURFAXIN commercial and manufacturing activities in 2015 to focus on AEROSURF clinical development and our other aerosolized KL4 surfactant products.

AEROSURF Phase 2b Clinical Trial

In June 2017, we announced that we had completed enrollment in our AEROSURF phase 2b clinical trial, a multicenter, randomized, controlled study with masked treatment assignment in 221 premature infants that was designed to evaluate aerosolized KL4 surfactant administered to premature infants 26 to 32 week gestational age receiving nCPAP, in two dose groups (25 and 50 minutes) with up to two potential repeat doses, compared to infants receiving nCPAP alone. This trial was conducted in approximately 50 clinical sites in the U.S., Canada, Europe and Latin America.

The key objectives of this trial were to:

- demonstrate 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

Based on the planned top-line results, AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours. We believe this result was attributable in large part to an unexpected rate of treatment interruptions, which occurred in about 24% of active enrollments, predominantly in the 50-minute dose group. These interruptions, we believe, were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. After excluding patients in the 50-minute dose group whose dose was interrupted, nCPAP failure rates were 44% in the control group (n=71) compared to 32% (n=44) in the AEROSURF 50-minute dose group, which is a 12% absolute reduction or a 27% relative reduction in nCPAP failure compared to control. These data suggest a meaningful treatment effect in line with our desired targeted outcome. The overall data suggest that the safety and tolerability profile of AEROSURF was generally comparable to the control group. 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. As expected, some peridosing events occurred (e.g., changes in oxygen requirements and blood pressure in the time around dosing) more commonly in the AEROSURF groups, however, these were transient in nature and occurred less frequently than seen in intratracheal administration.

In 2017, we also completed a 2a clinical trial assessing three AEROSURF doses in premature infants 26-28 week gestational age (*see*, "– AEROSURF Phase 2a Clinical Trial (2014 – 2017)"). Data from this trial has enabled (i) the expansion of the phase 2b clinical trial to include 28 week gestational age infants and (ii) inclusion of premature infants 26 weeks gestational age and greater in future clinical trials.

AEROSURF Phase 2a Clinical Trials (2014-2017)

Premature infants 29 to 34 week gestational age

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 KL4 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 trial was to establish proof of concept for our technology through assessments of (i) physiological safety data suggesting that aerosolized KL4 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 expanded this trial to explore higher doses and whether multiple (repeat) doses of AEROSURF may potentially reduce the need for invasive surfactant therapy.

In November 2015, after completing the expansion of the AEROSURF phase 2a clinical trial in an additional 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 trial was designed to evaluate safety and tolerability of administering aerosolized KL4 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 KL4 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.

Premature infants 26 to 28 week gestational age

In the third quarter of 2017, we completed the analysis of results from an AEROSURF phase 2a clinical trial in 48 premature infants 26 to 28 week gestational age receiving nCPAP for RDS. This trial was a multicenter, randomized, open-label, controlled study in premature infants 26 to 28 weeks gestational age receiving nCPAP for RDS, and was designed to evaluate the safety and tolerability of aerosolized KL_4 surfactant administered in three escalating doses (30, 45, and 60 minute), with a potential repeat dose, compared to infants receiving nCPAP alone. The overall data suggest that the safety and tolerability profile of AEROSURF was generally comparable to the control group. Reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS. Peridosing events occurred in the AEROSURF group but were not measured in the control group that had no aerosol therapy administered. Early nCPAP failures within 6 hours after randomization were less frequently observed in the AEROSURF treated groups compared to control group. The data also suggest that AEROSURF may have an early effect and may be prolonging the time to nCPAP failure compared to control; however, the overall rate of nCPAP failure was comparable at 72 hours between control and treatment groups. At 72 hours, nCPAP failure rates were 63%, 88% and 63% in the 30, 45 and 60 minute AEROSURF dose groups, respectively, compared to 67% in the control group. As was observed in the AEROSURF phase 2b clinical trial, some treatments in this trial were interrupted. These interruptions occurred in one-third of active enrollments, and we believe were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. Although complicated by small numbers, analysis of data of patients whose dose was not impacted by device-related treatment interruptions (n=16) resulted in nCPAP failure rates of 57%, 100% and 50% in the 30 (n=7), 45 (n=3) and 60 (n=6) minute AEROSURF dose groups, respectively compared to 67% in the control group. The results observed in this trial met the objective of demonstrating an acceptable safety and risk profile to allow inclusion of 26 – 28 week gestational age premature infants in any future studies in the AEROSURF development program.

An important observation emerged from the phase 2a trial in infants 26 to 28 week gestation age. AEROSURF treated patients experienced a significantly lower rate of neonatal bronchopulmonary dysplasia (BPD) or chronic lung disease of the newborn in compared to control. BPD is a costly syndrome that is associated with the prolonged use of respiratory support and oxygen supplementation and is diagnosed when premature infants require respiratory support or supplemental oxygen at 36 weeks post-menstrual age. Babies with BPD suffer from abnormal lung development and typically have a need for respiratory assistance – oftentimes for many months, as well as comprehensive care spanning years. In this trial, BPD rates were 0% (0 of 24) in the AEROSURF treated patients compared to 25% (6 of 24) in the control group.

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. Throughout the phase 2a trial in younger infants, we observed a potential early effect of AEROSURF on prolonging time to nCPAP failure. When the dose was delivered as intended, it appears that this gestational age group is responding better (less nCPAP failure) to larger delivered doses of AEROSURF similar to the 29-34 week gestational age group and we will be able to proceed with a common dosing approach across the gestational ages under study.

Clinical Summary to Date

Our AEROSURF phase 2 clinical work to date has produced a consistent, positive safety profile. Adverse events and serious adverse events have been those that are common and expected among premature infants with RDS and similar to control. A post-hoc pooled analysis summarizing patients treated with AEROSURF in the phase 2 program who received a dose of AEROSURF for periods of 45 minutes or greater (excluding patients who experienced device-related treatment interruptions) shows a nCPAP failure rate with AEROSURF of 36% compared to a nCPAP failure rate with nCPAP alone of 50%, representing a significant relative reduction of 28% (p=0.038). We also observed a consistent pattern across trials in the U.S. in which the phase 2b clinical trial results in premature infants 28 to 32 week gestational age are similar to the phase 2a clinical trial results in premature infants 29 to 34 week gestational age. In addition, we observed a potential effect on development of BPD in the 26 to 28 week gestational age group, with no cases of BPD observed in the AEROSURF treated infants as compared to 6 of 24 in infants on nCPAP alone. In the 2b clinical trial in 28-32 week gestational age, a population at lower risk for BPD, we saw fewer infants develop BPD also. Moreover, we noted that patients in the phase 2b clinical trial that were treated with AEROSURF but failed nCPAP appeared to experience beneficial effects from AEROSURF compared to nCPAP alone as reflected by reduced mean time on oxygen and fewer days on mechanical ventilation. While these observations are encouraging, there can be no assurance that we will observe similar results in future clinical trials.

The AEROSURF phase 2b clinical trial was supported to date, in part, by a $1.9 million Phase IIb award under a Small Business Innovation Research (SBIR) grant from the National Heart, Lung, and Blood Institute (NHLBI) of the NIH for up to $2.6 million under parent award number R44HL107000. The AEROSURF phase 2a clinical trials in premature infants 29 to 34 week gestational age was supported, in part, by a $1.9 million Phase II award under a SBIR grant from the NHLBI of the NIH for up to $2.5 million under award number 4R44HL107000-02. Previously, $0.6 million was awarded under this grant to support ADS development for use in the AEROSURF phase 2 clinical program. The content of this Annual Report on Form 10-K is solely our responsibility and does not necessarily represent the official views of the NIH.

Other KL4 Surfactant Development Initiatives

Lyophilized KL4 Surfactant

While we are focused primarily on AEROSURF, we are also assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant is the drug component in AEROSURF and may potentially provide benefits related to use, such as longer shelf life, reduced cold-chain requirements and lower viscosity. We are currently assessing potential development pathways with the goal of defining a development program that is achievable from a cost, timing and resource perspective and that would potentially provide approval for an additional KL4 surfactant product for intratracheal treatment of premature infants with RDS. If we were able to secure such approval, we potentially would be able to provide our KL4 surfactant in both liquid and aerosol dosage forms and strengthen our position in the RDS market. We have initiated discussions with FDA on a potential development program, trial design and regulatory plan for approval.

Nonclinical Initiatives

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 our clinical trials, and the RDS market opportunity. Based on this study, we have enhanced some of the operational aspects of the AEROSURF phase 2 program.

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 KL4 surfactant throughout all regions of the lung. Results from analysis of images obtained in the study show that aerosolized KL4 surfactant delivered using the ADS via nCPAP was generally uniformly deposited in all regions of the NHPs lungs. 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. *See*, "– Proprietary Platform – KL4 Surfactant and Aerosol Technologies – Aerosol Technologies."

Beyond RDS

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 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.

U.S. Government-funded Initiatives

We have pursued and plan to continue pursuing potential U.S. Government-funded research and preclinical development initiatives that provide non-dilutive funding to explore additional opportunities to apply our KL4 surfactant in the treatment of a range of respiratory diseases, including potential medical countermeasures to mitigate 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 August 2016, we announced a three-year phase II Small Business Innovation Research (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 in 2016, with up to an additional $1.6 million potentially available in the following two years. In 2017, we received $0.9 million of this award; the remaining funds of $0.7 million are potentially to be made available in mid-2018. 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 KL4 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.

Strategic Transactions and Liquidity Update

As of April 15, 2018, we believe that we will have sufficient cash resources available to support our development activities and business operations through May 2018. We believe that our ability to continue as a going concern beyond May 2018, both for the near and longer term, is highly dependent upon our ability to successfully secure additional capital through potential strategic transactions and/or private equity offerings, complete our NextGen ADS device verification activities with Battelle, and execute the planned AEROSURF bridge study to be in a position to initiate an AEROSURF phase 3 clinical program. As a development company, we will require significant additional capital and resources to advance our AEROSURF and other potential KL4 surfactant development programs, 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. To execute our AEROSURF development plan, we have hired and retained professional and scientific personnel and invested heavily in securing the resources and expertise needed to potentially achieve success. To leverage these capabilities, maximize the use of our resources and potentially reduce our dependency on a single product candidate, we seek to enter into strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction). We also seek licensing arrangements for AEROSURF and our other KL4 surfactant products in select geographic markets that could bring strategic partners with local development and commercial expertise to support development of AEROSURF in various markets outside the U.S., and financial resources to support our AEROSURF development program. Such financial resources could take the form of capital investments, upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses.

With the support of our largest stockholder, Lee's Pharmaceutical Holdings Limited (Lee's), a company incorporated in the Cayman Islands with limited liability whose common stock is listed on the Hong Kong Stock Exchange and which beneficially owns a majority interest in our common stock, we are currently engaged in active diligence and discussions with a third party for a potential strategic transaction. There can be no assurance, however, that we will be able to reach agreement on terms and within the time frame acceptable to both parties. Moreover, even if we reach agreement and complete a transaction, there can be no assurance that we will have sufficient resources to fund the continued development of AEROSURF or any other product candidates, that our development efforts would be successful, or that we would ever complete such development and obtain regulatory approvals needed to commercialize our product candidates in the world's markets.

In addition to pursuing potential strategic transactions that could diversify our assets and bring in additional capital, we also seek to raise additional capital through private placement offerings of equity securities. In January and March 2018, we entered into loan agreements with Lee's for advances of $1.5 million and $1 million, respectively, to support our development activities and operations while we work to complete an equity offering. To secure our obligations under these loans, we granted Lee's a security interest in substantially all of our assets.

In April 2018, we completed a private placement with an affiliate of Lee's for the purchase of $2.6 million of our common stock and warrants at a purchase price per share of $4.80. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date at an exercise price of $5.52 per share.

In March 2018, we announced a potential strategic collaboration with Eleison Pharmaceuticals, Inc. (Eleison), a specialty pharmaceutical company developing life-saving therapeutics for cancers, to assess the feasibility of using our proprietary ADS to deliver Eleison's inhaled lipid cisplatin (ILC) potentially in combination with our KL4 surfactant. There can be no assurance that we will be successful in these efforts or, even if we are successful, that we and Eleison will agree to undertake a full development program.

In June 2017, we entered into an exclusive license, development and commercialization agreement (license agreement) with Lee's Pharmaceutical (HK), Ltd. (Lee's (HK)), a Hong Kong company and a wholly-owned subsidiary of Lee's, for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets, with a future option potentially to add Japan. The agreement covered our non-aerosol products, SURFAXIN® (which was approved in the U.S. in 2012) and SURFAXIN LS™ (an improved lyophilized formulation of SURFAXIN) as well as AEROSURF. We also granted Lee's (HK) an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory and a future option to manufacture the device in the licensed territory. Under the License Agreement, Lee's (HK) paid an upfront license fee in the amount of $1 million, and agreed to pay up to an additional $37.5 million in potential clinical, regulatory and commercial milestone payments. We also will share in any sublicense income that Lee's (HK) may receive at a rate equal to low double digits, and Lee's (HK) has agreed to pay all development costs and expenses in and for the licensed territory, including for the planned AEROSURF phase 3 clinical program. In addition, Lee's (HK) will pay tiered royalties on a country-by-country basis based on a percent of net sales, depending on the product, in the range of high single to low-to-mid double digit percentages. Royalties are payable until the latest of (A) the expiration of the last valid patent claim covering the product in the country of sale, (B) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (C) ten (10) years after the first commercial sale in the country of sale; after which the royalties shall be reduced for a period of three years to low-to-mid single digits. In addition, the royalty rates will be reduced if one or more generic products are introduced. The license agreement also contains provisions related to sublicensing, non-competition, manufacturing and technology transfer and termination.

In August 2017, we entered into a Loan Agreement, pursuant to which Lee's (HK) agreed to lend us up to $3.9 million to support our activities through October 31, 2017, while we and Lee's worked to complete a $10 million securities purchase agreement (Lee's SPA) pursuant to which Lee's acquired a controlling interest in our Company effective on November 1, 2017. In connection with Lee's SPA, we amended the License Agreement to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. As a result, the additional amounts for potential clinical, regulatory and commercial milestones were reduced to $35.8 million.

In addition, on November 1, 2017, we completed a strategic transaction with affiliates of Deerfield Management Company L.P. (Deerfield) to restructure (Loan Restructuring) our outstanding $25 million long-term loan (Deerfield Loan), $12.5 million of which would have matured in each of February 2018 and February 2019. Under the Loan Restructuring, the notes and the warrants issued in connection with the Deerfield Loan were retired in exchange for $2.5 million in cash, common stock equal to 2% of our outstanding shares, plus potential future AEROSURF regulatory and commercial milestone payments of up to $15 million with the initial payment coming due upon our filing with the FDA a new drug application (NDA) for AEROSURF.

Also in connection with Lee's SPA, in October 2017, Battelle agreed to waive its right to any Liquidation Preference (as defined in the Designation of Preferences, Rights and Limitations) under the Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares) that we issued in February 2017 and we entered into a non-binding memorandum of understanding with Battelle potentially to restructure our payables with them. We are currently working with Battelle to finalize that arrangement.

In February 2017, we completed a private placement offering with selected investors covering 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 consisted of: (i) one Preferred Share, which was convertible into 50 shares of common stock at $27.40 per share, and (ii) Series A-1 Warrants to purchase 50 shares of common stock at an exercise price per share equal to $27.40. 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."

Market Data and Other Information

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 by our licensee in the Asia Pacifica region; 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

Since the withdrawal of SURFAXIN, all of the currently available pulmonary surfactants in the U.S. were introduced in the 1990's, are animal-derived and have been approved by FDA for RDS in premature infants. 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.

The current surfactant market for RDS is estimated to be approximately $70 to $90 million annually in the U.S. and approximately $400 to $425 million annually worldwide. We believe that this market has been constrained by a failure to address the risks associated with intubation and mechanical ventilation, two procedures generally required to administer surfactants. We estimate that approximately 350,000 to 400,000 low birth weight premature infants are born annually in the U.S. (and approximately 2 million in the major U.S., China, European and Japanese medical markets). In addition, with respect to China, where we have entered into a license agreement with Lee's, our current market data suggests that this market has the highest rates of births, RDS and current surfactant sales. Further, the number of low birth weight premature infants born annually in the Latin America markets may represent opportunities similar to or greater than Europe and Japan. 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 are treated with surfactant as the initial therapy for RDS, usually within the first hours of life, and generally because the perceived benefits of surfactant therapy for these very fragile infants tend to outweigh the perceived risks of invasive intubation and mechanical ventilation. The remaining infants are usually treated initially with respiratory support (such as nCPAP) alone. A large percentage of these patients (approximately 25% - 30%) experience nCPAP failure (*see*, "– Initial Focus – AEROSURF for Respiratory Distress Syndrome (RDS) in Premature Infants") and require delayed surfactant therapy using intubation and mechanical ventilation. We estimate that approximately 25,000 to 35,000 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 75,000 to 95,000.

Third-party market research conducted for us in 2014 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 KL4 surfactant as the initial treatment for RDS. Currently, surfactant therapy costs include the cost of drug, related disposables and respiratory support (which can be significant). With an easier, noninvasive, less costly method of administering aerosolized KL4 surfactant, we believe that AEROSURF, which, if approved, will include both drug and a medical device consisting of a durable unit and disposables, potentially may support a price that is higher than that of currently available surfactants. We also believe that this easier, noninvasive, less costly 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. Based on that potential increase, we believe that the estimated RDS worldwide market might then represent an annual market opportunity of $800 million to a $1.2 billion.

Potential Pharmacoeconomic Benefits of AEROSURF

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 generally 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 if complications normally associated with intubation and mechanical ventilation, including bronchopulmonary dysplasia, should develop. Other healthcare system costs might include the cost of transporting RDS patients to tertiary care neonatal intensive care units, if they require intubation and mechanical ventilation, as well as family relocation services. Thus, if AEROSURF were able to provide clinical and pharmacoeconomic benefits by reducing or eliminating 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 significantly.

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.) Thus, we believe that we may be able to further develop our KL4 surfactant technology and ADS to potentially address serious respiratory conditions affecting pediatric and adult patient populations, including 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 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 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. We currently 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. This dosage form 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. The KL4 surfactant technology was invented at The Scripps Research Institute, exclusively licensed to Johnson & Johnson, Inc. (J&J) and further developed by an affiliate of J&J and also by us. We have also been active in seeking patent protection for our innovations relating to the lyophilized dosage form and otherwise seeking to protect potential 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 in pediatric and adult populations that represent significant unmet medical needs.

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 our liquid instillate.

We have demonstrated that we can aerosolize 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 developing lyophilized KL4 surfactant for use in our AEROSURF development program to treat RDS in premature infants.

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 FDA in 2012 (SURFAXIN (lucinactant) Intratracheal Suspension). SURFAXIN is the first synthetic, peptide-containing surfactant approved by FDA for use in neonatal medicine in the U.S. Due to resource constraints, in the second quarter of 2015, we ceased commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and 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, 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).

Aerosol 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. In 2018, we plan to complete development of our new NextGen ADS 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 2037 and covers the core components of the system.

The ADS is designed to aerosolize KL4 surfactant and has been demonstrated to produce consistent and controlled output rates, particle size, and other aerosol characteristics throughout extended KL4 surfactant dosing periods. An aerosol is created by pumping KL4 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. We are developing the NextGen ADS to replace our AEROSURF phase 2 clinical device for ongoing AEROSURF development activities, including our planned phase 3 clinical development program, and, if AEROSURF is approved, our “go-to-market” aerosol device. It is based on the same aerosol delivery technology as the AEROSURF phase 2 ADS and is designed to produce key aerosol characteristics, including emitted dose and particle size, that are comparable to those of the phase 2 clinical ADS. In addition, the NextGen ADS is designed with enhanced ergonomics, an improved user interface and faster start-up and change-over processes. Other ease-of-use improvements include built in step-by-step instructions with detailed images, simplified setup for drug-contact disposable components, enhanced controls and dose monitoring, and easier maintenance with modular design.

During our phase 2b clinical trial, and to a lesser extent in certain of our phase 2a clinical trials, we experienced unexpected ADS shut downs during aerosol administration, which resulted in patient treatment interruptions. At no time did these shutdowns represent a safety issue as the triggering events occurred within the device away from the patient and the device performed as designed by shutting down. However, the treatment interruptions in the phase 2b clinical trial occurred at a higher, unexpected rate. Because the phase 2b trial was blinded, the impact of the interruptions on the results of our trial was not known until after we completed the trial and unblinded and analyzed the data. Based on our investigation, we believe that the interruptions are attributable to specific lots of frit filters that were used in certain lots of disposable drug-path components that had a tendency to clog. We assessed the results of our investigation in the context of the ongoing NexGen ADS design and implemented design changes to mitigate the risk of filter clogging. The modified design includes a larger filter with improved quality specifications, and a more controlled assembly process. In addition, we have initiated a technology transfer of our manufacture of the ADS to an experienced FDA-registered, medical device contract manufacturer with strong quality and control systems. Following implementation of the design changes, we currently are conducting a performance study consisting of test runs of 50 minute treatments and, at April 6, 2018, have completed 60 of approximately 65 planned test runs and have experienced only a single clogging-related interruption. The single interruption was attributable to an isolated software issue that we believe is correctable.

In 2018, we are planning to initiate an AEROSURF bridge study to transition in the clinic from our phase 2 prototype ADS to our NexGen ADS. Among other things, the purposes of this trial will include to (i) demonstrate adequate and consistent performance by the NextGen ADS and gain in-clinic experience, and (ii) provide sites the experience of setting up and using the device in advance of the planned phase 3 clinical development program. *See*, "– Business Strategy and Updates – AEROSURF Clinical and Device Development Update – Focus for 2018 – AEROSURF Bridge Study."

We believe the NextGen 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."

Lung Deposition Study

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 KL4 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 KL4 surfactant using the same model ADS used in the phase 2b clinical trial. After administration of KL4 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 KL4 surfactant delivered using the ADS via nCPAP was generally uniformly deposited in all regions of the NHPs lungs. A quantitative analysis further demonstrated that KL4 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 KL4 surfactant) and other inhaled therapies to critical-care infants requiring ventilatory support. This device, which we registered under the 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 believe that using a device such as AFECTAIR in the nCPAP circuit would facilitate the delivery of our KL4 surfactant to premature infants with RDS.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are currently directed to developing our proprietary lyophilized KL4 surfactant, NextGen ADS, and aerosol delivery technologies for the management of RDS in premature infants. We believe that our proprietary technologies may also be developed into a series of KL4 surfactant pipeline programs to potentially support a significant critical care franchise. We are continually reassessing our research and development investments and priorities to respond to events and circumstances, including our cash flow requirements, financial liquidity and perceived ability to secure necessary capital; the relative importance of a project to our near-term objectives; the results of our clinical trials, preclinical research and related activities; progress in our device development programs and technology innovation; and the potential for development of partnerships, collaboration agreements and other strategic transactions. We expect to modify and adapt our research and development plans and priorities from time to time and anticipate that we will continue to do so in the future.

