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

FORM 10-K/A

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

For the fiscal year ended December 31, 2018

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:

None

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	**The OTCQB® Market**

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 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.

(Check all that apply)

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	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, 2018 (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 5, 2019, there were 32,133,189 shares of the registrant’s common stock outstanding.

Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Windtree Therapeutics, Inc., and its wholly-owned, subsidiaries, CVie Investments Limited (CVie Investments) and its wholly-owned subsidiary, CVie Therapeutics Limited (CVie Therapeutics, and together with CVie Investments, CVie); and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

EXPLANATORY NOTE TO AMENDMENT NO. 1

Windtree Therapeutics, Inc. (the “Company”) is filing this Amendment No. 1 (this “Amendment”) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the “Form 10-K”) filed with the Securities and Exchange Commission on April 16, 2019. This Amendment is solely for the purpose of providing (i) Exhibit 101 – Interactive Data File (XBRL Exhibit) required by Rule 405 of Regulation S-T, which was not included with the original Form 10-K, and (ii) Part III information, which was previously omitted pursuant to General Instruction G(3), and (iii) included format adjustments for improved readability, corrected one rounding error, a single reference to the number of AEROSURF® warrants issued, and a description of the Private Placement Financing in the financial statements and/or MD&A. No other changes have been made to the Form 10-K. This Amendment speaks as of the original filing date of the Form 10-K, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way disclosures made in the original Form 10-K.

FORWARD-LOOKING STATEMENTS

This Amendment No. 1 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.

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:

- our ongoing capital resource requirements and our ability to raise funds to meet such requirements;
- our ability to successfully identify and enter into strategic and other non-dilutive transactions;
- our ability to successfully execute development activities;
- our ability to successfully integrate our company following our acquisition of CVie Investments;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices and other materials we need; 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 herein.

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.

WINDTREE THERAPEUTICS, INC.

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For the Fiscal Year Ended December 31, 2018

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 and medical device company focused on developing drug product candidates and medical device technologies to address acute pulmonary and cardiovascular diseases. Historically, our focus has been on the development of our proprietary KL4 surfactant technology and aerosol delivery system (ADS) technology for the treatment and or prevention of respiratory distress syndrome (RDS) in premature infants. Following our merger with CVie Investments in December 2018 (discussed below), we are also focusing on therapies for acute heart failure and hypertension and associated organ dysfunction.

Our four lead development programs are (1) istaroxime for treatment of acute decompensated heart failure (ADHF), (2) AEROSURF® (lucinactant for inhalation) for non-invasive delivery of our lyophilized KL4 surfactant to treat RDS in premature infants, (3) lyophilized KL4 surfactant intratracheal suspension for RDS, and (4) rostafuroxin for genetically associated hypertension.

Heart failure is a chronic, progressive condition in which patients often experience episodic periods of increased symptoms called ADHF, where the heart fails to adequately pump, resulting in worsening symptoms, including pulmonary and peripheral edema and other severe complications. In the US, nearly 6 million people (nearly two percent of the adult population) have heart failure and approximately half of these patients are expected to die within 5 years of diagnosis; and in the combined US, EU and Japan markets, there are over 14 million patients with heart failure. ADHF can be precipitated by many factors and puts patients at increased risk for morbidity, hospital readmission and mortality. Heart failure is the leading cause of hospitalization in patients age 65 years and older. There are more than 1.1 million hospital admissions for heart failure in the US each year and over 2.5 million hospital estimated admissions for ADHF in the combined US, EU and Japan markets. We estimate that ADHF may represent a potential addressable market of approximately $1.6 billion dollars annually (in the US, EU and Japan). Based on preclinical and clinical studies performed to date, we believe that istaroxime, if approved, may have the potential to address unmet medical needs of these patients by improving cardiac function and management of fluid accumulation that contributes to heart failure symptoms while potentially avoiding complications associated with current ADHF therapies. We are also focused on early development of oral and other intravenous therapies to potentially address both acute and chronic heart failure. In addition to the ADHF market, GlobalData has estimated that the sales market for chronic heart failure therapies in the base year (2016) totaled $3.6 billion within the seven major markets, with the US contributing just over 70% of these sales.

Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. RDS is a condition that occurs 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. We believe that the current surfactant market for RDS is estimated to be approximately $70 to $90 million annually in the US and approximately $400 to $425 million annually worldwide. We believe that this market has been constrained because surfactants are generally administered using intubation, frequently with mechanical ventilation, two invasive procedures that may result in serious respiratory and non-respiratory complications. By contrast, AEROSURF is a combination drug/device product that is designed to administer our KL4 surfactant noninvasively and, we believe, may avoid these invasive procedures and achieve a competitively advantageous position in an expanding RDS market. We also believe that AEROSURF may support an expansion of the RDS surfactant market by reducing the need for intubation and mechanical ventilation, reducing hospital costs, and enabling dosing and repeat dosing as needed using noninvasive delivery of AEROSURF via nasal continuous positive airway pressure (nCPAP). Moreover, while the current surfactant market represents drug-only revenues, we plan to capture revenues from the drug product and the ADS disposable cartridges, supported by anticipated pharmacoeconomic benefits associated with the successful use of nCPAP. As such, we believe that AEROSURF, if approved, may be administered in less specialized hospitals and birthing centers, potentially further expanding access to treatment and potentially achieving a higher price per patient in an addressable market that could be in excess of $1 billion annually. In addition, we are assessing a potential development plan potentially to gain regulatory approval for our lyophilized KL4 surfactant as an intratracheal suspension for RDS, which would allow us to make our KL4 surfactant available in an expanded market to treat the smallest infants and those who are unable to breathe on their own and may not be good candidates for AEROSURF.

Our fourth product candidate is rostafuroxin for the treatment of hypertension associated with certain patient genotypes. According to the Centers for Disease Control (CDC), patients with high blood pressure have a greater risk for heart disease and stroke, which are the leading causes of death in the US. Currently, an estimated 75 million adults, or approximately one third of the adult population in the US, have high blood pressure and the incidence is increasing. During 2014, high blood pressure was a primary or contributing cause of death for more than 410,000 adults in the US. The estimated annual cost of high blood pressure in the US, including for health care services, medications, and missed days of work, is approximately $48.6 billion. Unfortunately, hypertension is a heterogeneous disease in which a majority of treated patients (50-85% globally) do not reach their therapeutic target blood pressure and patients often have persistent hypertension despite being on multiple therapies. Ethnicity and genetic makeup are known to impact the response to anti-hypertensive treatments, and uncontrolled hypertension has been associated with certain genetic makeups. We believe, based on preclinical and clinical studies performed to date, that rostafuroxin may potentially reduce or normalize blood pressure and may address unmet medical needs in a genetically identified subset of patients that could represent approximately 20% - 25% of patients with hypertension. Given the size of the market and the prevalence of unmet medical needs, major pharmaceutical companies have maintained hypertension as a key area of focus and continue to seek new drugs to compete in markets they have established with previous anti-hypertensive therapies. We plan to develop rostafuroxin and potentially leverage the industry's interest in licensing opportunities in this market.

ISTAROXIME

Overview

Our lead cardiovascular product is istaroxime, an investigational drug that we are developing to treat acute decompensated heart failure (ADHF). Heart failure can result from structural or functional cardiac abnormalities. Heart failure is a chronic, progressive disease that commonly but episodically worsens to a point of decompensation, where cardiac output fails to meet the body's metabolic needs. The disease is characterized by inadequate pumping function of the heart that results in fluid accumulation manifesting as pulmonary congestion, peripheral edema and congestion in other parts of the body. Insufficient cardiac output can result in inadequate peripheral perfusion that increases the risk of other organ dysfunction such as renal failure. Chronic heart failure is commonly treated with multiple medications including diuretics, inhibitors of neurohumoral imbalances (angiotensin, renin, aldosterone, naturetic peptides) and beta blockers. Effective treatments for ADHF are lacking.

Intensification of heart failure therapy in the hospital typically includes intravenous diuretics and, if the blood pressure is low, supportive therapy with inotropes. Inotropes can be associated with adverse effects that include hypotension, arrhythmias and possibly increased mortality. These drugs are used only if needed to support blood pressure and cardiac function.