We are currently focused primarily on our AEROSURF development program and completing our NextGen ADS design verification activities with Battelle and initiation of our planned bridge study and phase 3 clinical development program and, if approved, early commercial application. We have completed three AEROSURF phase 2 clinical trials and are planning in 2018 to complete the design verification of the NextGen ADS and initiate a bridge study, among other things, to confirm whether our development objectives for our NextGen ADS have been achieved. *See*, "– Business Strategy and Updates - AEROSURF Clinical and Device Development Update." We also plan to seek regulatory advice and discuss with FDA and international regulatory authorities a potential development plan to advance AEROSURF in selected major markets around the world. We also plan to continue our efforts to identify and enter into a strategic transaction, which could entail expanded research and development activities to support development of additional pipeline products and/or and development and, if approved, commercial introduction of AEROSURF in various geographic 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 design and execution of preclinical experiments and studies to support drug development. We conduct certain experiments and bench studies in-house and otherwise 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. We have retained contract research organizations (CROs) to support our ongoing AEROSURF clinical activities, 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 expertise in FDA regulatory matters. We also consult extensively with independent FDA and international regulatory experts, including former senior scientific staff of FDA;
- engineering expertise to support development of our aerosol delivery technologies. Our team of engineering professionals are focused on further optimizing our NextGen ADS and working with Battelle, which has significant expertise in developing and integrating aerosol device technologies;
- quality operations expertise to assure compliance with applicable U.S. and international regulations. For our device development activities, we are working with a CMO that has quality operations to support our activities;
- CMOs to produce our lyophilized KL4 surfactant, APIs and other materials for our drug product. We also plan to rely on third-party manufacturers to manufacture and assemble our ADS; and
- our own analytical testing laboratory and research and medical device development laboratory where we perform certain release and stability testing. 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, 2017, and December 31, 2016, we invested approximately $17.3 million and $31.7 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 the AFECTAIR aerosol-conducting airway connector. 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 of 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 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 lyophilized drug, 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 Americas, 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, Pharma Services Group, Patheon, part of Thermo Fisher Scientific (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 program. We have manufactured a sufficient clinical supply of KL4 surfactant to support our remaining planned phase 2 clinical 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. 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 has performed 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 NextGen ADS currently is in development under our Collaboration Agreement with Battelle. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement." It is comprised of a durable reusable device that contains the heater, software and other componentry, and disposable parts that include the critical drug-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 under a research and development agreement focused on design, development and testing of a clinic-ready ADS for use in our AEROSURF phase 2 clinical trials. Battelle manufactured a sufficient number of these prototype ADSs to support our AEROSURF phase 2 clinical trials through the AEROSURF phase 2b clinical trial. We have continued to operate under the terms of the development agreement for certain matters that fall outside the scope of our Collaboration Agreement.

We entered into the Collaboration Agreement in October 2014 to develop and share in the expenses of developing our NextGen ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. We are on track to complete the three-stage development program outlined in the Collaboration Agreement in line with the time line for our AEROSURF clinical development program. We are currently engaged in design verification of the NextGen ADS, which is the final phase of the collaboration. We recently entered into an agreement with Mack Molding Company (Mack), a fully integrated medical device manufacturer in Arlington, Vermont and have begun work on a technology transfer to assure the continued availability of NextGen ADS for our future development activities and including our planned phase 2 and phase 3 clinical trials. When our needs are better known, we plan to enter into a supply agreement with Mack.

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

Distribution

We are currently evaluating Clinical Supply Organizations for the receipt, labeling, packaging and distribution services to support our planned AEROSURF bridge study.

Strategic Alliances and Collaboration Arrangements

Battelle Collaboration Agreement

In October 2014, we entered into a Collaboration Agreement with Battelle for the development of the NextGen ADS. This collaboration provided us the continued benefit of Battelle's expertise in developing and integrating aerosol devices using innovative and advanced technologies. Under the Collaboration Agreement, we and Battelle agreed to share the costs of development for a three-stage development plan.

Under the Collaboration Agreement, we jointly agreed to: (i) define the requirements of the NextGen ADS and develop a detailed project plan (stage 1), (ii) execute the project 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 remaining AEROSURF development activities and, if approved, the initial commercial activities. Throughout the development process, we retained final decision-making authority on all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of the NextGen ADS. We and Battelle agreed to share equally the costs of stage 1 and the planned costs of executing the project plan through final testing and documentation stages (stages 2 and 3). Battelle agreed to bear the cost of any cost overruns associated with the project plan and we agreed to bear the cost of any increase in cost resulting from changes in the scope of the product requirements.

During the project plan, we amended the anticipated costs and the scope of the project and adjusted the development schedule to align the project with our planned completion of the AEROSURF phase 2 clinical program.

As of March 31, 2018, we are advancing our development activities through design verification procedures and expect to complete this project plan mid-year 2018. In the fourth quarter of 2017, in connection with a restructuring related to Lee's acquisition of a controlling interest in our company, we and Battelle signed a non-binding memorandum of understanding that sets forth key terms for a potential restructuring of the amounts we owe Battelle under both the 2012 development agreement and the Collaboration Agreement. We are currently in discussions to finalize that arrangement.

In connection with the Collaboration Agreement, we issued to Battelle two warrants (the Battelle Warrants) to purchase shares of our common stock, each having an exercise price of $1,400 per share and a term of 10 years, subject to earlier termination under certain circumstances, including (i) a warrant to purchase up to 3,571 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 1786 shares of our common stock (Additional Warrant), exercisable if and only if Battelle successfully completed the project plan no later than a specified Milestone Date (November 15, 2016). The Additional Warrant was cancelled as of November 15, 2016 as the project plan had not been completed by that date.

In addition, if Battelle successfully completes the project plan, 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 initial 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.

In October 2017, we and Battelle signed a nonbinding memorandum of understanding (Battelle MOU) outlining potential terms to restructure certain accounts payable related to our device development activities with Battelle. In addition, the MOU provides that in connection with the restructuring, the aggregate limit of potential royalties will be increased from $25 million to $35 million. We are currently working with Battelle to finalize that arrangement.

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 (collectively, the territory). Under the alliance, 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 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, Esteve returned certain countries to us (Former Esteve Territories) and 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. In addition, with respect to our aerosolized KL4 surfactant, Esteve will pay us $500,000 upon the initial filing for regulatory approval with the European Medicines Agency and $500,000 upon receipt of regulatory 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 that we own or exclusively license, (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.

Lee's Pharmaceutical Holdings Ltd.

Lee's Pharmaceutical (HK) Ltd.

In June 2017, we entered into a License, Development and Commercialization Agreement (License Agreement) with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong (Lee's (HK)) and an affiliate of Lee's. Under the License Agreement, we granted to Lee's (HK) an exclusive license with a right to sublicense (i) to develop and commercialize our KL4 surfactant products, including SURFAXIN®, which was approved by FDA in 2012 for the prevention of respiratory distress syndrome (RDS) in premature infants, SURFAXIN LS™, the lyophilized dosage form of SURFAXIN, and AEROSURF, and (ii) to register and manufacture SURFAXIN and SURFAXIN LS for use in the licensed territory, which includes the People's Republic of China ("PRC"), Hong Kong, Thailand, Taiwan and 12 other countries. In addition, we granted Lee's (HK) options to potentially add Japan to the Licensed Territory, which was made effective in an August 2017 amendment (License Amendment, discussed below) and to manufacture our ADS in the licensed territory, in each case subject to conditions set forth in the License Agreement.

Under the License Agreement, Lee's (HK) made an upfront payment to us of $1 million. We also may receive up to $35.8 million (as amended by Lee's SPA, discussed below) in potential clinical, regulatory and commercial milestone payments and will share in any sublicense income Lee's (HK) may receive at a rate equal to low double digits. In addition, Lee's (HK) will be responsible for all costs and expenses in and for the Licensed Territory related to development activities, including a planned AEROSURF phase 3 clinical program, regulatory activities, and commercialization activities.

In August 2017, we entered into a loan agreement, pursuant to which Lee's (HK) agreed to lend us up to $3.9 million to support our activities through October 31, 2017, while we and Lee's worked to complete a $10 million securities purchase agreement (Lee's SPA) pursuant to which Lee's acquired a controlling interest in our Company effective on November 1, 2017. In connection with Lee's SPA, we entered into a License Amendment to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. As a result, the additional amounts for potential clinical, regulatory and commercial milestone were reduced from $37.5 million to $35.8 million.

We will be eligible to receive tiered royalties based on a percent of Net Sales (as defined in the License Agreement), depending on the product, in the range of high single to low-to-mid double digit percentages. Royalties are payable on a country-by-country basis until the latest of (A) the expiration of the last valid patent claim covering the product in the country of sale, (B) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (C) ten (10) years after the first commercial sale in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each product and, for the initial three years, shall be in the range of low-to-mid single digits. In addition, in the event that one or more generic products are introduced, the royalty rates will be reduced, subject to certain minimums if we are subject to continuing obligations at the time to pay royalties under our in-license agreements.

Under the License Agreement, Lee's (HK) will be responsible for all activities related to development, regulatory approval and commercialization of KL4 surfactant and combination drug/device products in the licensed territory. Lee's (HK) will hold the product licenses for all non-aerosolized products in the licensed territory and will seek regulatory approval initially for SURFAXIN and SURFAXIN LS for RDS. We will hold the product license in the Licensed Territory (except where prohibited by law) for all aerosolized products and will designate Lee's (HK) its exclusive agent and representative to develop and register AEROSURF and other aerosolized products in our name and on our behalf. Lee's (HK) also has agreed that, except as provided in the License Agreement, for a period of ten (10) years beginning with the later of the first commercial sale of the first aerosolized product and the first commercial sale of the first non-aerosolized product in the PRC, it will not develop, register, manufacture, or commercialize any product for the prevention and/or treatment of RDS in premature infants or other diseases and conditions in humans, in either case that administers, utilizes or contains pulmonary surfactant without our prior written consent.

Lee's (HK) may sublicense certain activities under the License Agreement to an affiliate of Lee's (HK), but may not grant sublicenses to unaffiliated third parties without our prior consent. A sublicensee and a subcontractor may not be a competitor that we identify to Lee's (HK). Sublicenses under the License Agreement do not include the right to further sublicense. In addition, we and Lee's (HK) have entered into a technology transfer agreement under which we will transfer to Lee's (HK) the manufacturing processes for SURFAXIN and SURFAXIN LS; and we and Lee's (HK) plan to negotiate (i) a manufacturing agreement providing for the manufacture of SURFAXIN and SURFAXIN LS by Lee's (HK) and giving us access to such products outside the licensed territory; (ii) a manufacturing and supply agreement providing for the manufacture and supply of AEROSURF drug and medical device components by us to Lee's (HK); and (iii) such other agreements and amendments as may be necessary for the parties to perform their obligations under the License Agreement.

The term of the License Agreement commenced on the effective date of the License Agreement and will continue on a country-by-country basis for the commercial life of the products. Either party may terminate the License Agreement in the event of bankruptcy or a material breach of the License Agreement by the other party that remains uncured for a period of sixty (60) days. In addition, either party may terminate the License Agreement in its entirety or with respect to any individual product or country if a regulatory authority terminates, suspends or discontinues development of a product and such termination, suspension or discontinuance persists for a period in excess of eighteen (18) months. Upon termination of the License Agreement in its entirety or with respect to a particular product or country, generally all related rights and licenses granted to Lee's (HK) will terminate, all rights under our technology will revert to us, and Lee's (HK) will cease all use of our technology.

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). All J&J Patents have expired. 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.

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 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 and European Patent No. 1841458B1 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 the U.S. and EPO) 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 or granted. U.S. Patents Nos. 8,748,396; 8,748,397 and 9,554,999 B2 and European Patent No. 2723323B1will expire on March 28, 2033.

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

In 2008, we restructured a December 2005 strategic alliance and 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).

Pursuant to the PM License Agreements, we have worldwide exclusive rights to the medical device component of our AEROSURF product candidate. 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 current ADS and our NextGen version are protected by a portfolio of issued patents, as well as pending and new patent applications, covering the core components of the system. These patents and applications will expire on dates ranging from 2018 to 2037, with the core patents expiring in 2033 or later.

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 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 KL_4 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 an 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 (i) increase the efficiency of aerosol delivery to the patient by allowing more efficient delivery of aerosols to the patient, and (ii) 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 2017. 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. European Patent No. 2265309 will expire on March 17, 2029.

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®, DISCOVERYLABS INSPIRED INNOVATION (logo)®, 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 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. 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.

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 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 FDA will facilitate and expedite the development and review of the application for the approval of the product. 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.

FDA granted "Fast Track" designation for (i) our KL4 surfactant 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. Lack of available resources could cause us to slow the pace of our programs and lessen the lead that we believe we have with AEROSURF. 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.

Currently, 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) and Survanta (beractant), which is derived from a chemical extraction process of bovine (cow) lung, are the market leaders. 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). 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. There is always a risk for an innovation or disruptive technology which can create new potential competition for our business and programs.

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 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 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 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 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 FDA as part of the IND.

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.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial 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.

After completion of the required clinical testing, an NDA is prepared and submitted to 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 $2,421,000 for fiscal year 2018, and the applicant under an approved new drug application is also subject to an annual program fee, currently exceeding $300,000 per product for fiscal year 2018. Beginning in Fiscal Year 2018, this annual program fee replaces the annual product and establishment fees. These fees are typically increased annually.

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, FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use. 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 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.

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. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, 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 FDA to reconsider the application. If, or when, those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, 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, 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 FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Orphan Drugs

Under the Orphan Drug Act, 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 FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by 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, 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 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 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 FDA concerning any patents listed for the approved product in 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 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 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 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 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 FDA. During the exclusivity period, 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 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 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 five-years of patent term 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 remaining 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 term extension increases the patent term by one year and may be renewed up to four times. For each interim patent term extension granted, the post-approval patent term 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 term 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. 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 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 FDA subjects entities to periodic unannounced inspections by 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. 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 except a product with a new active ingredient that is molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA or BLA submitted on or after August 18, 2020.

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 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 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 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 de novo classification process, 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, FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation (which requires that manufacturers report to 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 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 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, 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, 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, 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 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 FDA. In addition, international regulators may require different manufacturing practices than 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 30, 2018, we have 27 full-time employees, one part-time employee and one full-time temporary employee. All of our employees are based in the U.S.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy or stockholder information 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

As of April 15, 2018, we currently have sufficient capital to fund our research and development programs, support our business operations and reduce existing obligations on a timely basis to May 2018. If we do not secure additional capital to support our future activities before our existing cash resources are exhausted, we likely will be unable to continue as a going concern.

As of December 31, 2017, we had cash and cash equivalents of $1.8 million and current liabilities of $11.7 million. In November 2017, we successfully retired $25 million of long-term debt under the Deerfield Loan. In January 2018 and March 2018, we received interim loans from LPH, an affiliate of Lee's, in the amounts of $1.5 million and $1.0 million, respectively. In early April 2018, we completed a $2.6 million private placement offering with LPH II, from which we received net proceeds of approximately $2.5 million. As of April 15, 2018, and before any additional financings, including in connection with potential strategic transactions, we believe that we will have sufficient cash resources available to support our development activities and business operations through May 2018.

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 existing obligations on a timely basis. We are currently planning to secure the additional capital that we will require in the near-term, through a combination of public or private equity offerings, 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 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.

As of April 15, 2018, and before any additional financings or other strategic transactions, we believe that we will have sufficient cash resources to support our limited development programs and business operations and reduce obligations to May 2018. Since April 2015, we have focused our capital and resources primarily on the AEROSURF clinical development program, our lyophilized KL4 surfactant and design and development of our NextGen ADS for use in our remaining development activities, including our planned phase 3 clinical program. 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 loss of eligibility to use the registration statement Form S-3 and our at-the-market equity sales program (ATM Program), our delisting from The Nasdaq Capital Market in May 2017 and subsequent transfer to the OTC Markets Group Inc.'s OTCQB® market, our capital structure, which currently consists of common stock, convertible preferred stock and warrants to purchase common stock, as well as conditions in the global financial markets generally, 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. 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.

Future sales and issuances of our common stock or rights to purchase our common stock, 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) , 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. 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 or private financing, 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.

The exercise of stock options and other securities could also 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 Preferred Stock and debt obligations. As of December 31, 2017, we had cash and cash equivalents of $1.8 million and current liabilities of $11.7 million. 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 up to 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 stockholders.

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;
- changes in executive management; 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 has been quoted on the OTCQB® market tier operated by The OTC Markets since May 5, 2017. The price of our common stock has been, and we expect it to remain, volatile. The average daily trading volume in our common stock varies significantly and we have experienced extended periods where the trading volume has been low. 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 currently have loans in the amount of $2.5 million from an affiliate of Lee's, which we expect to satisfy through Lee's participation in a future equity financing. To secure our obligations under these loans, we granted to the Lee's affiliate a security interest in substantially all of our assets. We also have outstanding obligations related to our development activities and ongoing operations of $11.7 million.

Our debt and financial 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 and financial 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, 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 our ability to license our products in the U.S. and other markets around the world;
- could adversely affect our ability to enter into strategic transactions, public or private equity offerings, and similar agreements, or require us to obtain the consent to enter into such transactions;
- 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.

Should we fail to make pay our obligations or fail to comply with any covenants contained in any related agreements, we could be in default regarding that indebtedness. Since we have pledged substantially all of our assets to secure our obligations to the Lee's affiliate, a debt default could enable Lee's 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 other payment obligations.

We currently require significant additional capital to support our research and development activities and operations and have sufficient cash resources to pay our vendors, service providers and pay other business expenses. As such, we routinely closely monitor and control our cash resources to assure that investment and spending decisions advance our corporate objectives at any time. While we seek to raise the additional capital that we require, our relationships with important vendors and service providers may be affected. If any of our key vendors and service providers were to cease working with us or subject the delivery of products or services to timing or payment preconditions, our development activities may be adversely affected, which could have a material adverse effect on our business and operations.

During and since completion of our AEROSURF phase 2b clinical trial and announcement of the results, our cash resources have been constrained. To manage our cash, we have controlled and plan to tightly control purchasing and retention of consultants, monitor the release of funds and may defer payment on invoices to conserve cash. As a consequence, our aged accounts payables are expected to increase and our relationships with key vendors and service providers may be affected. Although LPH's first quarter loans to us and our recent equity offering in April 2018 have provided capital to support our development activities and business operations and pay our vendors and service providers, we still will require significant additional capital. While we seek the additional capital that we require, we are working closely with our vendors and service providers to preserve our key relationships. Failure to retain such key relationships could have a material adverse effect on our development activities and our business and operations.

Risks Related to our Development Activities

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

Based on the planned top-line results, our AEROSURF phase 2b clinical trial did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours. We believe this result was attributable in large part to an unexpected rate of treatment interruptions, which occurred in about 24% of active enrollments, predominantly in the 50-minute dose group. These interruptions, we believe, were primarily related to specific lots of disposable cartridge filters with a higher tendency to clog. We are currently preparing to conduct an AEROSURF "bridge" study to: (i) to gain in-clinic experience with the NextGen ADS, (ii) to confirm whether our device development objectives have been met and (iii) to generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial, which was adversely affected by device-related treatment interruptions. We have previously completed three phase 2 clinical trials for AEROSURF. To gain marketing authorization for AEROSURF, we will need to successfully complete our clinical trials, including a future potential pivotal phase 3 clinical development program. Such development programs generally take years to complete and may be delayed by a number of factors. We may not reach agreement with the U.S. Food and Drug Administration (FDA) or a foreign regulator on the extent of our phase 3 program, 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 common pivotal phase 3 clinical development program in the all markets of interest. Conditions imposed by 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 both 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. 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 device performance, lack of compatibility with complementary technologies, or long treatment times required to demonstrate effectiveness, were to delay the results, we might be forced to make changes to our clinical trial plan that we otherwise would not implement, which could adversely affect the results and potentially impair our ability to secure additional capital to fund our continued development program. Even if we 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 clinical trials to study 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 potentially:

- the number of clinical sites;
- the size of the patient population;
- the perceived risks and benefits of the product candidate;
- the existence of competing clinical trials;
- the severity of the disease under investigation;
- the existence of alternative available products;
- the eligibility and enrollment criteria for the study;
- the willingness of patients' parents or guardians to participate in the clinical trial;
- 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. 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 and may in the future engage 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, including potentially in Canada, the EU, Latin America and Asia Pacific. 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 ADS and our synthetic lyophilized KL_4 surfactant. We are working 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 design verification procedures with Battelle Memorial Institute (Battelle) to complete the collaboration development of our next generation (NextGen) ADS that will replace our prototype ADS used in our phase 2 clinical trials to date and be available for use in our remaining AEROSURF clinical development activities and, if approved, initial commercial activities. We are conducting ongoing assessments of our medical device performance and have incorporated and plan to incorporate performance enhancements into our NextGen ADS as we move forward. If our NextGen ADS should fail to perform as designed, such failures could adversely affect the 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), or manufacture our drug and medical device 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.

In addition, the medical practices and procedures associated with treating RDS can vary between clinicians, medical sites and countries. For instance, we observed differences among clinical sites and on a country by country basis in nCPAP failure rates, in our clinical trials (where nCPAP failure rates have served as control comparators for AEROSURF) and as demonstrated in our Prospective Observational Study. This variability must be accurately estimated when designing and sizing a clinical trial to assure demonstration of efficacy and meeting statistical significance in outcomes. Even when estimated and planned for appropriately, this variability brings additional risk of poor trial outcomes as the trials expand to new centers and countries where we have no prior clinical experience. This risk is inversely related to the size of the trial. Smaller trials may be impacted to a greater degree by variability and have a greater risk of not seeing a true effect when one is actually present. As such, unless an interim analysis is planned in the design, we do not know effects of this or other variability or the results until the trial is fully completed.

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. No assurance can be given that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical trials will be concluded successfully. Moreover, 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 2 clinical trials may not accurately predict phase 3 trial results, whether due to differences in sample size, study arms, duration, endpoints, features of the ADS used or other factors. We are currently planning to conduct an AEROSURF bridge study to transition in the clinic from the phase 2 ADS to the NextGen ADS, which will be used in our planned phase 3 program. 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 clinical results may not be replicated in subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may question the trial design or sufficiency for approval of the endpoints we select for our clinical trials or add new requirements, such as the completion of additional studies, as conditions for obtaining approval or obtaining an indication. Regulatory authorities may disagree with our view of the data or 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 may delay our clinical development and regulatory efforts, delay or prevent our obtaining regulatory approval for new product candidates and new indications for existing products, and result in significant additional costs and expenses, require 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. Moreover, after taking such events into account, we may make a strategic decision to discontinue development of a product or indication if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline.