Istaroxime represents a novel approach to the treatment of ADHF. It has a dual mechanism of action referred to as luso-inotropic, to improve cardiovascular physiology. First, it activates the SERCA2a calcium pump on the sarcoplasmic reticulum (SR) leading to enhanced SR calcium uptake and a reduction in cytoplasmic calcium that allows for improved myocardial relaxation (lusitropic). Second, it inhibits the sodium-potassium ATPase activity leading to improved myocardial contractility (inotropic). We believe that this mechanism of action may result in improvement in cardiac function and perfusion to reduce congestion and edema and preserve other organ function while avoiding the side effects associated with other classes of heart failure therapies. Preclinical and clinical studies performed to date suggest that istaroxime may improve cardiovascular physiology as assessed by parameters of pump function, decreases in pulmonary capillary wedge pressure, decreases in heart rate, increases in blood pressure without adverse events such as arrhythmias, cardiac damage (as indicated by elevated troponin values) or adverse impact on kidney function. We believe that these features of istaroxime, if approved, could potentially result in clinical improvement of patients' heart failure symptoms and reduce both complications and length of hospital stays when compared to current therapeutic regimens for ADHF.

In 2007, CVie Therapeutics completed a phase 2a randomized, double-blind, placebo-controlled, dose-escalation clinical trial that was designed to evaluate 3 doses of istaroxime in a study of 120 hospitalized patients (~30 patients per cohort) with ADHF and reduced left ventricular ejection fraction with 3 doses of istaroxime administered over a 6-hour infusion period. The primary endpoint, lowering of pulmonary capillary wedge pressure (PCWP) was significantly improved in all 3 doses relative to placebo, and the certain secondary hemodynamic endpoints (increased systolic blood pressure and decreased heart rate) also improved. The main side effects were vomiting (7.9%) and pain at the infusion site (5.6%); one severe adverse event of ventricular tachycardia was observed. The favorable effects on PCWP, blood pressure and heart rate with potential luso-inotropic effects provided the basis for moving the program forward into a phase clinical 2b trial and for selecting the doses to study.

In January 2019, we announced topline results of a phase 2b randomized, double-blind, placebo-controlled, dose-escalation clinical trial, a multicenter, randomized, placebo-controlled study in 120 hospitalized patients in Europe and Asia with ADHF that was designed to evaluate two doses of istaroxime administered over a 24-hour infusion period (~ 40 patients per dose group). The primary endpoint, E/Ea, (reflecting change in PCWP or left ventricle filling pressure) measured by echocardiography utilizing a single, central core laboratory, was significantly ($p<0.05$) improved by both doses of istaroxime. Stroke volume was substantially increased as well. There were no signs of increased risk for arrhythmias or increased troponin levels (a marker of heart muscle damage) during or after istaroxime infusion. Additionally, blood pressure tended to increase, and heart rate decrease, during the infusion. The most common adverse events were vomiting (2.4% and 25%) and infusion site pain (32% and 30%) in the 0.5 and 1.0 µg/kg/min groups, respectively. This study confirmed the physiologic improvements seen in the phase 2a study and replicates the effects of istaroxime in ADHF.

Focus for 2019 – Regulatory meetings and Clinical Development Plan

In 2019, we plan to work with top heart failure experts to review the program and engage with the FDA and regulators in the EU to determine next steps in clinical development for this potential novel therapy for ADHF.

Other

Istaroxime is manufactured for us by Zhaoke Pharmaceutical (Guangzhou) Co., Ltd. and/or Sigma Tau S.pA. Secondary packaging by DEPO PACK s.n.c.

The API used in production of the drug product is manufactured by Farmabios S.p.A. and / or ScinoPharm Taiwan, Ltd.

AEROSURF

Overview

One of our lead development programs is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that we are developing to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. 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 US are animal-derived and are generally administered using invasive endotracheal intubation, frequently with mechanical ventilation, procedures that may result in serious respiratory conditions and other complications. AEROSURF is designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary ADS technology and potentially may meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, has the potential to reduce the number of premature infants who are subjected to invasive surfactant administration, and potentially provide transformative clinical and pharmacoeconomic benefits. The FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

We have filed an investigational new drug application (IND) with the FDA for AEROSURF for the treatment of RDS in premature infants and have completed three AEROSURF phase 2 clinical trials. All three clinical trials assessed the safety and tolerability of AEROSURF and suggested evidence of a beneficial treatment effect when the treatment is delivered as intended.

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 US, Canada, Europe and Latin America.

In this phase 2b clinical trial, 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, in accordance with the predesignated statistical plan, 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.