For AEROSURF, we may conduct clinical development in the U.S., Canada, the 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 regional 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:

- one or both of the FDA or a foreign regulator may disagree with the design or implementation of one or more clinical trials;
- one or both of 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;
- one or both of 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;
- one or both of 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;
- one or both of the FDA or a foreign regulator may not deem the data collected from clinical trials to be sufficient to support the submission of an NDA or other applicable regulatory filing;
- one or both of the FDA or a foreign regulator may require additional preclinical studies or clinical trials;
- one or both of the FDA or a foreign regulator may identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- one or both of the FDA or a foreign regulator may grant approval contingent on the performance of costly additional post-approval clinical trials;

- one or both of 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;
- one or both of 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;
- one or both of 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
- one or both of 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. Even if we demonstrate the efficacy and safety of a product candidate, a regulator may require us to demonstrate superiority over comparative products before agreeing to grant marketing approval. 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 has adopted legislation intended 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 to implement new requirements for combination products, and whether such changes could have a material adverse effect on our business and results of operations.

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 timely development of our NextGen ADS intended for future development activities and, if approved, initial commercial activities in a manner that performs as intended in clinical studies, 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.

For our phase 2 clinical development activities, we developed a clinic-ready ADS and currently are working with Battelle to further develop a NextGen ADS 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, if at all, and on a timely basis, a NextGen ADS that is acceptable for use in our remaining AEROSURF development activities, with levels of efficiency, consistent performance, reliability and cost appropriate for commercial activities;
- we will require access to sophisticated engineering capabilities. We have our own medical device engineering staff and we are currently working with Battelle, which is assisting us under a collaboration agreement that is in the final phase of executions. If we are unable to identify design engineers and medical device experts to support our continued development efforts in the future, including, potentially, for commercial use and later versions of the NextGen 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; 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 ADS may perform to specifications in the bench setting and internal tests, however, at clinical sites with multiple operators of the device, we may experience an unanticipated issue with performance that could have a negative effect on trial outcomes.

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, our suppliers of APIs or excipients, our third-party analytical testing and other materials. If the parties we depend on for supplying our APIs, materials and excipients as well as analytical testing and 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, analytical testing and 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 three 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. We also have quality and service agreements with our third-party laboratories who provide the analytical testing and related services needed to support manufacture of our drug product. If we do not maintain these manufacturing and service relationships that are important to us and are not able to identify replacement suppliers, vendors and laboratories, 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, vendors and service providers 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 different 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 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 and subsequently retain 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.

For AEROSURF, we plan to rely on CMOs to manufacture and assemble the NextGen ADS and all subcomponents 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 worked with Battelle to develop a clinic-ready ADS to support our phase 2 clinical development program and currently are collaborating on design verification of our NextGen ADS. Although we have identified a CMO that we expect will be able to produce and assemble the ADS for our future development activities, as with many device development initiatives, there is a risk that, even if we are able to finalize a technology transfer and related agreement, the CMO that we have selected may be unable to consistently manufacture and assemble the subcomponents of our ADS to our specified standards. 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 NextGen ADS, it will adversely affect our timeline for the development and, if approved, commercialization of 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 even if we alter our strategy or plans, 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 capital resource and budget constraints have put our management under pressure to execute our business strategy with limited resources. Furthermore, as a result of our limited capital resources, our management team has had to dedicate an increasing amount of time towards raising capital, which diverts their attention away from our AEROSURF development program.

Our development program for AEROSURF has progressed to a planned bridge study following our phase 2b clinical trial. 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 the AEROSURF development program, from time to time, we support studies of other potential KL_4 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, Latin America 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. Moreover, if our strategic alliances or collaboration arrangements should require greater focus and attention on our part than we expect, we may be forced to divert our limited resources away from our own development programs, which could have a material adverse effect on our development activities and plans.

As part of our strategy, we intend to continue to evaluate opportunities for strategic alliances and collaboration arrangements, although there can be no assurance that we would be able to consummate any 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. Moreover, if we are forced to allocate unplanned resources to bolster our strategic alliances or collaboration arrangement, our limited resources may be diverted from our core activities, which could have a material adverse effect on our development activities and plans.

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. 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 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 partners 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, which could involve a significant investment and a potentially unacceptable delay. If we, our partners or our collaborators fail to conduct our respective activities in a timely manner, or otherwise breach or terminate the agreements that make up our arrangements, or if a dispute should arise under our agreements or 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 collaboration could impair our ability to enter into other strategic transactions, including a potential merger or acquisition. We may find it difficult, for example, to identify and enter into commercialization agreements acceptable terms, if at all, in limited territories in the EU, where we have a collaboration with Laboratorios del Dr. Esteve, S.A. (Esteve) in a territory consisting of Andorra, Greece, Italy, Portugal and Spain (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.

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. 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 globally 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.

The RDS market and sales of therapies to treat RDS are global (with most occurring outside the U.S.). Political, trade policy, currency and conflicts can arise which may affect our ability to develop and market globally.

Other Risks Affecting our Business

Lee's Pharmaceutical Holdings Limited has a significant influence on our business operations.

As of April 3, 2018, Lee's, beneficially owns, through its affiliates LPH and LPH II, approximately 60% of our issued and outstanding common stock, including shares issuable upon conversion of our Preferred Stock and shares issuable upon exercise of warrants. Because Lee's is by far our largest shareholder and owns a majority of our outstanding common stock, it has the voting power to approve any matter that requires shareholder approval by written consent without a stockholder meeting. As a result, Lee's has significant influence over our business operations and capital raising activities, and therefore, Lee's could cause corporate actions to be taken even if the interests of Lee's conflict with the interests of our other stockholders. This concentration of voting power could have the effect of deterring or preventing institutional investor interest in the Company or a change in control that might be beneficial to our other stockholders.

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 disclosure controls and to disclose any changes in 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, we could face severe consequences. 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, 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, human error, 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 as a result of legal claims or proceedings, under laws that protect the privacy of personal information, regulatory penalties. Furthermore, 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 at our headquarters in Warrington, Pennsylvania. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. We depend upon third-party manufacturers and laboratories, to manufacture our lyophilized KL_4 surfactant, our AFECTAIR device and our ADS and perform important API and drug product release testing and stability work. 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 and laboratories, such as a fire, flood or tornado, many of those products could not be produced until the manufacturing portion of such facility and the service laboratory 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, as well as 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 initially 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 have been important to our strategy of commercializing our KL4 surfactant products. These patents have all expired. However, during the course of our development activities, 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., Europe and elsewhere 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 alone 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 certain 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 as late as 2037. 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 assembled a team of qualified personnel to advance the AEROSURF development program. 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 Medical 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. 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 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, if our products are approved, 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 be required 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 costlier 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 21,189 square feet of space that we lease. In February 2018, as part of our effort to reduce cash outflows and conserve cash resources, we agreed to surrender 9,317 square feet to the landlord, reducing the size of our premises from 30,506 square feet to 21,189 square feet, and lowered our proportionate share of the building expense. Our base rent was adjusted effective January 1, 2019, as provided in the lease amendment; and our security deposit was reduced from $225,000 to $140,000, releasing $85,000 cash from a bank deposit account securing a letter of credit that we provided to the landlord as security. In addition, we agreed to cancel a right of first offer set forth in the lease and the landlord agreed to undertake at its expense the work required to separately demise the surrendered space.

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. We also maintain a controlled medical device development laboratory that is used by our engineering team to conduct development activities for AEROSURF and our aerosol delivery technologies. We believe our current facilities are adequate for our needs in 2018.

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.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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 quoted on the OTCQB market operated by the OTC Market Group under the symbol "WINT." As of April 6, 2018, we had 80 holders of record of shares of our common stock, and there were 3,769,088 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 through May 4, 2017 and as reported on the OTCQB from May 5, 2017 through December 31, 2017 (adjusted for the 1-for-20 reverse stock split that was effective December 22, 2017).

	2017		2016	
	High	Low	High	Low
Period:				
First Quarter	$ 36.98	$ 22.40	$ 58.80	$ 31.60
Second Quarter	$ 33.20	$ 4.80	$ 77.20	$ 33.00
Third Quarter	$ 7.00	$ 3.60	$ 58.40	$ 35.20
Fourth Quarter	$ 8.80	$ 3.00	$ 64.80	$ 24.60

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, 2017 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, 2017 and 2016.
- **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, including our proprietary aerosol delivery system (ADS), being developed to enable noninvasive administration of aerosolized KL4 surfactant at consistent and reproducible volumes suitable to deliver therapeutic dosages in a reasonable period of time. We are currently working with Battelle Memorial Institute (Battelle) to complete design verification procedures for a next generation (NextGen) ADS potentially for use in our remaining AEROSURF® development activities and, if approved, initial commercial activities. We believe that our proprietary technologies may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of respiratory distress syndrome (RDS) in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. The currently-available surfactants in the United States (U.S.) are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support such as nasal continuous positive airway pressure (nCPAP). Unfortunately, nCPAP does not address the underlying surfactant deficiency and consequently, many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require delayed surfactant therapy with invasive intubation (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.

AEROSURF is designed to administer aerosolized KL4 surfactant noninvasively and potentially meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. 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 following nCPAP failure. We also believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. Consistent with our belief, FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

While we are focused primarily on AEROSURF, we are also assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant may potentially provide benefits related to use, such as longer shelf life, reduced cold-chain requirements and lower viscosity. We have engaged with the FDA to discuss a potential development plan, trial design and regulatory plan for approval. If we can define an acceptable development program that is achievable from a cost, timing and resource perspective, we might seek approval to treat premature infants who, because they are unable to breathe on their own, cannot benefit from AEROSURF.

We also believe that our KL4 surfactant technology may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have received support, and plan to seek additional support, from the National Institutes of Health ("NIH") and other government funding sources to explore the utility of our KL4 surfactant to address a variety of 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). 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.

We have limited resources and no operating revenues and believe that our ability to continue as a going concern in the longer term is highly dependent upon our ability to successfully complete development of our NextGen ADS, execute the planned AEROSURF bridge study to be in a position to initiate an AEROSURF phase 3 clinical program, and attract interested investors, strategic partners and collaborators. Because our AEROSURF phase 2b program did not meet its primary endpoint, due, we believe, to a higher-than-anticipated rate of treatment interruptions experienced with the phase 2 prototype device, we adjusted our AEROSURF development plan to add a clinical study. During this period, we have found it difficult to attract investors that are willing to provide the additional capital that we require and, as such, we have depended upon the support or our majority stockholder and licensee in the Asia Pacific markets while we seek to advance our AEROSURF development program and identify potential strategic transactions that potentially may attract the interest of other investors.

To leverage our capabilities, maximize the use of our resources and potentially reduce our dependency on a single product candidate, we seek to enter into strategic alliances, collaboration agreements and other strategic transactions (including without limitation, by merger, acquisition or other corporate transaction) that could potentially provide access to additional pipeline products under development that we believe could diversify our portfolio and improve our ability to attract the significant capital that we will require. We also seek licensing arrangements for AEROSURF and our other KL4 surfactant products in select geographic markets that could bring strategic partners with local development and commercial expertise to support development of AEROSURF in various markets outside the U.S., and financial resources to support our AEROSURF development program. Such financial resources could take the form of capital investments, upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses.

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 contract research organization (CROs), contract manufacturing organizations (CMOs,) clinical trial sites, and other vendors supporting our research and development and manufacturing activities.

We base our expenses related to CROs, CMOs and clinical trial sites on our estimates of services received and efforts expended under quotations and contracts with those vendors that conduct research and development and manufacturing activities on our behalf. The financial terms of these agreements are negotiated, vary from contract to contract and may result in uneven payment flows. At times, payments made to our vendors may 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 operating loss for the years ended December 31, 2017 and 2016 was $22.5 million and $38.0 million, respectively. The decrease in operating loss from 2016 to 2017 was due to a $16.0 million decrease in operating expenses, partially offset by a $0.6 million decrease in revenue.

The net loss for the years ended December 31, 2017 and 2016 was $18.4 million and $39.5 million, respectively. Included in the net loss is (i) a gain on debt restructuring of $5.8 million in 2017; (ii) interest expense of $1.9 million and $2.5 million for 2017 and 2016, respectively; (iii) for 2017 and 2016, a severance charge of $0.2 and $1.6 million, respectively; (iv) for 2016, $0.4 million in proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits and (v) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million for 2016.

The net loss attributable to common stockholders for the years ended December 31, 2017and 2016 was $24.8 million (or $24.14 basic net loss per common share) and $39.5 million (or $94.84 basic net loss per common share), respectively. Included in the net loss attributable to common stockholders for 2017 is a $6.4 million non-cash deemed dividend on preferred stock (*see,* "Note 4 – Accounting Policies and Recent Accounting Pronouncements").

Grant Revenue

We recognized grant revenue of $1.4 million and $2.0 million for the years ended December 31, 2017 and 2016, respectively.

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

Grant revenue for 2016 includes $0.9 million of funds received and expended under the AEROSURF Grant, $1.0 million under the Radiation Grant, and $0.1 million under a fixed-price contract to support development of our aerosolized KL_4 surfactant to mitigate influenza-related lung injury (Influenza Grant).

As of December 31, 2017, all funding under the AEROSURF Grant, the Radiation Grant, and the Influenza Grant has been received and $0.1 million related to the Radiation Grant is currently recorded as deferred revenue and will be recognized as grant revenue when the funds are expended.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we account for such costs by category rather than by project. As many of our research and development activities form the foundation for the development of our KL4 surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical development programs. We also account for research and development and report by major expense category as follows: (i) salaries and benefits, (ii) contracted services, (iii) raw materials, aerosol devices and supplies, (iv) rents and utilities, (v) depreciation, (vi) contract manufacturing, (vii) travel, (viii) stock-based compensation and (ix) other.

Research and development expenses by category for the years ended December 31, 2017 and 2016 are as follows:

	Year Ended December 31,	
(in thousands)	**2017**	**2016**
Product development and manufacturing	$ 6,537	$ 10,172
Clinical, medical and regulatory operations	5,758	7,230
Direct preclinical and clinical programs	5,081	14,303
Total Research and Development Expenses	$ 17,376	$ 31,705

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.0 million and $0.8 million for 2017 and 2016, respectively.

For a description of the clinical development programs included in research and development expenses, s*ee,* "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 $3.6 million from 2016 to 2017, due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures, (ii) a $1.7 million decrease in costs related to development activities under our collaboration agreement with Battelle, (iii) a $0.3 million decrease in costs associated with the technology transfer of our lyophilized surfactant manufacturing process to a new facility at our CMO, and (iv) the July 2017 workforce reduction.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses decreased $1.5 million from 2016 to 2017 due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures, and (ii) the July 2017 workforce reduction.

Direct Preclinical and Clinical Development Programs

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

Direct preclinical and clinical development programs expenses decreased $9.2 million from 2016 to 2017 due to a decrease in AEROSURF phase 2 clinical development program costs following the completion of enrollment in the phase 2a and phase 2b clinical trials during the second quarter of 2017.

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)	Year Ended December 31, 2017	2016
Contracted services	$ 8,214	$ 16,543
Salaries & benefits	5,504	7,426
Rents and utilities	919	812
Stock-based compensation	837	614
Royalties	600	500
Travel	390	721
Contract manufacturing	355	809
Depreciation	178	231
Raw materials, aerosol devices and supplies	138	3,350
Other	241	699
	$ 17,376	$ 31,705

Contracted services include third-party costs 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 decrease from 2016 to 2017 is due to the completion of enrollment in the AEROSURF clinical trials in the second quarter of 2017 and to the investment in 2016 in clinic-ready ADSs for use in the AEROSURF clinical trials.

The decrease in salaries and benefits of $1.9 million from 2016 to 2017 is due to our continuing efforts, beginning in the second quarter of 2016, to conserve cash resources and implement other cost reduction initiatives.

Royalties represent minimum royalties due under our licensing agreements with Philip Morris USA Inc. and Philip Morris Products S.A. for our ADS technology.

Contract manufacturing represents costs related to the technology transfer of our lyophilized KL4 surfactant manufacturing processes to a CMO and manufacture of a sufficient supply of lyophilized KL4 surfactant to support our AEROSURF clinical development program. The decrease from 2016 to 2017 is related to adjustments that we made to the ongoing technology transfer of our lyophilized KL4 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.

Raw materials, aerosol devices and supplies consist of purchases of our active pharmaceutical ingredients (APIs) for the manufacture of KL4 surfactant, purchases of aerosol device components and supplies to support our manufacturing and analytical testing and development laboratories operations. Raw materials, aerosol devices and supplies purchases decreased $3.2 million from 2016 to 2017 due to a $2.4 million investment during 2016 in aerosol devices for use in our then-ongoing AEROSURF phase 2 clinical trials and a decrease of $0.7 million in clinical trial supply costs.

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

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 $49.0 million in expenses for the two-year period ended December 31, 2017. 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 activities have been focused over the past few years primarily on AEROSURF for the treatment of RDS in premature infants, and have involved the following projects (i) manufacturing development for our lyophilized KL4 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 of our NextGen ADS under our collaboration agreement with Battelle to support our remaining AEROSURF development activities, including our planned bridge study and phase 3 clinical program and, if approved, initial commercial activities; and (iii) AEROSURF clinical development program activities, which to date have included three phase 2 clinical trials. We are currently engaged in design verification of our NextGen ADS and preparing for initial preparatory work for the planned AEROSURF bridge study; however, as of April 15, 2018, we have sufficient cash resources available to support our development activities and business operations through May 2018 and our ability to move these activities forward will depend on our ability to successfully secure the necessary capital to fund our research and development programs, support our business operations and pay our existing obligations on a timely basis. Accordingly, we are unable to project the timing of completion of these activities and the overall anticipated expense we may incur.

Our key activities for AEROSURF, including the potential timing and anticipated milestones, are discussed in "Item 1 – Business – Business Strategy." In addition to our efforts to advance the AEROSURF clinical and device development programs, we believe that our aerosolized KL4 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 KL4 surfactant therapies to treat conditions such as 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. In addition, we recently announced that we are exploring a potential collaboration with Eleison Pharmaceuticals, Inc. (Eleison) to assess the feasibility of using our proprietary ADS to deliver Eleison's inhaled lipid cisplatin (ILC) potentially in combination with our KL4 surfactant. There can be no assurance that we will be successful in these efforts or, even if we are successful, that we and Eleison will agree to undertake a full development program.

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.

General and Administrative Expenses

(in thousands)	Year Ended December 31, 2017	2016
General and Administrative Expenses	$ 6,657	$ 8,373

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

General and administrative expenses include non-cash charges associated with stock-based compensation and depreciation of $0.7 million and $0.8 million for the years ended December 31, 2017 and 2016, respectively.

General and administrative expenses decreased $1.7 million from 2016 to 2017 due to a severance charge of $1.2 million (including $0.2 million in stock-based compensation expense) in 2016 related to the February 2016 termination of the Employment Agreement between ourselves and our then-President and Chief Executive Officer (Former CEO) and due to our efforts beginning in the second quarter of 2016 to conserve cash resources and implement other cost reduction initiatives.

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

	Year Ended December 31,	
(in thousands)	**2017**	**2016**
Change in Fair Value of Common Stock Warrant Liability	$ -	$ 223

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 five-year warrants that we issued in the February 2011 public offering (2011 Warrants) contained anti-dilutive provisions that adjusted the exercise price if we issued any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the 2011 Warrants. As such, 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. For 2016, the change in fair value of the common stock warrant liability represents the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

Other Income / (Expense)

	Year Ended December 31,	
(in thousands)	**2017**	**2016**
Gain on debt restructuring	5,824	-
Interest income	12	18
Interest expense	(1,863)	(2,518)
Other income	129	823
Other income / (expense), net	$ 4,102	$ (1,677)

In November 2017 we restructured and retired a secured loan with affiliates of Deerfield Management, L.P. (Deerfield Loan). This transaction was accounted for as an extinguishment of debt in accordance with ASC 470, *Debt-Modifications and Extinguishments*, and as a result, we recognized a $5.8 million non-cash gain on debt restructuring (*see,* "– Liquidity and Capital Resources – Long-term Debt").

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

Other income in 2016 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)	Year Ended December 31, 2017	2016
Amortization of prepaid interest expense	$ 911	$ 1,710
Cash interest expense	1,088	450
Total interest expense	$ 1,999	$ 2,160

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 Loan. Cash interest expense represents interest at an annual rate of 8.25% payable on a quarterly basis.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2017, we had cash and cash equivalents of $1.8 million and current liabilities of $11.7 million.

In January 2018 and March 2018, we received interim loans from our parent company, LPH Investments Limited (LPH), an affiliate of Lee's Pharmaceutical Holdings Limited, a company incorporated in the Cayman Islands with limited liability and majority holder of our common stock (Lee's), in the amounts of $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we continued our diligence efforts to identify one or more potential strategic or equity transactions. To secure our obligations under these loans, we granted LPH a security interest in substantially all of our assets. (S*ee,* "– Private Placement Offering")

In early April 2018, we completed a $2.6 million private placement offering with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee's, from which we received net proceeds of approximately $2.5 million (*see,* "– Private Placement Offering"). As of April 15, 2018, and before any additional financings, including in connection with potential strategic transactions, we believe that we will have sufficient cash resources available to support our development activities and business operations through May 2018.

We expect to continue to incur significant losses and require significant additional capital to advance our AEROSURF clinical development program, support our operations and satisfy existing obligations beyond May 2018, and we do not have sufficient 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 one or more of the following: (i) 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; we are currently engaged in active diligence and discussions with a third party for a potential strategic transaction, although there can be no assurance that we will be able to secure such agreement on acceptable terms, if at all; and (ii) through private placements of our equity securities. 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.

We believe that our ability to fund our activities in the longer term will be highly dependent upon whether we are able to timely advance our AEROSURF development program, including our planned bridge study and phase 3 clinical program and NextGen ADS development activities, in accordance with our plans and achieve results that are sufficiently positive to attract investor interest and/or support a strategic transaction (including by merger, acquisition of assets or license arrangement that could diversify our product portfolio). Our AEROSURF development program activities are subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing our clinical trials in accordance with our plans, or at all. If our AEROSURF development program activities should be delayed for any reason, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and potentially the results of our clinical program. Even if we complete our AEROSURF development program activities as planned, if the results are inconclusive, or present an unacceptable benefit/risk profile due to suboptimal efficacy and/or poor 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. If 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, if available. 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.

As we seek to secure the needed capital through equity financings and other similar transactions, we will be subject to regulatory and other restrictions, including the following: we are no longer eligible to use a registration statement on Form S-3 to register our securities and will have to use a long-form Form S-1, the preparation of which would be more time-consuming and costly; we no longer have access to an at-the-market equity sales program (ATM Program); our capital structure, which includes common stock, convertible preferred stock, and warrants to purchase common stock, may make it difficult to attract new investors; our controlling stockholder may not approve a strategic transaction recommended by our Board, or agree 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; and our efforts may be adversely affected by potentially unfavorable credit and financial markets. Under these circumstances, 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 addition, in May 2016, we received a deficiency notice from The Nasdaq Stock Market (Nasdaq) that we were no longer in compliance with the minimum stockholders' equity listing requirement. After securing extensions through May 15, 2017, we were unable to regain compliance with the listing requirement and consequently, our common stock was delisted from Nasdaq effective May 5, 2017. Since May 5, 2017, our common stock has been quoted on the OTC Markets Group Inc.'s OTCQB Market (OTCQB), and has experienced, over time, lower trading volumes and reduced analyst interest. In addition, effective December 22, 2017, we implemented a share combination (1-for-20 reverse split) that had the effect of reducing the number of shares outstanding and further lowering our trading volumes. These conditions may make it more difficult to raise capital when needed. Our stockholders may find it more difficult to trade our securities on the OTCQB, and the value and liquidity of our common stock may be adversely affected, which could have a material adverse effect on our ability to raise the additional capital that we require. Moreover, even if we are successful in raising the required capital, any equity financings could result in substantial equity dilution of stockholders' interests

In addition, we have from time to time collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. We announced in 2016 that we had 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 and in 2017, we received and expended $1.1 million of this award. We have also received grants that support medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. In June 2016, we announced the results of a study funded by the NIH that KL4 surfactant could potentially be an effective medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (pneumonopathy) due to exposure from a nuclear accident or act of terrorism. In addition, in February 2017 we announced the results of a study funded by the NIH that KL4 surfactant could be a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

As of December 31, 2017, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 114.1 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

Cash Flows

As of December 31, 2017 and 2016, we had cash and cash equivalents of $1.8 million and $5.6 million, respectively. Net cash outflows for 2017 consisted of $21.0 million used for ongoing operating activities, offset by cash inflows for 2017 of $17.3 million for financing activities.

Operating Activities

Net cash used in operating activities was $21.0 million and $33.6 million for the years ended December 31, 2017 and 2016, 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 $24,000 and $0.3 million for the years ended December 31, 2017 and 2016, respectively, and represents capital expenditures, partially offset by proceeds from sale of property and equipment in 2016.

Financing Activities

Net cash provided by financing activities was $17.3 million and $0.7 million for the years ended December 31, 2017 and 2016, respectively, summarized as follows:

(in thousands)	Years Ended December 31, 2017	2016
Proceeds from February 2017 Private Placement, net of expenses	$ 8,788	$ -
Proceeds from ATM Program, net of expenses	1,036	709
Proceeds from loan payable, net of expenses	3,900	-
Proceeds from Share Purchase Agreement, net of expenses	6,072	-
Principal payments on debt restructuring	(2,500)	-
Cash flows from financing activities, net	$ 17,296	$ 709

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. Since May 2017, we are no longer eligible to use a universal shelf registration statement on Form S-3. Accordingly, until we are again eligible to use the registration statement on Form S-3, we plan to conduct future equity offerings through private placement transactions

Private Placement Offerings

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) 50 Series A-1 Warrants to purchase one share of Common Stock at an exercise price equal to $27.40.

Effective October 27, 2017, we entered into a Securities Purchase Agreement (SPA) with LPH Investments Limited, a company incorporated in the Cayman Islands with limited liability (LPH). LPH an affiliate of Lee's. Under the SPA, LPH invested $10.0 million in the Company for 2,311,604 shares of our common stock, at a price of $4.326 per share, which represented a 15% premium over the average of the daily volume-weighted average price per share (VWAP) over the 10-day trading period ending on and including the date of the SPA. Following the transaction, Lee's beneficially owned 73% of our issued and outstanding shares of common stock. The investment included cancellation of $3.9 million in outstanding loans that the Company borrowed from Lee's Pharmaceutical (HK) Ltd., a Hong Kong company organized and existing under the laws of Hong Kong (Lee's (HK)) under that certain Loan Agreement, effective August 14, 2017, between ourselves and Lee's (HK).

In April 2018, we completed a private placement with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee's, for the purchase of $2.6 million of our common stock and warrants at a purchase price per share of $4.80. In connection with this offering, we issued 541,667 shares of common stock and warrants to purchase 135,417 shares of common stock at an exercise price of $5.52 per share. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date.

At-the-Market Program (ATM Program)

Stifel ATM Program

In 2013, we entered into an At-the-Market Equity Sales Agreement (ATM Agreement) with Stifel, under which Stifel, as our exclusive agent, agreed to sell on our behalf up to a maximum of $25 million of shares of our common stock (ATM Program). 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. In February 2016, we extended the term of the ATM Agreement until February 11, 2019. However, effective with our transition to the OTCQB® Market (OTCQB) tier in early May 2017, the ATM Program was no longer available to us.

During 2017, we completed registered offerings of our common stock under the ATM Program of 42,357 shares, resulting in aggregate gross and net proceeds to us of approximately $1.1 million and $1.0 million, respectively.

During 2016, we completed offerings of our common stock under our ATM Program of 18,013 shares, resulting in aggregate gross and net proceeds to us of approximately $0.7 million.

Loan Payable

In January 2018 and March 2018, we entered into loan agreements with LPH, an affiliate of Lee's, for loan proceeds of $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain its operations while we seek to identify and advance one or more potential strategic initiatives ("Funding Event"). To secure our obligations under these loans, we granted LPH a security interest in substantially all of our assets. The loans will accrue interest at a rate of 6% per annum and mature upon the earlier of the closing date of the Funding Event or December 31, 2018. The parties expect that, upon the closing of the Funding Event, the outstanding principal balance of the Loan will be applied in full satisfaction of a like amount of cash consideration payable by LPH for its participation in such Funding Event, and the Loan will be discharged in full thereby.

Long-term Debt

Long-term debt as of December 31, 2016 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:

	December 31,	
(in thousands)	**2017**	**2016**
Deerfield Loan	$ -	$ 25,000
Restructured debt liability - contingent milestone payments	$ 15,000	-

Under the terms of the Deerfield Loan, 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. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash.

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 10,000 shares of our common stock at an exercise price of $786.80 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 15,000 shares of our common stock at an exercise price of $786.80 per share. The warrants expired on the sixth anniversary of the Deerfield Loan agreement, or February 13, 2019.

In July 2015, we entered into two amendments to the Deerfield Loan agreement resulting in (i) prepayment of $5.0 million of principal, (ii) elimination of the principal installment originally due in February 2017, (iii) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million, (iv) 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 Loan, and (v) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Loan accrued at a rate of 8.25% per annum.

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) the promissory notes evidencing the aggregate principal amount of $25 million then owed under the Deerfield Loan, and (ii) warrants to purchase up to 25,000 shares of our common stock at an exercise price of $786.80 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) an aggregate of 71,111 shares of common stock and (iii) the right to receive certain milestone payments based on achievement of specified development and commercial milestones related to our AEROSURF development program, which, if achieved, could potentially total up to $15 million.

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

The November 2017 restructuring and retirement 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 recognized a $5.8 million non-cash gain on debt restructuring consisting of the difference between the $25 million carrying amount of the extinguished Deerfield Loan and the consideration to Deerfield under the Exchange and Termination Agreement, which includes $15 million in contingent milestone payments, $2.5 million in cash, a $1.4 million write-off of prepaid interest, and $0.3 million in fair value of common stock issued to Deerfield. We established a $15 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2017 or 2016, 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, 2017. 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, 2017.

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, 2017 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

Except as set forth below, the information required by Items 10 through 14 of Part III is incorporated herein by reference to our definitive proxy or information statement or an amendment to this annual report on Form 10-K, in any case, to be filed with the Securities and Exchange Commission on or before April 30, 2018 (within 120 days after the end of our 2017 fiscal year).

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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.

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: April 17, 2018

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)	April 17, 2018
/s/ John Tattory	John Tattory Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	April 17, 2018
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	April 17, 2018
/s/ Joseph M. Mahady	Joseph M. Mahady Director	April 17, 2018
/s/ Bruce A. Peacock	Bruce A. Peacock Director	April 17, 2018
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	April 17, 2018

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 February 15, 2018	Filed herewith
3.2	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
3.3	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 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
4.2	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
4.3	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
4.4	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
4.5	Form of Series C Warrant dated April 4, 2018	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018
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+	License, Development and Commercialization Agreement dated as of June 12, 2017, by and between Windtree and Lee's Pharmaceutical (HK) Ltd.	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, as filed with the SEC on August 21, 2017
10.7+	Amendment No. 1 dated as of August 14, 2017 to the License Development and Commercialization Agreement by and between the Company and Lee's Pharmaceutical (HK) Ltd. dated as of June 12, 2017	Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the SEC on November 14, 2017
10.8*	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
10.9*	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
10.10*	Windtree's 2011 Long-Term Incentive Plan, as amended	Filed herewith
10.11*	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
10.12*	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
10.13*	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
10.14*	Form of Restricted Stock Unit Award Agreement for Employees under Windtree's 2011 Long-Term Incentive Plan	Filed herewith
10.15*	Employment Agreement dated as of February 1, 2016, by and between Windtree and Craig Fraser	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
10.16*	Inducement Stock Option Award Agreement dated February 1, 2016, between Windtree and Craig Fraser 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
10.17*	Amendment dated as of March 13, 2018, to Employment Agreement dated as of February 1, 2016, by and between Windtree and Craig Fraser	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018
10.18*	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
10.19*	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

10.20*	Amendment dated as of March 13, 2018, to Employment Agreement dated as of December 19, 2014 by and between Windtree and Steven G. Simonson, M.D.	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018
10.21*	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
10.22*	Amendment dated December 29, 2014 to Employment Agreement dated as of March 21, 2014, effective as of April 1, 2015, 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
10.23*	Amendment dated March 13, 2018, to Employment Agreement dated as of March 21, 2014 by and between John A. Tattory	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018
10.24*	Form of Indemnification Agreement between Windtree 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
10.25	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
10.26	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
10.27	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
10.28	Fifth Amendment to Lease Agreement, dated February 23, 2018, by and between PH Stone Manor LP and Windtree	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 1, 2018
10.29+	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 10.3 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 12, 2013
10.30+	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
10.31+	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
10.32	Second Amendment dated March 31, 2016 to Collaboration Agreement dated as of October 14, 2014 between Windtree and Battelle Memorial Institute	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
10.33	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

10.34	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
10.35	Exchange and Termination Agreement dated as of October 27, 2017, between Windtree and Deerfield	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017
10.36	Registration Rights Agreement dated as of October 27, 2017, between Windtree and Deerfield	Incorporated by reference to Exhibit 99.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017
10.37	Registration Rights Agreement dated as of October 27, 2017, between Windtree and LPH Investments Limited	Incorporated by reference to Exhibit 99.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017
10.38	Loan Agreement dated as of January 10, 2018, between Windtree and LPH Investments Ltd.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 12, 2018
10.39	Loan Agreement dated as of March 1, 2018, between Windtree and LPH Investments Ltd.	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 5, 2018
10.40	Security Agreement dated as of March 1, 2018, between Windtree and LPH Investments Ltd.	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 5, 2018
10.41	Securities Purchase Agreement dated as of March 30, 2018, between Windtree and LPH II Investments Limited	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018
10.42	Registration Rights Agreement dated as of March 30, 2018, between Windtree and LPH II Investments Limited	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018
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, 2017, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2017 and December 31, 2016, (ii) Statements of Operations for the years ended December 31, 2017 and December 31, 2016, (iii) Statements of Changes in Equity for the years ended December 31, 2017 and December 31, 2016, (iv) Statements of Cash Flows for the years ended December 31, 2017 and December 31, 2016, 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

Consolidated Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Windtree Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Windtree Therapeutics, Inc. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2017, and the related notes collectively referred to as the consolidated financial statements. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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 financial statements, the Company has incurred recurring losses from operations, expects to continue to incur losses and requires significant additional capital to advance its clinical development program, support operations and satisfy existing obligations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst and Young LLP

We have served as the Company's auditor since 2000.

Philadelphia, Pennsylvania
April 17, 2018

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

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

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,815	$ 5,588
Prepaid interest, current portion	-	1,094
Prepaid expenses and other current assets	422	512
Total current assets	2,237	7,194
Property and equipment, net	885	1,054
Restricted cash	225	225
Prepaid interest, non-current portion	-	1,226
Total assets	$ 3,347	$ 9,699
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,048	$ 1,813
Collaboration payable	3,624	3,967
Accrued expenses	4,204	7,611
Deferred revenue - current portion	884	-
Total current liabilities	11,760	13,391
Long-term debt	-	25,000
Restructured debt liability - contingent milestone payments	15,000	-
Deferred revenue - non-current portion	407	-
Other liabilities	100	138
Total liabilities	27,267	38,529
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 2,701 and 0 shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Common stock, $0.001 par value; 120,000,000 and 60,000,000 shares authorized at December 31, 2017 and 2016, respectively; 3,227,495 and 436,253 shares issued at December 31, 2017 and 2016, respectively; 3,227,421 and 436,179 shares outstanding at December 31, 2017 and 2016, respectively	3	4
Additional paid-in capital	616,245	592,888
Accumulated deficit	(637,114)	(618,668)
Treasury stock (at cost); 74 shares	(3,054)	(3,054)
Total stockholders' equity	(23,920)	(28,830)
Total liabilities & stockholders' equity	$ 3,347	$ 9,699

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,	
	2017	**2016**
Revenues:		
Grant revenue	$ 1,383	$ 2,042
License revenue	102	-
Total revenues	1,485	2,042
Expenses:		
Research and development	17,376	31,705
General and administrative	6,657	8,373
Total operating expense	24,033	40,078
Operating loss	(22,548)	(38,036)
Change in fair value of common stock warrant liability	-	223
Other income / (expense):		
Gain on debt restructuring	5,824	-
Interest income	12	18
Interest expense	(1,863)	(2,518)
Other income	129	823
Other income / (expense), net	4,102	(1,677)
Net loss	$ (18,446)	$ (39,490)
Deemed dividend on Series A preferred stock	(6,370)	-
Net loss attributable to common shareholders	$ (24,816)	$ (39,490)
Net loss per common share		
Basic and diluted	$ (24.14)	$ (94.84)
Weighted average number of common shares outstanding		
Basic and diluted	1,028	416

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

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

	Preferred Stock		Common Stock				Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Shares	Amount	Total
Balance - December 31, 2015	**-**	**$ -**	**410**	**$ -**	**$ 590,498**	**$ (579,178)**	**-**	**$ (3,054)**	**$ 8,266**
Net Loss	-	-	-	-	-	(39,490)	-	-	(39,490)
Issuance of common stock, ATM Program	-	-	18	-	709	-	-	-	709
Issuance of common stock, 401(k) Plan employer match	-	-	8	-	274	-	-	-	274
Stock-based compensation expense	-	-	-	-	1,411	-	-	-	1,411
Balance - December 31, 2016	**-**	**$ -**	**436**	**$ -**	**$ 592,892**	**$ (618,668)**	**-**	**$ (3,054)**	**$ (28,830)**
Net Loss	-	-	-	-	-	(18,446)	-	-	(18,446)
Issuance of preferred stock, February 2017 Private Placement	7	-	-	-	10,433	-	-	-	10,433
Conversions of preferred stock	(4)	-	217	-	(2)	-	-	-	(2)
Issuance of common stock, ATM Program	-	-	42	-	1,030	-	-	-	1,030
Issuance of common stock, Share Purchase Agreement	-	-	2,312	2	9,969	-	-	-	9,971
Issuance of common stock, 401(k) Plan employer match	-	-	7	-	95	-	-	-	95
Issuance of common stock, equity consideration in debt restructuring	-	-	71	-	267	-	-	-	267
Exercise of prefunded common stock warrants	-	-	143	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	1	1,561	-	-	-	1,562
Balance - December 31, 2017	**3**	**$ -**	**3,227**	**$ 3**	**$ 616,245**	**$ (637,114)**	**-**	**$ (3,054)**	**$ (23,920)**

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2017	2016
Cash flows from operating activities:		
Net loss	$ (18,446)	$ (39,490)
Adjustments to reconcile net loss to net cash used in operating activities:	-	-
Depreciation and amortization	192	255
Stock-based compensation and 401(k) plan employer match	1,655	1,685
Fair value adjustment of common stock warrants	-	(223)
Amortization of prepaid interest	912	1,709
Gain on debt restructuring	(5,824)	-
Loss on sale or disposal of equipment	-	(16)
Changes in:	-	-
Prepaid expenses and other current assets	90	(150)
Accounts payable	2,433	1,444
Collaboration payable	(343)	686
Accrued expenses	(2,995)	387
Deferred revenue - current	884	-
Deferred revenue - non-current	407	-
Other liabilities	(10)	124
Net cash used in operating activities	(21,045)	33,589
Cash flows from investing activities:		
Purchase of property and equipment	(24)	(281)
Proceeds from sale of property and equipment	-	27
Net cash used in investing activities	(24)	(254)
Cash flows from financing activities:		
Proceeds from private placement issuance of securities, net of expenses	14,860	-
Proceeds from ATM Program, net of expenses	1,036	709
Proceeds from loan payable, net of expenses	3,900	-
Principal payments on debt restructuring	(2,500)	-
Net cash provided by financing activities	17,296	709
Net increase/(decrease) in cash and cash equivalents	(3,773)	(33,134)
Cash, cash equivalents and restricted cash - beginning of year	5,813	38,947
Cash, cash equivalents and restricted cash - end of year	$ 2,040	$ 5,813
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,088	$ 280

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 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, including our proprietary aerosol delivery system (ADS), being developed to enable noninvasive administration of aerosolized KL4 surfactant at consistent and reproducible volumes suitable to deliver therapeutic dosages in a reasonable period of time. We are currently working with Battelle Memorial Institute (Battelle) to complete design verification procedures for a next generation (NextGen) ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. We believe that our proprietary technologies may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of respiratory distress syndrome (RDS) in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. The currently-available surfactants in the United States (U.S.) are administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support such as nasal continuous positive airway pressure (nCPAP). Unfortunately, nCPAP does not address the underlying surfactant deficiency and consequently, many premature infants respond poorly to nCPAP alone (typically within the first 72 hours of life) and may require delayed surfactant therapy with invasive intubation (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.

AEROSURF is designed to administer aerosolized KL4 surfactant noninvasively and potentially meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. 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 following nCPAP failure. We also believe that AEROSURF has the potential to address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. Consistent with our belief, FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

While we are focused primarily on AEROSURF, we are also assessing potential development pathways to potentially gain marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant may potentially provide benefits related to use, including longer shelf life, reduced cold-chain requirements and lower viscosity. We have engaged with the FDA to discuss a potential development plan, trial design and regulatory plan for approval. If we can define an acceptable development program that is achievable from a cost, timing and resource perspective, we might seek approval to treat premature infants who, because they are unable to breathe on their own, cannot benefit from AEROSURF.

We also believe that our KL4 surfactant technology may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We have received support, and plan to seek additional support, from the National Institutes of Health ("NIH") and other government funding sources to explore the utility of our KL4 surfactant to address a variety of 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). 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.

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.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Note 2 – Basis of Presentation

The accompanying consolidated financial statements reflect a 1-for-20 reverse split of our common stock that was approved by our Board of Directors and controlling stockholder and made effective on December 22, 2017. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Note 3 – Liquidity Risks and Management's Plans

As of December 31, 2017, we had cash and cash equivalents of $1.8 million and current liabilities of $11.7 million.

In January 2018 and March 2018, we received interim loans from our parent company, LPH Investments Limited (LPH), an affiliate of Lee's Pharmaceutical Holdings Ltd (Lee's), a company incorporated in the Cayman Islands with limited liability whose common stock is listed on the Hong Kong Stock Exchange and which beneficially owns a majority interest in our common stock, in the amounts of $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we continued our diligence efforts to identify one or more potential strategic or equity transactions. To secure our obligations under these loans, we granted Lee's a security interest in substantially all of our assets (*see,* "– Note 17 – Subsequent Events.")

In early April 2018, we completed a $2.6 million private placement offering with LPH II Investments Limited (LPH II), a wholly-owned subsidiary of Lee's, from which we received net proceeds of approximately $2.5 million (*see,* "– Note 17 – Subsequent Events"). As of April 15, 2018, before any additional financings, including in connection with potential strategic transactions, we believe that we will have sufficient cash resources available to support our development activities and business operations through May 2018.

We expect to continue to incur significant losses and require significant additional capital to advance our AEROSURF clinical development program, support our operations and satisfy existing obligations beyond May 2018, and we do not have sufficient 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 one or more of the following: (i) 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; we are currently engaged in active diligence and discussions with a third party for a potential strategic transaction, and (ii) through private placements of our equity securities, although there can be no assurance that we will be able to secure such transaction or complete a private placement on acceptable terms, if at all. 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.

As of December 31, 2017, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 114.1 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

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.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Consolidation

The consolidated financial statements include all 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, 2017 and 2016, respectively. 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 to secure our obligations under our Lease Agreement dated May 26, 2004 for our headquarters location in Warrington, Pennsylvania (*see,* " – Note 12 – 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, 2017 and 2016 as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Collaborative arrangements

We account for collaborative arrangements in accordance with applicable accounting guidance provided in ASC Topic 808, *Collaborative Arrangements*. *See,* "– Note 11 – Collaboration, Licensing and Research Funding Agreements – Collaboration Agreement - Battelle Memorial Institute," for a description of our accounting for the Battelle collaboration Agreement.

Restructured debt liability – contingent milestone payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*see,* " – Note 8 – Long-term Debt/Restructured debt liability,"), we have established a $15 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017 (Exchange and Termination Agreement), between ourselves and affiliates of Deerfield Management Company L.P. (Deerfield). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Deferred revenue

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

Revenue recognition

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.

License revenue

We recognize license revenue under the License Agreement with Lee's in accordance with ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which provides guidance for separating and allocating consideration in a multiple-element arrangement. Deliverables under the arrangement are separate units of accounting if the delivered item has value to the customer on a standalone basis and if the arrangement includes a general right of return relative to the delivery, or performance of the undelivered item is considered probable and substantially within the company's control. The consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. We exercise significant judgement in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, we evaluate whether the components have standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Whenever we determine that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

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 10 – 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.