Bronchopulmonary Dysplasia (BPD) is a chronic lung disease of premature infants who have required intubation, mechanical ventilation and oxygen therapy. BPD is associated with ongoing pulmonary disease and neurodevelopmental impairment that contributes to substantial patient morbidity. This is associated with increased health care utilization and higher healthcare costs. Notwithstanding, effective prevention and treatment strategies for BPD have been elusive and there is no approved treatment. In the post hoc pooled analysis of the AEROSURF phase 2b clinical trial and phase 2a clinical trial in infants 26-28 weeks gestational age, AEROSURF treatment was associated with significantly lowered incidence and severity of BPD compared to infants on nCPAP alone. This effect was observed without excluding patients whose treatment was interrupted.

In 2018, we transitioned from our prototype 2 ADS used in the phase 2 clinical program (phase 2 ADS) to a newly-designed ADS for use in our phase 3 program (phase 3 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. We successfully concluded design verification activities through a detailed assessment of the phase 3 ADS design and implemented design changes to potentially mitigate the risks of device-related treatment interruptions experienced in the prototype phase 2 device used in the phase 2b clinical trial. We believe that the phase 3 ADS will be easier and faster to use and 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.

With respect to our ADS, we are currently engaged in a technology transfer of our device manufacturing process from Battelle Memorial Institute (Battelle) to Mack Molding Company (Mack), an FDA-registered medical device manufacturer that we have engaged to produce a new phase 3 ADS for use in our planned AEROSURF bridging study and potentially address the unexpected rate of treatment interruptions (we previously referred to this new version as the NextGen ADS). If AEROSURF is approved for marketing, we expect that the phase 3 ADS will also support our commercial market platform. We currently have a Memorandum of Understanding with Mack to cover this transfer.

Focus for 2019 – AEROSURF Bridging Study

We are planning to conduct an additional AEROSURF clinical bridging study that is designed among other things, to clinically evaluate the design and performance of our new phase 3 ADS. This trial will not be powered to establish statistical significance but will generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial. 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 an extended initial dose (consisting of two 50 minute-doses) with up to 3 repeat doses (each 50-minutes, 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 phase 3 ADS. We plan to conduct this trial in 15 to 25 of our previous phase 2b, higher-performing clinical sites. We anticipate that this trial will start late in the third quarter or early fourth quarter of 2019; however, we will require additional capital to be in a position to complete the trial in accordance with our development plan, (*see*, Item 1A – Risk Factors – Risks Related to Capital Resource Requirements).

Other

We have contracted with Clinical Supplies Management, Inc. for the receipt, labeling, packaging and distribution of drug and materials to support our planned AEROSURF bridging study.

Our lyophilized KL4 surfactant is manufactured for us by 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 which will be completed during the manufacture of drug product to complete the planned phase 3 clinical program.

In our Warrington laboratory we conduct certain analytical and quality control activities including release testing of all API's and release and stability testing of our lyophilized and aerosolized KL4 surfactant drug product. 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.

KL4 surfactant is comprised of four active pharmaceutical ingredients (API's). Our API suppliers are Bachem Americas, Inc., Corden Pharma and Avanti Polar Lipids, Inc. We have supply agreements for KL4 and POPG and source the other two under purchase orders. With respect to KL4, we received a notice of nonrenewal from Bachem in connection with an expiration date in June 2019. We are working to develop a new manufacturing process and will select a successor based on request-for-proposal submissions. To provide a sufficient supply of KL4 to support our AEROSURF development plan through the planned phase 3 clinical program, we are manufacturing an inventory of KL4 with Bachem.

Lyophilized KL4 Surfactant – Other Studies

We are assessing potential development pathways to secure marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant is the drug product component of AEROSURF and a lyophilized (freeze-dried) dosage form of the liquid KL4 surfactant intratracheal instillate (SURFAXIN®) that was approved by the FDA in 2012. In April 2015, we voluntarily ceased commercializing SURFAXIN to focus our resources on the development of aerosolized KL4 surfactant for respiratory diseases, beginning with AEROSURF.

Our KL4 surfactant can be lyophilized (freeze-dried) and reconstituted to a liquid just prior to administration. We currently maintain continuous cold chain storage for this product. 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 previously discussed with the FDA a potential development plan, trial design and regulatory plan for approval and plan potentially to re-engage with the FDA in the second half of 2019. If we can define an acceptable development program that is achievable from a cost, timing and resource perspective, we may seek approval to treat premature infants who, because they are unable to breathe on their own or other reason, are not candidates for AEROSURF.