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.

Beneficial Conversion Feature

The issuance of our Preferred Shares in the first quarter of 2017 (*see*, "– Note 9 – Stockholders' Equity") resulted in a beneficial conversion feature, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor (or in the money) at inception due to the conversion option having an effective conversion price that is less than the fair value of the underlying stock at the commitment date. We recognized the beneficial conversion feature by allocating the relative fair value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital, resulting in a discount on the Preferred Shares. As the Preferred Shares are immediately convertible by the holders, the discount allocated to the beneficial conversion feature was immediately accreted and recognized as a $3.6 million one-time, non-cash deemed dividend to the preferred shareholders during the first quarter of 2017.

An additional discount to the Preferred Shares of $4.5 million was created due to the allocation of proceeds to the Warrants which were issued with the Preferred Shares. This discount is amortized proportionately as the Preferred Shares are converted. For the year ended December 31, 2017, we recognized a non-cash deemed dividend to the preferred shareholders of $2.8 million related to the Preferred Shares converted during the period.

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, 2017 and 2016, the number of shares of common stock potentially issuable upon the conversion of preferred stock or the exercise of certain stock options and warrants was 1.0 million and 0.5 million shares, respectively. As of December 31, 2017 and 2016, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

In accordance with 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, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive. In February 2016, the warrants underlying the derivative liability expired.

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.

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

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

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic* 718*): Improvements to Employee Share-Based Payment Accounting*. This update addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. We adopted ASU 2016-09 during the three months ended March 31, 2017 and will continue to recognize stock compensation expense with estimated forfeitures. The adoption did not have a material impact on our 2017 financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic* 230*): Restricted Cash*. The new standard requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. We adopted ASU 2016-18 on March 31, 2017 on a retrospective basis. As a result, beginning-of-period cash, cash equivalents and restricted cash in the statement of cash flows increased by $0.2 million for each of the years ended December 30, 2017 and 2016.

Recent Accounting Pronouncements

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

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 of ASU 2016-02 and believe it may have a material impact on our consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic* 718*): Scope of Modification Accounting*. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The ASU is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. We are currently evaluating the effect that ASU 2017-09 may have on our consolidated financial statements and related disclosures, but we do not expect it to have a material impact on our financial statements.

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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, 2017 and 2016:

(in thousands)	Fair Value December 31, 2017	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 1,815	$ 1,815	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 2,040	$ 2,040	$ -	$ -

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

The following table summarizes changes in the fair value of common stock warrant liability measured on a recurring basis using Level 3 inputs. For 2016, the change in fair value of common stock warrant liability represents the write-off of the remaining liability upon expiration of the underlying 2011 warrants in February 2016.

(in thousands)

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

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Note 6 – Property and Equipment

Property and equipment comprises the following:

(in thousands)	December 31, 2017	2016
Manufacturing, laboratory & office equipment	$ 4,965	$ 4,940
Furniture & fixtures	615	615
Leasehold improvements	2,458	2,459
Subtotal	8,038	8,014
Accumulated depreciation and amortization	(7,153)	(6,960)
Property and equipment, net	$ 885	$ 1,054

Depreciation expense on property and equipment for the years ended December 31, 2017 and 2016 was $0.2 million and $0.3 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 11 – Collaboration, Licensing and Research Funding Agreements). As of December 31, 2017 and 2016, collaboration payable was $3.6 million and $4.0 million, respectively, including accrued interest.

Accrued expenses comprise the following:

(in thousands)	December 31, 2017	2016
Salaries, bonus & benefits	$ 1,008	$ 1,309
Research and development	1,848	5,174
Manufacturing operations	537	454
Professional fees	412	305
Other	399	369
Total accrued expenses	$ 4,204	$ 7,611

Note 8 – Long-term Debt / Restructured Debt Liability

As of December 31, 2016, long-term debt consists solely of amounts due under a loan (Deerfield Loan) with Deerfield for the periods presented:

(in thousands)	December 31, 2017	2016
Deerfield Loan	$ -	$ 25,000
Restructured debt liability - contingent milestone payments	$ 15,000	-

Under the terms of the Deerfield Loan, 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. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash.

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 10,000 shares of our common stock at an exercise price of $786.80 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 15,000 shares of our common stock at an exercise price of $786.80 per share. The warrants had a six-year term through the sixth anniversary of the Deerfield Loan agreement, or February 13, 2019.

In July 2015, we entered into two amendments to the Deerfield Loan agreement resulting in (i) prepayment of $5.0 million of principal, (ii) elimination of the principal installment originally due in February 2017, (iii) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million, (iv) 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 Loan, and (v) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Loan accrued at a rate of 8.25% per annum.

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) the promissory notes evidencing the aggregate principal amount of $25 million then owed under the Deerfield Loan, and (ii) warrants to purchase up to 25,000 shares of our common stock at an exercise price of $786.80 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) an aggregate of 71,111 shares of common stock and (iii) the right to receive certain milestone payments based on achievement of specified development and commercial milestones related to our AEROSURF® development program, which, if achieved, could potentially total up to $15 million.

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

The November 2017 restructuring and retirement 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 a $5.8 million non-cash gain on debt restructuring consisting of the difference between the $25 million carrying amount of the extinguished Deerfield Loan and the consideration to Deerfield under the Exchange and Termination Agreement, which includes $15 million in contingent milestone payments, $2.5 million in cash, a $1.4 million write-off of prepaid interest, and $0.3 million in fair value of common stock issued to Deerfield. We established a $15 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement (*see*, "–Note 4 – Accounting Policies and Recent Accounting Pronouncements – Restructured debt liability – contingent milestone payment").

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

(in thousands)	Year Ended December 31, 2017	2016
Amortization of prepaid interest expense	$ 911	$ 1,710
Cash interest expense	1,088	450
Total interest expense	$ 1,999	$ 2,160

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 Loan. Cash interest expense represents interest at an annual rate of 8.25% payable on a quarterly basis.

Note 9 – Stockholders' Equity

Private Placement Offerings

February 2017 *Private Placement*

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units at a price per unit of $1,495, for an aggregate purchase price of approximately $10.5 million, including $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares); and (ii) Series A-1 Warrants ("Warrants") to purchase 50 shares of common stock at an exercise price equal to $27.40 per share. Each Preferred Share may be converted at the holder's option at any time into 50 shares of common stock. The Warrants may be exercised through February 15, 2024. The Preferred Shares and the Warrants may not be converted or exercised to the extent that the holder would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of our outstanding shares of common stock. In the event of a liquidation, including without limitation, the sale of substantially all of our assets and certain mergers and other corporate transactions (as defined in the Certificate of Designation of Preferences, Rights and Limitations relating to the Preferred Shares), the holder of Preferred Shares will have a liquidation preference that could result in the holder receiving a return of its initial investment before any payments are made to holders of common stock, and then participating with other equity holders until it has received in the aggregate up to three times its original investment. In addition to the offering, the securities purchase agreement also provides that, until February 13, 2018, the investors are entitled to participate in subsequent bona fide capital raising transactions that we may conduct.

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To facilitate consummation of the Share Purchase Agreement in October 2017 (see – *Share Purchase Agreement*), Battelle, holder of an aggregate of 1,095 shares of our Series A Convertible Preferred Stock, par value $0.001 per share, executed a waiver wherein Battelle waived its right to the liquidation preference with respect to their Preferred Shares. We considered the relevant accounting guidance and concluded that the waiver did not remove a substantive term or otherwise fundamentally change the Preferred Shares. As a result, the Preferred Shares were modified rather than extinguished, and Battelle did not receive incremental fair value in the modification. There was, therefore, no incremental expense to be recognized related to the waiver. In addition, we and Battelle entered into a non-binding memorandum of understanding outlining the key terms for a potential restructuring of the amounts due to Battelle under development and collaboration agreements between ourselves and Battelle.

As of December 31, 2017, 4,348 Preferred Shares have been converted into 217,400 shares of common stock and 2,701 Preferred Shares remain outstanding.

Share Purchase Agreement

Effective October 27, 2017, we entered into a Share Purchase Agreement (SPA) with LPH Investments Limited (LPH), a company incorporated in the Cayman Islands with limited liability and an affiliate of Lee's. Under the SPA, LPH invested $10 million (the Investment) in our Company and acquired 2,311,604 shares of our common stock (the Shares), at a price of $4.326 per share, which represented a 15% premium over the average of the daily volume-weighted average price per share (VWAP) over the 10-day trading period ending on and including the date of the SPA. Following the transactions described in the SPA, LPH beneficially owned 73% of our issued and outstanding shares of common stock. The Investment included cancellation of $3.9 million in outstanding loans that we borrowed from Lee's (HK) under the Loan Agreement, effective August 14, 2017, between ourselves and Lee's (HK). Pursuant to the SPA, we granted LPH the right to appoint up to two individuals to serve on our Board of Directors, and LPH may designate such individuals on or prior to the 30th day following the closing of the transactions contemplated by the SPA (the Closing). In addition, the SPA also amended the executive employment agreement of each of our President and Chief Executive Officer (Craig Fraser), Senior Vice President and Chief Financial Officer (John A. Tattory) and Senior Vice President and Chief Medical Officer (Steven G. Simonson, M.D.), such that the executives agreed to waive the guaranteed Annual Bonuses (as defined in each executive's employment agreement) that otherwise would have been payable to the executives during the 24-month period following the change of control to Lee's. Also under the SPA, each executive was awarded restricted stock units under our 2011 Long-Term Incentive Plan, as amended, having a value when issued equal to the combined total value of the 2017 and 2018 Target Bonus Amounts (as defined in each executive's employment agreement) and initially vesting in two equal installments on March 15, 2018 and March 15, 2019. Under the terms of the SPA, we also granted to LPH a preemptive right to purchase in future offerings of equity securities up to that number of shares of our equity securities needed to maintain LPH's percentage of beneficial ownership of our outstanding voting stock immediately prior to each such offering, subject to certain limitations and exclusions.

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

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 million 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.

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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. 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 2017, we completed registered offerings of our common stock under the ATM Program of 42,357 shares, resulting in aggregate gross and net proceeds to us of approximately $1.1 million and $1.0 million, respectively.

During 2016, we completed offerings of our common stock under our ATM Program of 18,013 shares, resulting in aggregate gross and net proceeds to us of approximately $0.7 million.

Effective with our transition to the OTCQB® Market (OTCQB) tier in early May 2017, the ATM Program was no longer available to us.

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). During 2017 and 2016 we provided 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, 2017 and 2016, the match resulted in the issuance of 7,561 and 8,437 shares of common stock, respectively. Expense associated with the 401(k) match for the years ended December 31, 2017 and 2016 was $0.1 million and $0.3 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, 2017	December 31, 2016	Exercise Price	Expiration Date
Investors - February 2017 financing	352	-	$ 27.40	2/15/2024
Investors - July 2015 financing	240	240	$ 196.00	7/22/2022
Investors - July 2015 financing (prefunded)	-	143	$ -	7/22/2022
Battelle - 2014 collaboration agreement (1)	4	5	$ 1,400.00	10/10/2024
Deerfield - 2013 loan	-	500	$ 786.80	2/13/2019
Total	596	888		

(1) *See*, "– Note 11 – 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

At the 2017 Annual Meeting of Stockholders, our stockholders approved an increase in the number of shares available for issuance under our Amended and Restated 2011 Long-Term Incentive Plan (the "2011 Plan") by 37,500. On October 25, 2017 the Board of Directors approved an increase to the number of shares available for issuance under the Plan by 1.75 million, which increase was approved by an action of the majority stockholder by written consent without a meeting of stockholders dated as of November 13, 2017.

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As of December 31, 2017 and 2016, we had 1.6 million and 0.1 million shares, respectively, available for potential future issuance under the 2011 Plan.

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

As of December 31, 2017 and 2016, we had 807 and 8,368 common shares, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 10 – 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.

There are 1.9 million shares of our common stock authorized under the 2011 Plan, of which 1.6 million shares remain available for issuance. 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:

	December 31,	
(in thousands)	**2017**	**2016**
Stock Options and RSUs Outstanding		
2011 Plan	263	47
2007 Plan	-	1
1998 Plan	-	0
Non-Plan	10	10
Total Outstanding	273	58
Available for Future Grants under 2011 Plan	1,623	52

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.

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

(in thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2017	57	$ 293.20	
Granted	41	24.60	
Forfeited or expired	(14)	281.80	
Outstanding at December 31, 2017	84	$ 163.20	7.8
Vested and exercisable at December 31, 2017	55	$ 228.60	7.3
Vested and expected to vest at December 31, 2017	82	$ 164.00	7.8

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2017	1	$ 36.80
Awarded	190	4.33
Vested	(1)	36.80
Unvested at December 31, 2017	190	$ 4.33

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, 2017 and 2016 was $17.44 and $27.80, respectively. The weighted-average grant-date fair value of RSUs granted during the years ended December 31, 2017 and 2016 was $4.33 and $36.80, respectively. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2017 are each $0.

Stock-Based Compensation

We recognized stock-based compensation expense in accordance with ASC Topic 718 of $1.6 million for each of the years ended December 31, 2017 and 2016.

Stock-based compensation expense was classified as follows:

(in thousands)	Year Ended December 31, 2017	2016
Research and development	$ 837	$ 614
General and administrative	724	809
Total	$ 1,561	$ 1,423

Under the 2011 Plan, outstanding awards fully vest upon a change in control. Concurrent with the execution of the share purchase agreement with LPH (*see*, Note 9 – Stockholders' Equity – Private Placement Offerings) and the resulting change in control, all outstanding awards under the 2011 Plan, except for those held by certain executive officers, fully vested and resulted in a $0.4 million charge to stock based compensation expense in 2017.

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.

	Year Ended December 31,	
	2017	2016
Weighted average expected volatility	79%	78%
Weighted average expected term (in years)	6.6	5.7
Weighted average risk-free interest rate	2.2%	1.4%
Expected dividends	-	-

The total fair value of the underlying shares of the options vested during 2017 and 2016 equals $3.1 million and $1.9 million, respectively. As of December 31, 2017, there was $0.9 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 11 – 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 $1.2 million and $2.9 million for the years ended December 31, 2017 and 2016, 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 $1,400 per share and a term of 10 years, subject to earlier termination under certain circumstances, including (i) a warrant to purchase up to 3,571 shares of our common stock, exercisable upon successful completion by Battelle of the three stage project plan (Initial Warrant), and (ii) a warrant to purchase up to 1786 shares of our common stock (Additional Warrant), exercisable if and only if Battelle successfully completed the project plan no later than a specified Milestone Date (November 15, 2016). The Additional Warrant was cancelled as of November 15, 2016 as the project plan had not been completed by that date. 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.

On October 27, 2017, we entered into a nonbinding memorandum of understanding with Battelle (Battelle MOU) outlining potential terms to restructure certain accounts payable related to our device development activities with Battelle and accordingly, we have written off approximately $0.6 million of previously accrued interest on collaboration invoices. Among other things, the MOU provides that in connection with the restructuring, the aggregate limit of potential royalties will be increased from $25 million to $35 million.

Licensing and Research Funding Agreements

Lee's Pharmaceutical (HK) Ltd.

In June 2017, we entered into a License, Development and Commercialization Agreement ("License Agreement") with Lee's Pharmaceutical (HK) Ltd., a company organized under the laws of Hong Kong (**"**Lee's"). Under the License Agreement, we granted to Lee's an exclusive license with a right to sublicense, (i) to develop and commercialize our KL4 surfactant products, including SURFAXIN®, which was approved by the U.S. Food and Drug Administration ("FDA") in 2012 for the prevention of respiratory distress syndrome ("RDS") in premature infants, SURFAXIN LS™, the lyophilized dosage form of SURFAXIN; and AEROSURF®, an investigative combination drug/device product that is designed to deliver aerosolized KL4 surfactant noninvasively, and (ii) to register and manufacture SURFAXIN and SURFAXIN LS for use in the Licensed Territory, which includes the People's Republic of China ("PRC"), Hong Kong, Thailand, Taiwan and 12 other countries (the "Licensed Territory"). In addition, we granted Lee's options to potentially add Japan to the Licensed Territory and to manufacture our ADS in the Licensed Territory, in each case subject to conditions set forth in the License Agreement.

Under the License Agreement, Lee's made an upfront payment to us of $1 million. We also may receive up to $37.5 million in potential clinical, regulatory and commercial milestone payments and will share in any sublicense income Lee's may receive at a rate equal to low double digits. In addition, Lee's will be responsible for all costs and expenses in and for the Licensed Territory related to development activities, including a planned AEROSURF phase 3 clinical trial, regulatory activities, and commercialization activities.

In August 2017, we entered into a Loan Agreement, pursuant to which Lee's (HK) agreed to lend us up to $3.9 million to support our activities through October 31, 2017, while we and Lee's worked to complete a $10 million securities purchase agreement (Lee's SPA) pursuant to which Lee's acquired a controlling interest in our Company effective on November 1, 2017. In connection with Lee's SPA, we amended the License Agreement to expand certain of Lee's (HK) rights, including by immediately adding Japan to the licensed territory, accelerating the right to manufacture the ADS in and for the licensed territory, reducing or eliminating certain of the milestone and royalty payments and adding an affiliate of Lee's (HK) as a party to the License Agreement. As a result, the additional amounts for potential clinical, regulatory and commercial milestone were reduced to $35.8 million.

We will be eligible to receive tiered royalties based on a percent of Net Sales, depending on the product, in the range of high single to low-to-mid double digit percentages. Royalties are payable on a country-by-country basis until the latest of (A) the expiration of the last valid patent claim covering the product in the country of sale, (B) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (C) ten (10) years after the first commercial sale in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each product and, for the initial three years, shall be in the range of low-to-mid single digits. In addition, in the event that one or more generic products are introduced, the royalty rates will be reduced, subject to certain minimums if we are subject to continuing obligations at the time to pay royalties under our in-license agreements.

Under the License Agreement, Lee's will be responsible for all activities related to development, regulatory approval and commercialization of KL_4 surfactant and combination drug/device products in the Licensed Territory. Lee's will hold the product licenses for all non-aerosolized products in the Licensed Territory and will seek regulatory approval initially for SURFAXIN and SURFAXIN LS for RDS. We will hold the product license in the Licensed Territory (except where prohibited by law) for all aerosolized products and will designate Lee's its exclusive agent and representative to develop and register AEROSURF and other aerosolized products in our name and on our behalf. Lee's also has agreed that, except as provided in the License Agreement, for a period of ten (10) years beginning with the later of the first commercial sale of the first aerosolized product and the first commercial sale of the first non-aerosolized product in the PRC, it will not develop, register, manufacture, or commercialize any product for the prevention and/or treatment of RDS in premature infants or other diseases and conditions in humans, in either case that administers, utilizes or contains pulmonary surfactant without our prior written consent.

Lee's may sublicense certain activities under the License Agreement to an affiliate of Lee's, but may not grant sublicenses to unaffiliated third parties without our prior consent. A sublicensee and a subcontractor may not be a competitor that we identify to Lee's. Sublicenses under the License Agreement do not include the right to further sublicense. In addition, we and Lee's have entered into a technology transfer agreement under which we will transfer to Lee's the manufacturing processes for SURFAXIN and SURFAXIN LS; and we and Lee's plan to negotiate (i) a manufacturing agreement providing for the manufacture of SURFAXIN and SURFAXIN LS by Lee's and giving us access to such products outside the Licensed Territory; (ii) a manufacturing and supply agreement providing for the manufacture and supply of AEROSURF drug and medical device components by us to Lee's; and (iii) such other agreements and amendments as may be necessary for the parties to perform their obligations under the License Agreement.

The term of the License Agreement commenced on the effective date of the License Agreement and will continue on a country-by-country basis for the commercial life of the products. Either party may terminate the License Agreement in the event of bankruptcy or a material breach of the License Agreement by the other party that remains uncured for a period of sixty (60) days. In addition, either party may terminate the License Agreement in its entirety or with respect to any individual product or country if a regulatory authority terminates, suspends or discontinues development of a product and such termination, suspension or discontinuance persists for a period in excess of eighteen (18) months. Upon termination of the License Agreement in its entirety or with respect to a particular product or country, generally all related rights and licenses granted to Lee's will terminate, all rights under our technology will revert to us, and Lee's will cease all use of our technology.

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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 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. 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. For 2017, we paid the minimum royalty of $300,000 to PMUSA and paid $487,500 to PMPSA, which included the minimum royalty of $300,000 as well as the $187,500 in deferred 2016 payments.

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 12 – Commitments

Operating Leases

Our operating leases consist primarily of a facility lease for our operations in Pennsylvania.

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 as of December 31, 2017 were approximately $3.9 million.

In February 2018, the lease was amended to (i) reduce the leased space from 30,506 square feet to 21,189 square feet and (ii) reduce the security deposit under the lease in the form of a letter of credit from $225,000 to $140,000. The total aggregate base rental payments remaining under the lease as of the date of the amendment were approximately $2.5 million.

Rent expense under these leases was $0.7 million and $0.8 million for the years ended December 31, 2017 and 2016, respectively.

Severance

Effective February 1, 2016, we terminated the Employment Agreement between ourselves and our then-President and Chief Executive Officer (Former CEO). During the first quarter of 2016, we incurred a severance charge of $1.2 million in general and administrative expense under the terms of the Former CEO's employment agreement, including $0.2 million related to stock option expense for certain options that continued to vest through August 1, 2017. Of the $1.0 million in severance not related to stock-based compensation, $0.9 million was paid as of December 31, 2017.

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

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

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Note 13 – 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 14 – 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, 2017 and 2016 is as follows:

(in thousands)	December 31, 2017	2016
Income tax benefit, statutory rates	$ (6,272)	$ (13,426)
State taxes on income, net of federal benefit	(398)	(2,599)
Impact of tax reform	71,151	-
Research and development tax credit	(797)	(1,305)
Employee related	953	1,215
Interest related	(147)	(890)
Warrant valuation related	-	(76)
Income tax expense / (benefit), statutory rates	64,490	(17,081)
Valuation allowance	(64,490)	17,081
Income tax benefit, net	$ -	$ -

On December 22, 2017, the U.S. government enacted the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act), which significantly revises U.S. tax law by, among other provisions, lowering the U.S. federal statutory income tax rate to 21%, imposing a mandatory one-time transition tax on previously deferred foreign earnings, and eliminating or reducing certain income tax deductions. As a result of the reduction in the U.S. corporate income tax rate, we revalued our ending net deferred tax assets as of December 31, 2017 which resulted in a provisional benefit of $71.2 million. However, this adjustment was offset by a related change in the valuation allowance. The 2017 Tax Act also imposed a tax for a one-time deemed repatriation of post-1986 unremitted foreign E&P through the year ended December 31, 2017. We did not record any provisional tax expense related to the deemed repatriation as we do not have any undistributed foreign earnings.

ASC 740, Income Taxes requires the effects of changes in tax laws to be recognized in the period in which the legislation is enacted. However, due to the complexity and significance of the 2017 Tax Act's provisions, the SEC issued SAB 118, which allows companies to record the tax effects of the 2017 Tax Act on a provisional basis based on a reasonable estimate, and then, if necessary, subsequently adjust such amounts during a limited measurement period as more information becomes available. The measurement period ends when a company has obtained, prepared, and analyzed the information necessary to finalize its accounting, but cannot extend beyond one year from enactment. The 2017 Tax Act did not have a material impact on our financial statements since our deferred temporary differences are fully offset by a valuation allowance and we do not have any off shore earnings from which to record the mandatory transition tax. However, given the significant complexity of the 2017 Tax Act, anticipated guidance from the U.S. Treasury about implementing the 2017 Tax Act, and the potential for additional guidance from the SEC or the FASB related to the 2017 Tax Act, these estimates may be adjusted during the measurement period. The provisional amounts disclosed in this footnote were based on the present interpretations of the 2017 Tax Act and current available information, including assumptions and expectations about future events, such as our projected financial performance, and are subject to further refinement as additional information becomes available (including our actual full fiscal 2018 results of operations, as well as potential new or interpretative guidance issued by the FASB or the Internal Revenue Service and other tax agencies) and further analyses are completed. We continue to analyze the changes in certain income tax deductions and gather additional data to compute the full impacts on our deferred and current tax assets and liabilities.

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2017 and 2016, are as follows:

(in thousands)	December 31, 2017	2016
Long-term deferred assets:		
Net operating loss carryforwards (Federal and state)	$ 168,263	$ 234,825
Research and development tax credit	16,813	15,700
Compensation expense on stock	1,191	2,157
Charitable contribution carryforward	5	6
Other accrued	2,547	342
Deferred revenue	317	-
Depreciation	297	460

Total long-term deferred tax assets	189,433	253,490
Valuation allowance	(189,433)	(253,490)
Deferred tax assets, net	$ -	$ -

We are in a net deferred tax asset position at December 31, 2017 and 2016 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, 2017 or 2016, nor were any incurred in 2017 or 2016.

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At December 31, 2017 and 2016, we had available carryforward net operating losses for Federal tax purposes of $590.0 million and $581.4 million, respectively, and a research and development tax credit carryforward of $16.8 million and $15.7 million, respectively. The Federal net operating loss and research and development tax credit carryforwards will continue to expire through 2037.

At December 31, 2017, 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, 2017 and 2016, we had available carryforward losses of approximately $567.7 million and $570.3 million, respectively, for state tax purposes. Of the $567.7 million state tax carryforward losses, $553.6 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.

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Note 15 – Selected Quarterly Financial Data (Unaudited)

The following tables contain unaudited statement of operations information for each quarter of 2017 and 2016. The operating results for any quarter are not necessarily indicative of results for any future period.

2017 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30 (1)	Sept. 30 (1)	Dec. 31	Total Year
Revenues:					
Grant revenue	$ 219	$ 1,147	$ 17	$ -	$ 1,383
License revenue	-	-	-	102	102
Total revenues	219	1,147	17	102	1,485
Expenses:					
Research and Development	6,413	5,483	3,062	2,418	17,376
Selling, general and administrative	1,922	1,804	1,749	1,182	6,657
Total expenses	8,335	7,287	4,811	3,600	24,033
Operating loss	(8,116)	(6,140)	(4,794)	(3,498)	(22,548)
Change in fair value of common stock warrant liability	-	-	-	-	-
Other income / (expense), net	(608)	(612)	(649)	5,971	4,102
Net (loss) / income	$ (8,724)	$ (6,752)	$ (5,443)	$ 2,473	$ (18,446)
Deemed dividend on preferred stock	(3,604)	(532)	(2,234)	-	(6,370)
Net (loss) / income attributable to common shareholders	$ (12,328)	$ (7,284)	$ (7,677)	$ 2,473	$ (24,816)
Net (loss) / income per common share - basic	$ (27.40)	$ (14.37)	$ (10.53)	$ 1.03	$ (24.14)
Net (loss) / income per common share - diluted	$ (27.40)	$ (14.37)	$ (10.53)	$ 0.97	$ (24.14)
Weighted average number of common shares outstanding - basic	450	507	729	2,405	1,028
Weighted average number of common shares outstanding - diluted	450	507	729	2,540	1,028

2016 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues:					
Grant revenue	75	106	961	900	2,042
License revenue	-	-	-	-	-
Total revenues	75	106	961	900	2,042
Expenses:					
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 and diluted	$ (34.00)	$ (25.80)	$ (20.00)	$ (15.40)	$ (94.84)
Weighted average number of common shares outstanding - basic and diluted	410	412	418	426	416

(1) Net loss per common share – basic and diluted and weighted average number of common shares outstanding for the quarters ended June 30, 2017 and September 30, 2017 have been corrected for immaterial calculation errors related to the conversion of preferred stock to common stock during those periods (*see*, " – Note 9 – Stockholders' Equity – Private Placement Offerings – February 2017 Private Placement," for further discussion of our preferred stock). The loss per share for the three and six months ended June 30, 2017 was reduced by $0.80. The loss per share for the three and nine months ended September 30, 2017 was reduced by $3.40.

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Note 16 - Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2017 through the date we issued these financial statements. During this period, we noted a subsequent event as described below:

In January 2018 and March 2018, we entered into loan agreements with LPH Investments Limited (LPH), an affiliate of Lee's, for loan proceeds of $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain its operations while the parties seek to identify and advance one or more potential strategic initiatives ("Funding Event"). To secure our obligations under these loans, we granted Lee's a security interest in substantially all of our assets. The loans will accrue interest at a rate of 6% per annum and mature upon the earlier of the closing date of the Funding Event or December 31, 2018. The parties expect that, upon the closing of the Funding Event, the outstanding principal balance of the Loan will be applied in full satisfaction of a like amount of cash consideration payable by LPH for its participation in such Funding Event, and the Loan will be discharged in full thereby.

In April 2018, we completed a private placement with LPH II for the purchase of $2.6 million of our common stock and warrants at a purchase price per share of $4.80. In connection with this offering, we issued 541,667 shares of common stock and warrants to purchase 135,417 shares of common stock at an exercise price of $5.52 per share. The warrants are exercisable after 6 months and through the seventh anniversary of the issue date. In addition, under a Registration Rights Agreement, we agreed to file within 90 days from March 30, 2018, an initial resale registration statement with the SEC to register for subsequent resale the shares and the warrant shares. We are required to seek registration of 25% of the shares and warrant shares on such initial resale registration statement. From time to time, following the 180th day from March 30, 2018, LPH II or a majority of the holders of the Shares and Warrant Shares may require us to file additional registration statement(s) to register the resale of the balance of the Shares and Warrant Shares, subject to certain limitations.

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
WINDTREE THERAPEUTICS, INC.

(Pursuant to Sections 228, 242, and 245 of the
General Corporation Law of the State of Delaware)

A. The Corporation was originally incorporated on November 6, 1992, under the name "Ansan, Inc." The Corporation changed its name on November 25, 1997, to Discovery Laboratories, Inc. The Corporation changed its name again on April 15, 2016, to Windtree Therapeutics, Inc.

B. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware ("Delaware Corporation Law") and restates, integrates and further amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation, as amended.

C. The text of the Amended and Restated Certificate of Incorporation, as amended, of the Corporation is hereby amended and restated in its entirety to read as follows:

"ARTICLE ONE
The name of the corporation (hereinafter called the "Corporation") is Windtree Therapeutics, Inc.

ARTICLE TWO
The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, Wilmington, DE 19808, County of New Castle; and the name of the registered agent of the Corporation in the State of Delaware at such address is Corporation Service Company.

ARTICLE THREE
The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

ARTICLE FOUR
The total number of shares of all classes of stock which the Corporation shall have the authority to issue is 125,000,000 consisting of 120,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock").

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance.

ARTICLE FIVE
In furtherance and not in limitation of the powers conferred by statute, the Board of Directors shall have the power, both before and after receipt of any payment for any of the Corporation's capital stock, to adopt, amend, repeal or otherwise alter the Bylaws of the Corporation without any action on the part of the stockholders; provided, however, that the grant of such power to the Board of Directors shall not divest the stockholders of nor limit their power to adopt, amend, repeal, or otherwise alter the Bylaws.

ARTICLE SIX

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

ARTICLE SEVEN

The Corporation reserves the rights to adopt, repeal, rescind or amend in any respect any provisions contained in this Certificate of Incorporation in the manner now or hereafter prescribed by applicable law, and all rights conferred on stockholders herein are granted subject to this reservation.

ARTICLE EIGHT

A director of the Corporation shall, to the fullest extent permitted by the General Corporation Law of the State of Delaware as it now exists or as it may hereafter be amended, not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article EIGHT, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article EIGHT, shall eliminate or reduce the effect of this Article EIGHT in respect of any matter occurring or any cause of action, suit or claim that, but for this Article EIGHT, would accrue or arise prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE NINE

The Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation arising pursuant to any provision of the Delaware Corporation Law or the Corporation's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim against the Corporation governed by the internal affairs doctrine."

IN WITNESS WHEREOF, Windtree Therapeutics, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 15th day of February, 2018.

Windtree Therapeutics, Inc.

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

WINDTREE THERAPEUTICS, INC.
2011 LONG-TERM INCENTIVE PLAN (AS AMENDED)

SECTION 1. PURPOSE

The purposes of this 2011 Long-Term Incentive Plan (the "Plan") are to encourage selected Employees, Directors and Consultants of Windtree Therapeutics, Inc. (together with any successor thereto, the "Company") and its Subsidiaries to acquire a proprietary interest in the growth and performance of the Company, to generate an increased incentive to contribute to the Company's future success and prosperity, thus enhancing the value of the Company for the benefit of its shareholders, and to enhance the ability of the Company and its Subsidiaries to attract and retain exceptionally qualified individuals upon whom, in large measure, the sustained progress, growth and profitability of the Company depend. This Plan shall be effective on the Effective Date (as defined in Section 16 below).

SECTION 2. DEFINITIONS

As used in the Plan, the following terms shall have the meanings set forth below:

(a) "Award" shall mean any Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit, Performance Award, Dividend Equivalent, Other Stock-Based Award, or cash granted under the Plan.

(b) "Award Agreement" shall mean any written agreement, contract, or other instrument or document, including an electronic communication, as may from time to time be designated by the Company as evidencing any Award granted under the Plan.

(c) "Board" shall mean the Board of Directors of the Company.

(d) "Cause", with respect to any Employee or Consultant of the Company or a Subsidiary, shall have the meaning set forth in such person's employment, consulting or other applicable agreement, or, in the absence of any such agreement or if such term is not defined in any such agreement, shall mean any one or more of the following, as determined by the Committee:

(i) willful misconduct or gross negligence in the performance of such person's duties;

(ii) willful and continued failure or refusal to perform satisfactorily any duties reasonably requested in the course of such person's employment by, or service to, the Company (other than a failure resulting from such person's disability); or

(iii) fraudulent, dishonest or other improper conduct engaged in by such person that causes, or has the potential to cause, harm to the Company or any of its Subsidiaries, or its or their business or reputation, including, without limitation, such person's violation of any policies of the Company applicable to such person, such person's violation of laws, rules or regulations applicable to such person, criminal activity, habitual drunkenness or use of illegal drugs.

(e) "Change in Control" shall have the meaning, if any, set forth in a Participant's employment, consulting or other applicable agreement, or, if such term is not defined in any such agreement, shall mean either a "Change in Control" as defined in subsection (e)(i) or a "409A Change in Control" as defined in subsection (e)(ii), as specified in the applicable Award Agreement. If no definition is specified, the term shall mean a 409A Change in Control.

(i) A "Change in Control" shall mean the occurrence of any of the following events:

(A) the acquisition, directly or indirectly by any Person (other than the Company, any trustee or other fiduciary under an employee benefit plan of the Company, or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than thirty-five percent (35%) of the total combined voting power of the Company's outstanding securities;

(B) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board ceases to consist of Incumbent Members, which term means members of the Board on the first day of such period and any person becoming a member of the Board subsequent to such date whose election or nomination for election was approved by not less than two-thirds of the members of the Board who then comprised the Incumbent Directors;

(C) the Company combines with another company and is the surviving corporation but, immediately after the combination, the shareholders of the Company immediately prior to the combination hold, directly or indirectly, by reason of their being stockholders of the Company, fifty percent (50%) or less of the voting stock of the combined entity; or

(D) a liquidation of the Company, a sale of all or substantially all of the Company's assets, or a merger, consolidation or similar transaction in which the Company is not the surviving entity or survives as a wholly-owned or majority-owned subsidiary of another entity.

(ii) "409A Change in Control" shall mean the occurrence of any of the following events:

(A) any Person (other than (1) the Company, or (2) any trustee or other fiduciary under an employee benefit plan of the Company), is or becomes the beneficial owner (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, of securities of the Grantee's Employer (as defined below) by reason of having acquired such securities during the 12-month period ending on the date of the most recent acquisition (not including any securities acquired directly from the Company or its Affiliates) representing thirty percent (30%) or more of the total voting power of the Grantee's Employer's then outstanding voting securities;

(B) the majority of members of the Board of the Grantee's Employer is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of the Grantee's Employer before the date of the appointment;

(C) there is consummated a merger or consolidation of the Grantee's Employer or any subsidiary thereof with any other corporation or other entity, resulting in a change described in clauses (A), (B), (D), or (E) of this definition, other than (1) a merger or consolidation that would result in the voting securities of the Grantee's Employer outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving or parent entity) more than sixty percent (60%) of the total voting power of the voting securities of the Grantee's Employer or such surviving or parent entity outstanding immediately after such merger or consolidation or (2) a merger or consolidation effected to implement a recapitalization of the Company or the Grantee's Employer (or similar transaction) in which no Person, directly or indirectly, acquired forty percent (40%) or more of the total voting power of the then outstanding securities of the Grantee's Employer (not including any securities acquired directly from the Company or its Affiliates);

(D) a liquidation of the Grantee's Employer involving the sale to any Person of at least forty percent (40%) of the total gross fair market value of all of the assets of the Grantee's Employer immediately before the liquidation; or

(E) the sale or disposition by the Grantee's Employer or any direct or indirect subsidiary of the Grantee's Employer to any Person (other than any Subsidiary) of assets that have a total fair market value equal to forty percent (40%) or more of the total gross fair market value of all of the assets of the Grantee's Employer and its subsidiaries (taken as a whole) immediately before such sale or disposition (or any transaction or related series of transactions having a similar effect), other than a sale or disposition by the Company or the Grantee's Employer or any direct or indirect subsidiary of either to an entity at least sixty percent (60%) of the total voting power of the voting securities of which is beneficially owned by shareholders of the Company or the Grantee's Employer in substantially the same proportions as their beneficial ownership of the Company or the Grantee's Employer immediately prior to such sale.

For purposes of this subsection 2(e)(ii), "Grantee's Employer" shall mean (1) the corporation for which the Grantee directly provides services or (2) the corporation that is liable for payments of deferred compensation to Grantee (if any) hereunder, or (3) a corporation that is a majority shareholder of either such corporation, or any corporation in a chain of corporations each of which is a majority shareholder of another corporation in the chain, ending with the corporation described in (A) or (B).

(f) "Code" shall mean the Internal Revenue Code of 1986, as amended from time to time.

(g) "Committee" shall mean a committee of the Board, acting in accordance with the provisions of Section 3, designated by the Board to administer the Plan and composed of not less than two Directors. Each member of the Committee shall qualify as an "outside director" as defined under Section 162(m) of the Code and the regulations promulgated thereunder and as a "non-employee director" under Rule 16b-3 promulgated under the 1934 Act, and shall satisfy any other requirements designated by the Board. To the extent the Committee has delegated authority (including as described in Section 3(b)) the term "Committee" shall refer to such delegate.

(h) "Consultant" shall mean any person, including a Director, who is not an Employee and who is engaged by the Company or any Subsidiary thereof, to render services to or for the benefit of the Company or any Subsidiary and is compensated for such services.

(i) "Director" shall mean a member of the Board.

(j) "Disability" for each respective Participant shall have the meaning set forth in the Participant's employment agreement, Award Agreement or other similar agreement with the Company; provided, that if such term is not defined in any such agreement to which the Participant is a party or if Participant is not a party to any such agreement, then "Disability" shall mean (i) with respect to any ISO, a permanent and total disability, within the meaning of Section 22(e)(3) of the Code, and (ii) with respect to any deferred compensation subject to Code Section 409A such term as defined in Treasury Regulation Section 1.409A-3(i)(4)(i)(A) or (B) or 1.409A-3(i)(4)(iii), or (iii) for any other purpose, "disability" as defined in the Company's long term disability program applicable to the Grantee (or that would be applicable to the Grantee if the Grantee elected coverage).

(k) "Dividend Equivalent" shall mean any right granted under Section 10 of the Plan.

(l) "Eligible Person" shall mean an Employee, Director or Consultant.

(m) "Employee" shall mean any person treated as an employee (including officers and directors) in the records of the Company or any Subsidiary and who is subject to the control and direction of the Company or any Subsidiary with regard to both the work to be performed and the manner and method of performance. For purposes of the Plan, the payment of a director's fee by the Company to a Director shall not be sufficient to constitute "employment" of the Director by the Company.

(n) "Fair Market Value" of a Share on any date of reference shall be determined by the Committee, in its sole discretion, and may be different for different purposes. For this purpose, the Fair Market Value of a Share on any trading day shall be (i) if the Shares are listed or admitted for trading on any United States national securities exchange, or if actual transactions are otherwise reported on a consolidated transaction reporting system, the price of the last sale before or the first sale after the grant, the closing price on the trading day before or the trading day of the grant, the arithmetic mean of the high and low prices on the trading day before or the trading day of the grant, or shall be determined by any other reasonable method using actual transactions in the Shares as reported on such market. The determination of fair market value for purposes of setting the exercise price or strike price of an award also may be determined using an average selling price during a specified period that is written 30 days before or 30 days after the applicable valuation date, provided the Committee irrevocably commits to grant the Award with an exercise or strike price set using such an average selling price before the beginning of the specified period, or (ii) if clause (i) is not applicable, the mean of the high bid and low asked quotations for a Share as reported by the National Quotation Bureau, Incorporated if at least two securities dealers have inserted both bid and asked quotations for the Shares on at least five of the 10 preceding trading days. If the information set forth in clauses (i) and (ii) above is unavailable or inapplicable to the Company (e.g., if the Shares are not then publicly traded or quoted), then the "Fair Market Value" of a Share shall be the value as determined by the Committee by the reasonable application of a reasonable valuation method.

(o) "Incentive Stock Option" and "ISO" shall mean an option granted under Section 6 of the Plan that is intended to meet the requirements of Section 422 of the Code, or any successor provision thereto.

(p) "1934 Act" shall mean the Securities Exchange Act of 1934, as amended.

(q) "Non-Qualified Stock Option" shall mean an option granted under Section 6 of the Plan that is not intended to be an Incentive Stock Option.

(r) "Option" shall mean an Incentive Stock Option or a Non-Qualified Stock Option.

(s) "Other Stock-Based Award" shall mean any right granted under Section 11 of the Plan.

(t) "Participant" shall mean an Eligible Person granted an Award under the Plan.

(u) "Performance Award" shall mean any right granted under Section 9 of the Plan.

(v) "Performance Criteria" shall mean any quantitative and/or qualitative measures, as determined by the Committee, which may be used to measure the level of performance of the Company or any individual Participant during a Performance Period, including any Qualifying Performance Criteria.

(w) "Performance Period" shall mean any period as determined by the Committee in its sole discretion.

(x) "Person" shall have the meaning ascribed to such term in Section 3(a)(9) of the 1934 Act and used in Sections 13(d) and 14(d) thereof, including "group" as defined in Section 13(d) thereof.

(y) "Qualifying Performance Criteria" shall mean one or more of the following performance criteria, either individually, alternatively or in any combination, applied to either the Company as a whole or to a business unit or related Subsidiary, and measured either annually or cumulatively over a period of years, on an absolute basis or relative to a pre-established target, to a previous year's results or to a designated comparison group, in each case as specified by the Committee in the Award: achieving specified milestones in the discovery and development, commercialization or manufacturing of one or more of the Company product candidates, obtaining debt or equity financing, achieving personal management objectives, achieving sales, revenue, net income (before or after taxes), net earnings, earnings per share, return on total capital, return on equity, cash flow, cash flow from operations, operating profit and/or margin rate targets, subject to adjustment by the Committee to remove the effect of charges for restructurings, discontinued operations, extraordinary items and all items of gain, loss or expense determined to be extraordinary or unusual in nature or infrequent in occurrence, related to the disposal of a segment or a business, or related to a change in accounting principle or otherwise.

(z) "Restricted Securities" shall mean Awards of Restricted Stock or other Awards under which issued and outstanding Shares are held subject to certain restrictions.

(aa) "Restricted Stock" shall mean any award of Shares granted under Section 8 of the Plan.

(bb) "Restricted Stock Unit" shall mean any right granted under Section 8 of the Plan that is denominated in Shares.

(cc) "Shares" shall mean the common shares of the Company par value $0.001 per share, and such other securities as may become the subject of Awards, or become subject to Awards, pursuant to an adjustment made under Section 4(b) of the Plan.

(dd) "Stock Appreciation Right" shall mean any right granted under Section 7 of the Plan.

(ee) "Subsidiary" shall mean a subsidiary company as defined in Section 424(f) of the Code (with the Company being treated as the employer corporation for purposes of this definition).

(ff) "2007 Plan" shall mean the Company's 2007 Long-Term Incentive Plan as amended from time to time.

SECTION 3. ADMINISTRATION

Except as otherwise provided herein, the Plan shall be administered by the Committee, which shall have the power to interpret the Plan and to adopt such rules and guidelines for implementing the terms of the Plan as it may deem appropriate. The Committee shall have the ability to modify the Plan provisions, to the extent necessary, or delegate such authority, to accommodate any changes in law and regulations in jurisdictions in which Participants will receive Awards.