In addition, on March 12, 2018, we announced a collaboration with Eleison Pharmaceuticals, Inc., a specialty pharmaceutical company developing life-saving therapeutics for rare cancers, to assess the feasibility of using our ADS potentially to deliver Eleison's inhaled lipid cisplatin (ILC), potentially in combination with our KL4 surfactant. Eleison is developing ILC for non-small cell lung cancer (NSCLC) and completed a phase II study of ILC in patients with bone cancer (osteosarcoma) metastatic to the lung.

We believe our lyophilized KL4 surfactant and ADS technologies 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).

Rostafuroxin

Overview

Rostafuroxin is a novel investigational drug product candidate that is designed to be a selective antagonist of adducin polymorphisms and endogenous ouabain, both known triggers of hypertension, and creates functional effects by enhancing renal tubular sodium reabsorption and increasing vascular tone. Rostafuroxin targets resistant hypertensive patients with a specific genetic profile, which is found in approximately 20% – 25% of the adult hypertensive population. Based on the preclinical and clinical studies performed to date, we believe that rostafuroxin may reduce or normalize blood pressure in this genetically identified subset of patients and may reduce the risk of hypertension-related sequelae beyond the level normally associated with the absolute reduction of blood pressure, per se, because the molecular mechanism blocked by rostafuroxin may also be involved in organ damage.

CVie Therapeutics conducted three phase 2 clinical trials assessing reduction in blood pressure when rostafuroxin is administered in a hypertensive population selected in accordance with a specified genetic profile. A phase 2b clinical trial was conducted as a two-part study with the first part conducted in Italy with Caucasian patients and the second part conducted in Taiwan with ethnic Chinese patients. The efficacy results in Italy were positive in both this trial and in an earlier phase 2a clinical trial; however, the blood pressure response in Chinese patients in the second part of the phase 2b study was minimal.

We are analyzing the results of these clinical trials potentially to identify the reasons for the limited response in Chinese patients, including with respect to potential differences between the populations in drug metabolism, bioavailability or drug interaction with traditional Chinese medicines that the patients may have been taking to manage their hypertension.

Focus for 2019

In 2019, we plan to focus on finalizing the drug formulation and defining drug product analytical methods supporting release and stability measures and assessments. Once we have developed a product profile, we plan to seek opportunities to out-license rostafuroxin to a larger company that has interest in and/or operates in the very large and broad antihypertension market.

Other

The drug product for rostafuroxin is manufactured by Doppel Farmaceutici S.r.l. The API used in the manufacture of rostafuroxin is manufactured by China Gateway Pharmaceutical Development Co., Ltd.

ACQUISITION OF CVIE THERAPEUTICS AND PRIVATE PLACEMENT FINANCING

CVie Acquisition

On December 21, 2018, we entered into an Agreement and Plan of Merger (CVie Acquisition) with, and thereby acquired, CVie Investments Limited (CVie Investments), an exempted company with limited liability incorporated under the laws of the Cayman Islands. Under the terms of the Acquisition Agreement, we issued shares of our common stock, par value $0.001 per share (common stock) to CVie Investments' former shareholders, at an exchange ratio of 0.3512 share of common stock for each share of CVie Investments outstanding prior to the merger, resulting in the issuance of 16,265,060 shares of common stock being issued in exchange for the shares of CVie Investments. The merger closed on December 21, 2018.

In connection with the CVie Acquisition, we entered into an indemnity agreement with Lee's Pharmaceutical Holdings Limited (Lee's), pursuant to which Lee's agreed to indemnify our shareholders and holders of certain warrants of record on December 20, 2018 (the Indemnitees) for one year for any loss, liability, damage or expense incurred by us in connection with or, as a result of, any material inaccuracy in any representation or warranty made by CVie Therapeutics in the Acquisition Agreement. To secure its performance under the indemnity agreement, 984,000 shares of common stock issued to a Lee's affiliate in the merger were placed in escrow with our transfer agent. A portion of the escrowed shares will be transferred to the Indemnitees as the sole and exclusive remedy for a successful indemnity claim.