(a) Subject to the terms of the Plan and applicable law, the Committee shall have full power and authority to:

(i) designate Participants and grant Awards under the Plan;

(ii) determine the size and type or types of Awards to be granted to each Participant under the Plan;

(iii) determine the number of Shares to be covered by (or with respect to which payments, rights, or other matters are to be calculated in connection with) Awards;

(iv) determine the terms and conditions of any Award, and to prescribe Award Agreements evidencing or setting terms thereof, which need not be the same for each Participant;

(v) determine whether, to what extent, and under what circumstances Awards may be settled or exercised in cash, Shares, other securities, or other Awards, or canceled, forfeited, or suspended, and the method or methods by which Awards may be settled, exercised, canceled, forfeited, or suspended;

(vi) determine whether, to what extent, and under what circumstances cash, Shares, other securities, other Awards, and other amounts payable with respect to an Award under the Plan shall be deferred either automatically or at the election of the holder thereof or of the Committee;

(vii) interpret and administer the Plan and any instrument or agreement relating to, or Award made under, the Plan;

(viii) establish, amend, suspend, or waive such rules and guidelines;

(ix) appoint such agents as it shall deem appropriate for the proper administration of the Plan;

(x) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of the Plan; and

(xi) correct any defect, supply any omission, or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem desirable to carry the Plan into effect.

(b) Unless otherwise expressly provided in the Plan, all designations, determinations, interpretations, and other decisions under or with respect to the Plan or any Award shall be within the sole discretion of the Committee, may be made at any time, and shall be final, conclusive, and binding upon all Persons, including the Company, any Subsidiary, any Participant, any holder or beneficiary of any Award, any shareholder, and any employee of the Company or of any Subsidiary. Subject to the requirements of applicable law and regulations, actions of the Committee may be taken by:

(i) a subcommittee, designated in writing by the Committee;

(ii) the Committee but with one or more members abstaining or recusing himself or herself from acting on the matter, so long as two or more members remain to act on the matter. Such action, authorized by such a subcommittee or by the Committee upon the abstention or recusal of such members, shall be the action of the Committee for purposes of the Plan; or

(iii) one or more officers or managers of the Company or any Subsidiary, or a committee of such officers or managers, to whom authority to perform such functions as the Committee may determine, to the fullest extent permitted under Section 157 and other applicable provisions of the Delaware General Corporation Law and the Company's bylaws, have been delegated and whose authority is subject to such terms and limitations set forth by the Committee in writing, and whose authority shall not extend to any matter relating to Participants who are officers or directors of the Company for purposes of Section 16 of the 1934 Act.

SECTION 4. SHARES AVAILABLE FOR AWARDS

(a) Shares Available.

(i) Subject to adjustment as provided in Section 4(b) and to the terms of this Section 4, the total number of Shares reserved and available for delivery pursuant to Awards granted under the Plan shall be (A) one million eight hundred eight thousand four hundred twenty-nine (1,886,429), plus (B) the number of shares that, immediately prior to the Effective Date, remain available for issuance or delivery under the 2007 Plan; plus (C) the number of shares subject to awards under the 2007 Plan which become available for grant under the Plan in accordance with Section 4(c) after the Effective Date.

(ii) The Committee may adopt reasonable counting procedures to ensure appropriate counting, avoid double counting (as, for example, in the case of tandem or substitute awards) and make adjustments if the number of Shares actually delivered differs from the number of Shares previously counted in connection with an Award. Shares subject to an Award or an award under the 2007 Plan that is canceled, expired, forfeited, settled in cash or otherwise terminated or settled without delivery of the full number of Shares subject to such Award to the Participant will again be available for Awards. In addition, in the case of any Award granted in substitution for an award of a company or business acquired by the Company or an Affiliate, shares delivered or to be delivered in connection with such substitute Award shall not be counted against the number of shares reserved under the Plan, but shall be available under the Plan by virtue of the Company's assumption of the plan or arrangement of the acquired company or business. This Section 4(a)(ii) shall apply to the number of Shares reserved and available for ISOs only to the extent consistent with applicable regulations relating to ISOs under the Code. Because Shares will count against the number reserved upon delivery (or later vesting) and subject to these share counting rules, the Committee may determine that Awards may be outstanding that relate to more Shares than the aggregate remaining available under the Plan, so long as Awards will not result in delivery and vesting of Shares in excess of the number then available under the Plan. The Company shall at all times during the term of the Plan retain as authorized and unissued Shares or treasury Shares at least the number of Shares from time to time required under the provisions of the Plan, or otherwise assure itself of its ability to perform its obligations hereunder.

(iii) Any Shares delivered pursuant to an Award may consist, in whole or in part, of authorized and unissued Shares or of treasury Shares.

(iv) Upon the Effective Date, no further Awards shall be granted under the 2007 Plan.

(b) Adjustments.

(i) In the event that the Committee shall determine that any dividend or other distribution (whether in the form of cash, Shares, or other securities), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, issuance of warrants or other rights to purchase Shares or other securities of the Company, or other similar corporate transaction or event constitutes an equity restructuring transaction, as that term is defined in Statement of Financial Accounting Standards No. 123 (revised) or otherwise affects the Shares, then the Committee shall adjust the following in a manner that is determined by the Committee to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan:

(A) the number and type of Shares or other securities which thereafter may be made the subject of Awards;

(B) the number and type of Shares or other securities subject to outstanding Awards;

(C) the number and type of Shares or other securities specified as the annual per-participant limitation under Sections 14(e), (f), and (g);

(D) the grant, purchase, or exercise price with respect to any Award, or, if deemed appropriate, make provision for a cash payment to the holder of an outstanding Award; and

(E) other value determinations applicable to outstanding awards;

provided, however, in each case, that with respect to Awards of Incentive Stock Options no such adjustment shall be authorized to the extent that such authority would cause the Plan to violate Section 422(b)(1) of the Code or any successor provision thereto; and provided further, however, that the number of Shares subject to any Award denominated in Shares shall always be a whole number.

(ii) In the event the Company or any Subsidiary shall assume outstanding employee awards or the right or obligation to make future such awards in connection with the acquisition of another business or another corporation or business entity, the Committee may make such adjustments, not inconsistent with the terms of the Plan, in the terms of Awards as it shall deem appropriate in order to achieve reasonable comparability or other equitable relationship between the assumed awards and the Awards granted under the Plan as so adjusted.

(iii) The Committee shall be authorized to make adjustments in the terms and conditions of, and the criteria included in, Awards in recognition of unusual or nonrecurring events affecting the Company, any Subsidiary, or the financial statements of the Company or any Subsidiary, or of changes in applicable laws, regulations, or accounting principles, whenever the Committee determines that such adjustments are appropriate in order to prevent dilution or enlargement of the benefits or potential benefits to be made available under the Plan.

(c) Prior Plans. Except as otherwise provided herein, (i) any award made under the Company's Amended and Restated 1998 Stock Incentive Plan, as amended before the expiration of such plan, shall continue to be subject to the terms and conditions of such plan and the applicable award agreement, and (ii) any award made under the 2007 Plan before the Effective Date shall continue to be subject to the terms and conditions of the 2007 Plan and the applicable award agreement.

SECTION 5. ELIGIBILITY

Any Eligible Person shall be eligible to be designated a Participant.

SECTION 6. OPTIONS

The Committee is authorized to grant Options to Eligible Persons with the following terms and conditions and with such additional terms and conditions, in either case not inconsistent with the provisions of the Plan, as the Committee shall determine:

(a) Exercise Price. The purchase price per Share purchasable under an Option shall be determined by the Committee no later than the date of grant of such Option; provided, however, and except as provided in Section 4(b), that such purchase price shall not be less than 100% of the Fair Market Value of a Share on the date of grant of such Option.

(b) Option Term. The term of each Option shall be specified in the applicable Award Agreement and shall not exceed ten (10) years from its date of grant.

(c) Time and Method of Exercise. The Committee shall establish in the applicable Award Agreement the time or times at which and the circumstances under which (including based on achievement of performance goals and/or future service requirements) an Option may be exercised in whole or in part, and the method or methods by which, and the form or forms, including, without limitation, cash, Shares (including Shares deliverable on exercise), other Awards, or other property that does not have a deferral feature, (including through "net exercise" or "cashless exercise" arrangements to the extent permitted by applicable law), or any combination thereof, having a Fair Market Value on the exercise date equal to the relevant exercise price, in which, payment of the exercise price with respect thereto may be made or deemed to have been made, and the method or forms in which Shares will be delivered or deemed delivered in satisfaction of Options. In addition, the Committee may allow a Participant to exercise any Option by delivering to the Company or its designated agent an executed irrevocable option exercise form together with irrevocable instructions to a broker-dealer to sell Shares and deliver the sale proceeds directly to the Company to the extent required to pay the Option exercise price.

(d) Incentive Stock Options. Only employees (as determined in accordance with Section 3401(c) of the Code) of the Company or a Subsidiary may be granted Incentive Stock Options. The terms of any Incentive Stock Option granted under the Plan shall be designed to comply in all respects with the provisions of Section 422 of the Code, or any successor provision thereto, and any regulations promulgated thereunder. In addition, Options designated as Incentive Stock Options shall not be eligible for treatment under the Code as Incentive Stock Options (and will be deemed to be Non-Qualified Stock Options) to the extent that either (1) the aggregate Fair Market Value of Shares (determined as of the time of grant) with respect to which such Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Subsidiary) exceeds $100,000, taking Options into account in the order in which they were granted, or (2) such Options otherwise remain exercisable but are not exercised within three (3) months of termination of employment (or such other period of time provided in Section 422 of the Code).

SECTION 7. STOCK APPRECIATION RIGHTS

The Committee is authorized to grant Stock Appreciation Rights to Eligible Persons. Subject to the terms of the Plan and any applicable Award Agreement, a Stock Appreciation Right granted under the Plan shall confer on the Participant a right to receive, upon exercise thereof, the excess of (i) the Fair Market Value of one Share on the date of exercise over (ii) the grant price of the right as specified by the Committee.

(a) Grant Price. The grant price of any Stock Appreciation Right shall be determined by the Committee no later than the date of grant, provided, however, that such price shall not be less than 100% of the Fair Market Value of one Share on the date of grant of the Stock Appreciation Right, and if a Stock Appreciation Right is granted in tandem to an Option, the grant price of the Stock Appreciation Right shall not be less than the exercise price of such Option.

(b) Term. The term of each Stock Appreciation Right shall be specified in the applicable Award Agreement and shall not exceed ten (10) years from the date of grant.

(c) Time and Method of Exercise. The Committee shall establish in the applicable Award Agreement the time or times at which and the circumstances under which a Stock Appreciation Right may be exercised in whole or in part (including achievement of performance goals and/or future service requirements, and the method of exercise, method of settlement, form of consideration payable in settlement (whether cash, Shares or other property) and the methods or forms in which Shares will be delivered or deemed to be delivered, and whether or not a Stock Appreciation Right shall be freestanding or in tandem or combination with any other Award).

SECTION 8. RESTRICTED STOCK AND RESTRICTED STOCK UNITS

(a) Grant. The Committee is authorized to grant Awards of Restricted Stock and Restricted Stock Units to Eligible Persons.

(b) Restrictions. Shares of Restricted Stock and Restricted Stock Units shall be subject to such restrictions as the Committee may establish in the applicable Award Agreement (including, without limitation, any limitation on the right to vote a Share of Restricted Stock or the right to receive any dividend or other right), which restrictions may lapse separately or in combination at such time or times, under such circumstances (including based on achievement of performance goals and/or future service requirements), in such installments or otherwise, as the Committee may deem appropriate. Unrestricted Shares, evidenced in such manner as the Committee shall deem appropriate, shall be delivered to the holder of Restricted Stock or Restricted Stock Unit promptly after such restrictions have lapsed.

(c) Registration. Any Restricted Stock or Restricted Stock Units granted under the Plan may be evidenced in such manner as the Committee may deem appropriate, including, without limitation, book-entry registration or issuance of a stock certificate or certificates. In the event any stock certificate is issued in respect of Shares of Restricted Stock granted under the Plan, such certificate shall be registered in the name of the Participant and shall bear an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock.

(d) Consideration. A Participant shall pay such consideration for Restricted Stock as the Committee may require; provided that the minimum consideration for shares of Restricted Stock (other than treasury shares) shall be the par value of such Shares.

(e) Forfeiture. Upon termination of service during the applicable restriction period, except as set forth herein or in the applicable Award Agreement or as otherwise determined by the Committee, all Shares of Restricted Stock and all Restricted Stock Units still, in either case, subject to restriction shall automatically be forfeited and reacquired for no additional consideration by the Company.

(f) Dividend Equivalents. Unless otherwise determined by the Committee, and subject to Section 10, Dividend Equivalents on Restricted Stock Units shall be either (A) paid with respect to such Restricted Stock Units at the dividend payment date in cash or unrestricted Shares having a Fair Market Value equal to the amount of such dividends, or (B) deferred with respect to such Restricted Stock Units, either as a cash deferral or with the amount or value thereof automatically deemed reinvested in Restricted Stock Units, other Awards or other investment vehicles having a Fair Market Value equal to the amount of such dividends, as the Committee shall determine or permit a Participant to elect, and shall be paid when the Restricted Stock Units to which they relate are settled. Notwithstanding the foregoing, Dividend Equivalents (whether in the form of Restricted Stock Units or otherwise) on Restricted Stock Units that are contingent on satisfying performance criteria shall be forfeited if the Restricted Stock Units to which they relate are forfeited or otherwise not earned. Unless otherwise determined by the Committee, cash, Shares or other property distributed in connection with a stock split or stock dividend, and other property distributed as a dividend, shall be subject to restrictions and a risk of forfeiture to the same extent as the Restricted Stock and Restricted Stock Units with respect to which such Shares or other property has been distributed.

SECTION 9. PERFORMANCE AWARDS

The Committee is hereby authorized to grant Performance Awards to Participants. Performance Awards include arrangements under which the grant, issuance, retention, vesting and/or transferability of any Award is subject to such Performance Criteria and such additional conditions or terms as the Committee may designate. Performance Awards may be made in cash. Subject to the terms of the Plan and any applicable Award Agreement, a Performance Award granted under the Plan:

(a) may be denominated or payable in cash, Shares (including, without limitation, Restricted Stock), other securities, or other Awards; and

(b) shall confer on the holder thereof rights valued as determined by the Committee and payable to, or exercisable by, the holder of the Performance Award, in whole or in part, upon the achievement of such performance goals during such Performance Periods as the Committee shall establish.

SECTION 10. DIVIDEND EQUIVALENTS

The Committee is hereby authorized to grant to Participants Awards under which the holders thereof shall be entitled to receive payments equivalent to dividends or interest with respect to a number of Shares determined by the Committee, and the Committee may provide that such amounts (if any) shall be deemed to have been reinvested in additional Shares or otherwise reinvested. Subject to the terms of the Plan and any applicable Award Agreement, such Awards may have such terms and conditions as the Committee shall determine.

SECTION 11. OTHER STOCK-BASED AWARDS

The Committee is hereby authorized to grant to Participants such other Awards that are denominated or payable in, valued in whole or in part by reference to, or otherwise based on or related to, Shares (including, without limitation, securities convertible into Shares), as are deemed by the Committee to be consistent with the purposes of the Plan, provided, however, that such grants must comply with applicable law. Subject to the terms of the Plan and any applicable Award Agreement, the Committee shall determine the terms and conditions of such Awards. Shares or other securities delivered pursuant to a purchase right granted under this Section 11 shall be purchased for such consideration, which may be paid by such method or methods and in such form or forms, including, without limitation, cash, Shares, other securities, or other Awards, or any combination thereof, as the Committee shall determine, the value of which consideration, as established by the Committee, and except as provided in Section 4(b), shall not be less than the Fair Market Value of such Shares or other securities as of the date such purchase right is granted.

SECTION 12. TERMINATION OF EMPLOYMENT OR SERVICE

(a) For Cause. Except as otherwise provided by the Committee in an Award Agreement, if a Participant's employment or service is terminated for Cause (i) the Participant's Restricted Stock or Restricted Stock Units that are then forfeitable shall thereupon be forfeited, and (ii) any unexercised Option, Stock Appreciation Right, Performance Award, Other Stock-Based Award or cash Award shall terminate effective immediately upon such termination of employment or service.

(b) On Account of Death. Except as otherwise provided by the Committee in an Award Agreement, if a Participant's employment or service terminates on account of death (or if a Participant dies within ninety (90) days following termination of employment due to Disability), then:

(i) the Participant's Restricted Stock and Restricted Stock Units that were forfeitable shall thereupon become nonforfeitable;

(ii) any unexercised Option or Stock Appreciation Right, to the extent exercisable on the date of such termination of employment or service, may be exercised, in whole or in part, within the first twelve (12) months after such termination of employment or service (but only during the term of such Award) after the death of the Participant by (A) his or her personal representative or by the person to whom an Option or Stock Appreciation Right, as applicable, is transferred by will or the applicable laws of descent and distribution or (B) the Participant's designated beneficiary; and, to the extent that any such Option or Stock Appreciation Right was not exercisable on the date of such termination of employment or service, it will immediately terminate; and

(iii) the Participant's rights with respect to any unexercised Performance Shares, Other Stock-Based Awards or cash Awards shall be as set forth in the applicable Award Agreement.

(c) On Account of Disability. Except as otherwise provided by the Committee in an Award Agreement, if a Participant's employment or service terminates on account of Disability, then:

(i) the Participant's Restricted Stock and Restricted Stock Units that were forfeitable shall thereupon become nonforfeitable;

(ii) any unexercised Option or Stock Appreciation Right, to the extent exercisable on the date of such termination of employment or service, may be exercised in whole or in part, within the first ninety (90) days after such termination of employment or service (but only during the term of such Award) by the Participant, or by (A) his or her personal representative or by the person to whom an Option or Stock Appreciation Right, as applicable, is transferred by will or the applicable laws of descent and distribution or (B) the Participant's designated beneficiary; and, to the extent that any such Option or Stock Appreciation Right was not exercisable on the date of such termination of employment, it will immediately terminate; and

(iii) the Participant's rights with respect to any unexercised Performance Shares, Other Stock-Based Awards or cash Awards shall be as set forth in the applicable Award Agreement.

(d) Any Other Reason. Except as otherwise provided by the Committee in an Award Agreement, if a Participant's employment or service terminates for any reason other than for Cause, death, or Disability, then:

(i) the Participant's Restricted Stock and Restricted Stock Units, to the extent forfeitable on the date of the Participant's termination of employment or service, shall be forfeited on such date;

(ii) any unexercised Option or Stock Appreciation Right, to the extent exercisable immediately before the Participant's termination of employment or service, may be exercised in whole or in part, not later than three (3) months after such termination of employment or service (but only during the term of such Award); and, to the extent that any such Option or Stock Appreciation Right was not exercisable on the date of such termination of employment or service, it will immediately terminate; and

(iii) the Participant's rights with respect to any unexercised Performance Shares, Other Stock-Based Awards or cash Awards shall be as set forth in the applicable Award Agreement.

(e) Repurchase Rights. Except as otherwise provided by the Committee in an Award Agreement, if at any time a Participant's employment or service with the Company is terminated for Cause or a Participant breaches any post-termination covenants set forth in any written agreement between the Participant and the Company, the Company may, in its discretion, for a period of one year after the termination for Cause or the actual discovery by the Company of the breach, as applicable, and upon 10 (ten) days' notice to the Participant, (i) repurchase all or any portion of any Shares acquired by the Participant upon the Participant's exercise of an Award, and/or (ii) require any such Participant to repay to the Company the amount of any profits derived by such Participant upon the sale or other disposition of any Shares underlying an Award during the preceding three years. The purchase price for any Shares repurchased by the Company pursuant to clause (i) of this Section 12(e) shall be the lesser of the price paid to acquire such Share and the Fair Market Value thereof on the date of such purchase by the Company.

SECTION 13. CHANGE IN CONTROL

Except as otherwise expressly provided in a Participant's employment or consulting agreement, Award Agreement, or other applicable agreement:

(a) In the event of any Change in Control, the vesting of each outstanding Option and Stock Appreciation Right shall automatically accelerate so that each such Option and Stock Appreciation Right shall, immediately prior to the effective date of the Change in Control, become fully exercisable with respect to the total number of Shares at the time subject to such Option or Stock Appreciation Right and may be exercised for any or all of those Shares as fully-vested Shares. However, an outstanding Option or Stock Appreciation Right shall not so accelerate if and to the extent: (i) such Option or Stock Appreciation Right is, in connection with the Change in Control, either to be assumed by the successor corporation (or parent thereof) or to be replaced with a comparable Option to purchase shares of the capital stock of the successor corporation (or parent thereof) or stock appreciation right, (ii) such Option or Stock Appreciation Right is to be replaced with a cash incentive program of the successor corporation which preserves the spread existing on the unvested Option Shares or Stock Appreciation Right at the time of the Change in Control and provides for subsequent payout in accordance with the same vesting schedule applicable to the Option or Stock Appreciation Right or (iii) the acceleration of such Option or Stock Appreciation Right is subject to other limitations under the applicable Award Agreement. The determination of comparability under clause (i) above shall be made by the Committee, and its determination shall be final, binding and conclusive.

(b) All outstanding restrictions with respect to any Restricted Stock or Restricted Stock Units shall also terminate automatically, and the Shares subject to those restrictions shall immediately vest in full, in the event of any Change in Control, except to the extent: (i) those repurchase rights are to be assigned to the successor corporation (or parent thereof) in connection with such Change in Control or (ii) such accelerated vesting is precluded by other limitations imposed under the applicable Award Agreement or would trigger additional taxes under Section 409A of the Code.

(c) The Committee shall have the discretion, exercisable either at the time an Award is granted or at any time while the Award remains outstanding, to provide for the automatic acceleration of one or more outstanding Awards upon the occurrence of a Change in Control, whether or not those Awards are to be assumed or replaced in the Change in Control.

(d) The outstanding Options or other Awards shall in no way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

SECTION 14. GENERAL

(a) No Cash Consideration for Awards. Awards shall be granted for no cash consideration or for such minimal cash consideration as may be required by applicable law.

(b) Awards May be Granted Separately or Together. Awards may, in the discretion of the Committee, be granted either alone or in addition to, in tandem with, or in substitution for any other Award or any award granted under any other plan of the Company or any Subsidiary. Awards granted in addition to or in tandem with other Awards, or in addition to or in tandem with awards granted under any other plan of the Company or any Subsidiary, may be granted either at the same time as or at a different time from the grant of such other Awards or awards.

(c) Forms of Payment Under Awards. Subject to the terms of the Plan and of any applicable Award Agreement, payments or transfers to be made by the Company or a Subsidiary upon the grant, exercise, or payment of an Award may be made in such form or forms as the Committee shall determine, including, without limitation, cash, Shares, rights in or to Shares issuable under the Award or other Awards, other securities, or other Awards, or any combination thereof, and may be made in a single payment or transfer, in installments, or on a deferred basis, in each case in accordance with rules and procedures established by the Committee. Such rules and procedures may include, without limitation, provisions for the payment or crediting of reasonable interest on installment or deferred payments or the grant or crediting of Dividend Equivalents in respect of installment or deferred payments.

(d) Limits on Transfer of Awards. Except as provided by the Committee, no Award and no right under any such Award, shall be assignable, alienable, saleable, or transferable by a Participant otherwise than by will or by the laws of descent and distribution provided, however, that, if so determined by the Committee, a Participant may, in the manner established by the Committee, designate a beneficiary or beneficiaries to exercise the rights of the Participant with respect to any Award upon the death of the Participant. Each Award, and each right under any Award, shall be exercisable, during the Participant's lifetime, only by the Participant or, if permissible under applicable law, by the Participant's guardian or legal representative. No Award and no right under any such Award, may be pledged, alienated, attached, or otherwise encumbered, and any purported pledge, alienation, attachment, or encumbrance thereof shall be void and unenforceable against the Company or any Affiliate.

(e) Per-Person Limitation on Options and SARs. The number of Shares with respect to which Options and Stock Appreciation Rights may be granted under the Plan during any year to an individual Participant shall not exceed 1,500,000 Shares, subject to adjustment as provided in Section 4(b).

(f) Per-Person Limitation on Certain Awards. Other than Options and Stock Appreciation Rights, the aggregate number of Shares with respect to which Restricted Stock, Restricted Stock Units, Performance Awards and Other Stock-Based Awards may be granted under the Plan during any year to an individual Participant shall not exceed 750,000 Shares, subject to adjustment as provided in Section 4(b).

(g) Per-Person Limit on Performance-Based Awards. Subject to Section 4, the aggregate number of Shares subject to Awards that are intended to qualify as "performance-based compensation" under Code Section 162(m) granted during any calendar year to any one Eligible Person (taking into account the maximum number payable based on performance exceeding target objectives) shall not exceed three (3) million Shares. The maximum amount payable as a cash Award for any performance period to an Eligible Person that is intended to satisfy the requirements for "performance-based compensation" under Code Section 162(m) shall be five (5) million dollars per calendar year. In the case of an award with a multi-year performance period, these limits shall apply to each calendar year (or portion thereof) in the performance period. The limitation on cash Awards is separate from and not affected by the limitation on Awards denominated in Shares.

(h) Conditions and Restrictions Upon Securities Subject to Awards. The Committee may provide that the Shares issued upon exercise of an Option or Stock Appreciation Right or otherwise subject to or issued under an Award shall be subject to such further agreements, restrictions, conditions or limitations as the Committee in its discretion may specify prior to the exercise of such Option or Stock Appreciation Right or the grant, vesting or settlement of such Award, including without limitation, conditions on vesting or transferability and forfeiture or repurchase provisions or provisions on payment of taxes arising in connection with an Award. Without limiting the foregoing, such restrictions may address the timing and manner of any resales by the Participant or other subsequent transfers by the Participant of any Shares issued under an Award, including without limitation: (A) restrictions under an insider trading policy or pursuant to applicable law, (B) restrictions designed to delay and/or coordinate the timing and manner of sales by Participant and holders of other Company equity compensation arrangements, (C) restrictions as to the use of a specified brokerage firm for such resales or other transfers and (D) provisions requiring Shares to be sold on the open market or to the Company in order to satisfy tax withholding or other obligations.

(i) Share Certificates. All Shares or other securities delivered under the Plan pursuant to any Award or the exercise thereof shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under the Plan or the rules, regulations, and other requirements of the Securities and Exchange Commission, any stock exchange upon which such Shares or other securities are then listed, and any applicable Federal, state, or local securities laws, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

(j) No Rights to Awards. No Participant or other Person shall have any claim to be granted any Award under the Plan, or, having been selected to receive an Award under this Plan, to be selected to receive a future Award, and further there is no obligation for uniformity of treatment of Employees, Directors, Consultants, Participants, or holders or beneficiaries of Awards under the Plan. The terms and conditions of Awards need not be the same with respect to each recipient.

(k) Tax Provisions.

(i) *Withholding*. The Company and any Subsidiary is authorized to withhold, at the time of grant or settlement or other time as appropriate, from any Award, any payment relating to an Award, including from a distribution of Shares, or any payroll or other payment to a Participant, amounts of withholding and other taxes required to be withheld. This authority shall include authority to withhold or receive Shares or other property and to make cash payments in respect thereof in satisfaction of the Company's (or a Subsidiary's) withholding obligations, either on a mandatory or elective basis in the discretion of the Committee. The Committee is specifically authorized to allow Participants to satisfy withholding tax amounts by electing to have the Company (or a Subsidiary) withhold from the Shares to be delivered upon exercise of an Option or vesting or settlement of a Stock Award that number of Shares having a Fair Market Value equal to the amount required to be withheld.

(ii) *Required Consent to and Notification of Code Section 83(b) Election*. No election under Code Section 83(b) (to include in gross income in the year of transfer the amounts specified in Code Section 83(b)) or under a similar provision of the laws of a jurisdiction outside the United States may be made unless expressly permitted by the terms of the Award Agreement or by action of the Committee in writing prior to the making of such election. In any case in which a Participant is permitted to make such an election in connection with an Award, the Participant shall notify the Committee of such election within ten days of filing notice of the election with the Internal Revenue Service or other governmental authority, in addition to any filing and notification required pursuant to regulations issued under Code Section 83(b) or other applicable provision.

(iii) *Requirement of Notification Upon Disqualifying Disposition Under Code Section 421(b)*. If any Participant shall make any disposition of shares of Stock delivered pursuant to the exercise of an ISO under the circumstances described in Code Section 421(b) (relating to certain disqualifying dispositions), such Participant shall notify the Committee of such disposition within ten days thereof.

(iv) *Payment of Tax Amount*. Notwithstanding anything herein to the contrary, in the event the Internal Revenue Service should finally determine that part or all of an Award that has not been settled is nevertheless required to be included in the Participant's gross income for federal income tax purposes, then an amount necessary to pay applicable federal, state or local income taxes on such includible value shall be distributed with respect to the Award in a lump sum cash payment within sixty (60) days after such determination, without the requirement of separate approval by the Committee. A "final determination" of the Internal Revenue Service is a determination in writing ordering the payment of additional tax, reporting of additional gross income or otherwise requiring an Award or portion thereof to be included in gross income, which is not appealable or which the Participant does not appeal within the time prescribed for appeals.

(v) *Construction in Compliance with Code Section 409A*. The Company intends that none of the grant, exercise, settlement or amendment or termination of any Award under the Plan will cause the Participant to be liable for payment of interest or a tax penalty under Code Section 409A. The provisions of the Plan and any Award Agreement shall be construed consistent with that intent.

(vi) "Termination of service," "resignation" or words of similar import, as used in this Plan shall mean, with respect to any payments of deferred compensation subject to Section 409A of the Code, the Participant's "separation from service" as defined in Section 409A of the Code. For this purpose, a "separation from service" is deemed to occur on the date that the Company and the Participant reasonably anticipate that the level of bona fide services the Participant would perform after the date (whether as an employee or independent contractor) would permanently decrease to a level that, based on the facts and circumstances would constitute a separation from service; provided that a decrease to a level that is 50% or more of the average level of bona fide services provided over the prior 36 months shall not be a separation from service, and a decrease to a level that is 20% or less of the average level of such bona fide services shall be a separation from service. The bona fide services taken into account for purposes of determining whether there has been a separation from service shall be services performed for the Company and any person or entity that would be considered a single employer with the Company under Section 414(b) or 414(c) of the code; provided that, in applying Section 1563(a)(1), (2), and (3) of the Code, the language "at least 50 percent" shall be used instead of "at least 80 percent;" and further provided that "at least 20 percent" shall be used instead of "at least 50 percent" where based on legitimate business criteria.

(vii) *Six-Month Delay*. Any distribution or settlement of an Award triggered by the separation from service of a Specified Employee that would otherwise be made prior to the Deferred Distribution Date (as defined below) shall not occur earlier than the Deferred Distribution Date. The "Deferred Distribution Date" is the day that is six (6) month and one (1) day after a Participant's separation from service.

(l) No Limit on Other Compensation Arrangements. Nothing contained in the Plan shall prevent the Company or any Subsidiary from adopting or continuing in effect other or additional compensation arrangements, and such arrangements may be either generally applicable or applicable only in specific cases.

(m) No Right to Employment. The grant of an Award shall not constitute an employment contract nor be construed as giving a Participant the right to be retained in the employ or service of the Company or any Subsidiary. Further, the Company or a Subsidiary may at any time dismiss a Participant from employment, free from any liability, or any claim under the Plan, unless otherwise expressly provided in the Plan or in any Award Agreement.

(n) Governing Law. The validity, construction, and effect of the Plan and any rules and regulations relating to the Plan shall be determined in accordance with the laws of the State of Delaware and applicable Federal law without regard to conflict of laws.

(o) Severability. If any provision of the Plan or any Award is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction, or as to any Person or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to applicable laws, or if it cannot be so construed or deemed amended without, in the determination of the Committee, materially altering the intent of the Plan or the Award, such provision shall be stricken as to such jurisdiction, Person, or Award, and the remainder of the Plan and any such Award shall remain in full force and effect.

(p) No Trust or Fund Created. Neither the Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company or any Subsidiary and a Participant or any other Person. To the extent that any Person acquires a right to receive payments from the Company or any Subsidiary pursuant to an Award, such right shall be no greater than the right of any unsecured general creditor of the Company or any Subsidiary.

(q) No Fractional Shares. No fractional Shares shall be issued or delivered pursuant to the Plan or any Award, and the Committee shall determine whether cash, or other securities shall be paid or transferred in lieu of any fractional Shares, or whether such fractional Shares or any rights thereto shall be canceled, terminated, or otherwise eliminated.

(r) Headings. Headings are given to the sections and subsections of the Plan solely as a convenience to facilitate reference. Such headings shall not be deemed in any way material or relevant to the construction or interpretation of the Plan or any provision thereof.

(s) No Representations or Covenants With Respect to Tax Qualification. Although the Company may endeavor to (i) qualify an Award for favorable U.S. or foreign tax treatment (e.g., incentive stock options under Section 422 of the Code) or (ii) avoid adverse tax treatment (e.g., under Section 409A of the Code), the Company makes no representation to that effect and expressly disavows any covenant to maintain favorable or avoid unfavorable tax treatment. The Company shall be unconstrained in its corporate activities without regard to the potential negative tax impact on holders of Awards under the Plan.

(t) Compliance With Laws. The granting of Awards and the issuance of Shares under the Plan shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or stock exchanges on which the Company is listed as may be required. The Company shall have no obligation to issue or deliver evidence of title for Shares issued under the Plan prior to:

(i) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable; and

(ii) completion of any registration or other qualification of the Shares under any applicable national or foreign law or ruling of any governmental body that the Company determines to be necessary or advisable or at a time when any such registration or qualification is not current, has been suspended or otherwise has ceased to be effective.

The inability or impracticability of the Company to obtain or maintain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

SECTION 15. AMENDMENT AND TERMINATION

Except to the extent prohibited by applicable law and unless otherwise expressly provided in an Award Agreement or in the Plan:

(a) Amendments to the Plan. The Board of Directors of the Company may amend, alter, suspend, discontinue, or terminate the Plan, in whole or in part; provided, however, that without the prior approval of the Company's shareowners, no material amendment shall be made if shareholder approval is required by law, regulation, or stock exchange, and; provided, further, that, notwithstanding any other provision of the Plan or any Award Agreement, no such amendment, alteration, suspension, discontinuation, or termination shall be made without the approval of the shareholders of the Company that would:

(i) increase the total number of Shares available for Awards under the Plan, except as provided in Section 4 hereof; or

(ii) except as provided in Section 4(b), permit Options, Stock Appreciation Rights, or Other Stock-Based Awards encompassing rights to purchase Shares to be repriced, replaced, or regranted through cancellation, or by lowering the exercise price of a previously granted Option or the grant price of a previously granted Stock Appreciation Right, or the purchase price of a previously granted Other Stock-Based Award.

(b) Amendments to Awards. The Committee may waive any conditions or rights under, amend any terms of, or amend, alter, suspend, discontinue, or terminate, any Awards theretofore granted, prospectively or retroactively. Except for amendments authorized under Section 13, no such amendment or alteration shall be made which would impair the rights of any Participant, without such Participant's consent, under any Award theretofore granted, provided that no such consent shall be required with respect to any amendment or alteration if the Committee determines in its sole discretion that such amendment or alteration either (i) is required or advisable in order for the Company, the Plan or the Award to satisfy or conform to any law or regulation or to meet the requirements of any accounting standard, or (ii) is not reasonably likely to significantly diminish the benefits provided under such Award.

SECTION 16. EFFECTIVE DATE OF THE PLAN

The Plan shall be effective on the date that it is approved by the Company's shareholders (the "Effective Date").

SECTION 17. TERM OF THE PLAN

Unless earlier terminated by action of the Board of Directors, the Plan will remain in effect until such time as no Shares remain available for delivery under the Plan and the Company has no further rights or obligations under the Plan with respect to outstanding Awards under the Plan. No incentive stock option shall be granted under the Plan after the tenth anniversary of the adoption of the Plan by the Board. However, unless otherwise expressly provided in the Plan or in an applicable Award Agreement, any Award theretofore granted may extend beyond the termination of the Plan, and the authority of the Committee to amend, alter, adjust, suspend, discontinue, or terminate any such Award, or to waive any conditions or rights under any such Award, and the authority of the Board of Directors of the Company to amend the Plan, shall extend beyond such date.

Exhibit 10.14

RESTRICTED STOCK UNIT AWARD AGREEMENT

RESTRICTED STOCK UNIT AWARD AGREEMENT (this "Agreement") between WINDTREE THERAPEUTICS, INC., a Delaware corporation (the "Company"), and _____, an employee of the Company ("Participant").

WHEREAS, in order to generate an increased incentive to contribute to the Company's future success and prosperity, the Company has agreed to award to Participant that number of restricted stock units (the "Restricted Stock Units") representing on a one-for-one basis the same number of Shares of the Company;

NOW, THEREFORE, in consideration of the above premises and the mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

SECTION 1. General.

(a) All capitalized terms used in this Agreement without definition shall have the meanings ascribed to them in the Windtree Therapeutics, Inc., 2011 Long-Term Incentive Plan, as it may have been amended from time to time ("the "Plan").

(b) The Award is subject to the terms, conditions and restrictions set forth in this Agreement, the Plan (the terms of which are incorporated in this Agreement by reference), and the Notice of Award of Restricted Stock Units issued by the Company (the "Notice"). In the event of any inconsistency between the Plan, this Agreement or the Notice, the terms of the Plan shall control.

SECTION 2. Award and Vesting of Restricted Stock Units. Effective as of the Grant Date set forth in the Notice, the Company hereby grants to Participant named in the Notice an award of Restricted Stock Units, as set forth in the Notice. Subject to the earlier vesting or forfeiture of Restricted Stock Units as provided in Section 4 below, the Restricted Stock Units awarded to Participant shall vest and the Shares shall be delivered to Participant as set forth in the Notice.

SECTION 3. Restrictions. The Restricted Stock Units are bookkeeping entries only. The Participant shall have no rights as a stockholder of the Company, no dividend rights and no voting rights with respect to the Restricted Stock Units. Participant is an unsecured general creditor of the Company.

(a) Subject to Section 4, the Restricted Stock Units shall vest and restrictions shall lapse in accordance with the vesting schedule set forth in the Notice. Participant shall not be entitled to delivery of the certificate or certificates for the Shares pursuant to Section 5 hereof until the applicable vesting date and upon the satisfaction of all other applicable conditions.

(b) Participant shall not, without the prior written consent of the Company, offer, transfer, sell, pledge, assign, hypothecate or otherwise encumber or dispose of or attempt to dispose of any unvested Restricted Stock Units otherwise than by will or by the laws of descent and distribution. Any attempt by the Participant to offer, transfer, sell, pledge, assign, hypothecate or otherwise encumber or dispose of unvested Restricted Stock Units or any interest in such Restricted Stock Units in a manner contrary to the restrictions set forth in this Agreement shall be void and of no effect.

SECTION 4. Acceleration; Forfeiture of Restricted Stock.

(a) If Participant's Service as an employee of the Company is terminated due to Participant's death or Disability, then Participant shall be entitled to the immediate full vesting on the date of termination of all Restricted Stock Units. Upon the occurrence of a Corporate Transaction or Change in Control, all Restricted Stock Units that have not then vested shall vest as of the effective date of such Corporate Transaction or Change in Control in accordance with the provisions of the Plan including, without limitation, Section 13 of the Plan.

(b) If Participant's Service as an employee of the Company terminates for any reason other than as set forth in Section 4(a) above, all unvested Restricted Stock Units granted hereunder shall automatically be forfeited as of the date of termination and reacquired for no additional consideration and without the need for any further action on behalf of the Company. In the event of any such forfeiture, all such forfeited Restricted Stock Units shall be returned to the Plan in accordance with Section 8(e) of the Plan.

SECTION 5. Book Entry Form; Conditions to Issuance of Certificates; Tax Withholding.

(a) The Restricted Stock Units will be recorded in the name of the Participant in the books and records of the Company.

(b) On or as soon as reasonably practical after the vesting of any Restricted Stock Units granted hereby and the satisfaction of all other applicable conditions, the Company shall (i) cause certificates representing the Shares to be issued to the Participant or (ii) credit the Shares to which Participant is entitled to Participant's (or designee's) balance account with the Depository Trust Company (DTC) through its Deposit / Withdrawal At Custodian (DWAC) system; provided, however, that the Company shall not be required to issue or deliver any such certificate(s) or credit for any Shares prior to the fulfillment of all of the following conditions:

1. The Participant or his legal representative shall pay to the Company the full amount of all federal and state withholding or other taxes applicable to the taxable income of Participant resulting from the issuance of stock upon the vesting of the Restricted Stock Units or the lapse or removal of the restrictions. The Committee shall be authorized, in its sole discretion, to establish such rules and procedures relating to the use of Shares to satisfy tax withholding obligations as it deems necessary or appropriate to facilitate and promote the conformity of Participant's transactions under the Plan and this Agreement with Rule 16b-3 under the 1934 Act, as amended, if such Rule is applicable to a transaction by Participant;

2. The completion and continued effectiveness of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Committee shall, in its sole and absolute discretion, deem necessary and advisable; and

3. The obtaining of any approval or other clearance from any state or federal governmental agency that the Committee shall, in its absolute discretion, determine to be necessary or advisable.

SECTION 6. Representations and Warranties.

(a) Participant hereby represents to the Company that Participant has read in their entirety and fully understands the provisions of this Agreement and the Plan, has had an opportunity to obtain the advice of counsel prior to executing this Agreement, and fully understands all provisions of this Agreement and the Plan, and the Participant acknowledges that Participant is relying solely on his or her own advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences of this Award. Participant understands that Participant (and not the Company) shall be responsible for Participant's own tax liability that may arise as result of the transactions contemplated by this Agreement.

(b) Participant acknowledges and agrees that the vesting of Restricted Stock Units pursuant to this Agreement is earned only through his or her continued and satisfactory service as an employee of the Company.

(c) Participant acknowledges and agrees that this Agreement is not a contract of employment and that nothing in this Agreement shall confer upon Participant any right with respect to continuation of service to the Company, nor shall it interfere in any way with his or her right or the Company's right to terminate Participant's service to the Company at any time, with or without cause.

(d) Participant hereby accepts this Agreement subject to all of the terms and provisions hereof.

(e) Participant acknowledges that, as a condition to the vesting of the Restricted Stock Units, the representations and warranties of this Section 6 shall be true and correct as of the vesting date or the date of receipt of any distributions with respect to the Restricted Stock Units, as applicable, as if they had been made on such date with respect to vested Restricted Stock Units or any such other distributions, as applicable.

SECTION 7. Notices. Any notice required to be given or delivered to the Company under the terms of this Agreement shall be in writing and addressed to the Company at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: Legal Department, or to such other address as shall be provided in writing to Participant. Any notice required to be given or delivered to Participant shall be in writing and addressed to the most recent address of Participant as set forth in the books and records of the Company. All notices shall be deemed effective one day after being sent by Federal Express or similar overnight delivery or three days after being mailed registered or certified mail, postage prepaid, and properly addressed to the party to be notified.

SECTION 8. Miscellaneous.

(a) Assignment; Binding Agreement. This Agreement shall be binding upon and inure to the benefit of the heirs and representatives of the Participant and the assigns and successors of the Company, but neither this Agreement nor any rights hereunder shall be assignable or otherwise subject to hypothecation by the Participant.

(b) Entire Agreement; Amendment. This Agreement represents the entire agreement of the parties with respect to the subject matter hereof, except that the provisions of the Plan are incorporated in this Agreement in their entirety. In the event of any conflict between the provisions of this Agreement and the Plan, the provisions of the Plan shall control. This Agreement may be amended by the Committee without the consent of the Participant except in the case of an amendment adverse to the Participant (except as may be permitted under Section 16(b) of the Plan), in which case the Participant's consent shall be required.

(c) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles of such state.

(d) Severability. Whenever possible, each provision in this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be held to be prohibited by or invalid under applicable law, then (i) such provision shall be deemed amended to accomplish the objectives of the provision as originally written to the fullest extent permitted by law and (ii) all other provisions of this Agreement shall remain in full force and effect.

(e) Conformity to Securities Laws. The Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act of 1933, as amended, and the 1934 Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, including without limitation Rule 16b-3 under the 1934 Act. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Awards are granted, only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

(f) Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the 1934 Act, the Plan and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the 1934 Act (including any amendment to Rule 16b-3 of the 1934 Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

(g) No Strict Construction. No rule of strict construction shall be implied against the Company, the Committee or any other person in the interpretation of any of the terms of the Plan, this Agreement or any rule or procedure established by the Committee.

(h) Use of the Word "Participant". Wherever the word "Participant" is used in any provision of this Agreement under circumstances where the provision should logically be construed to apply to the executors, the administrators, or the person or persons to whom the Restricted Stock Units may be transferred by will or the laws of descent and distribution, the word "Participant" shall be deemed to include such person or persons.

(i) Further Assurances. The Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all additional documents, instruments and agreements (including, without limitation, stock powers with respect to Shares issued as a dividend or distribution on Restricted Stock Units) which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Agreement and the Plan.

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-1 No. 333-217161) of Windtree Therapeutics, Inc. and in related Prospectuses.

(2) 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.

(3) 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

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

(5) 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.

(6) 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.

(7) 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 April 17, 2018, 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, 2017.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
April 17, 2018

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: April 17, 2018

/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: April 17, 2018

/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, 2017 ("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: April 17, 2018

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

/s/ John Tattory
John 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.