Since the closing, we have operated CVie Investments, and its wholly-owned subsidiary, CVie Therapeutics Ltd., (CVie Therapeutics) a Taiwan corporation organized under the laws of the Republic of China, as a business division (the entities may be collectively referred to in this Form 10-K as CVie) focused on early development of drug product candidates for cardiovascular diseases. We undertook the merger as part of a strategic initiative to create stockholder value that resulted from a multi-year process focused on identifying strategic opportunities, including potential strategic alliances, collaborations (primarily outside the United States (US)), joint development opportunities, acquisitions, technology licensing arrangements, as well as potential combinations (including by merger or acquisition) or other corporate transactions. In connection with the merger, we declared a dividend to the holders of record of outstanding shares of common stock, and holders of certain warrants to purchase common stock, that were outstanding on December 20, 2018 of 0.6148 Series H AEROSURF Warrant, for each share of common stock held by a shareholder or each warrant held by a warrant holder, as applicable, on the record date (the AEROSURF Warrants). We distributed AEROSURF Warrants that are exercisable for an aggregate of approximately 2.96 million shares of common stock. Each AEROSURF Warrant has a term of five years and provides for automatic exercise into one share of common stock, without any exercise price, upon our public announcement of the dosing of the first human subject enrolled in a phase 3 clinical trial for AEROSURF.

Private Placement Financing

On December 21, 2018, we also completed a private placement offering with select institutional investors (Investors) for the purchase of an aggregate of 11,785,540 shares of common stock at a price per share of $3.3132, for an aggregate purchase price of approximately $39.0 million (Private Placement Financing). Included in the purchase price, each of LPH II Investments Limited (LPH II), an affiliate of Lee's, and Battelle Memorial Institute converted $6.0 million and $1.0 million, respectively, of existing debt obligations on the same terms as the other Investors. In connection with this financing, we issued (i) Series F Warrants to purchase an aggregate of 2,003,541 shares of common stock, at an exercise price equal to $3.68 per share, which are exercisable through the 18-month anniversary of the date of issuance (the Series F Warrants), and (ii) Series G Warrants to purchase an aggregate of 3,889,229 shares of common stock, at an exercise price equal to $4.05 per share, which are exercisable through the 5-year anniversary of the date of issuance (the Series G Warrants and, together with the Series F Warrants, the December 2018 Warrants). The December 2018 Warrants (i) may not be exercised to the extent that, following such exercise, the holder would beneficially own more than 9.99% (or other percent as designated by each holder) of our outstanding shares of common stock, and (ii) otherwise contain customary provisions that adjust the exercise price and the number of shares of common stock into which they may be exercised in the event of a corporate transaction.

LEE'S PHARMACEUTICAL HOLDINGS LIMITED AND AFFILIATES

During the period of this report, we have received substantial support from Lees, our largest shareholder. Lee's is a company incorporated in the Cayman Islands with limited liability, whose common stock is listed on the Hong Kong Stock Exchange, and which along with its affiliates currently owns approximately 40% of our issued and outstanding common stock.

In February 2017, Lee's invested $2.0 million in our $10.5 million private placement offering of Series A Convertible Preferred Stock Units at a purchase price per unit of $1,495 per unit. In June 2017, we entered into an exclusive License Agreement with an affiliate of Lee's for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets (*see*, – Licensing, Patents, and Other Proprietary Rights and Regulatory Designations – Licensing – Lee's Pharmaceutical (HK) Ltd.

In October 27, 2017, LPH Investments Limited, an affiliate of Lee's, purchased $10 million of our common stock, resulting in Lee's controlling a 73% interest in our common stock (this transaction included cancellation of $3.9 million in loans advanced by Lee's (HK) to sustain our operations while we negotiated the purchase agreement). In April 2018, LPH II Investments Limited purchased $2.6 million of our common stock and warrants at a purchase price of $4.80.

Throughout the period of this report, Lee's also supported our development activities and operations with loans made through certain subsidiaries as follow: August 2017, $3.9 million loaned by Lee's (HK); January and March 2018, $1.5 million and $1 million, respectively, loaned by LPH; on August 14, August 29, September 12, September 27, October 19, November 2, and November 19, 2018, $0.3 million, $0.48 million, $0.5 million, $0.5 million, $0.43 million, $0.5 million, and $0.35 million, respectively, loaned by LPH; and on December 5, 2018, $.6 million, loaned by LPH II, to support our development activities and operations while we pursued our potential strategic transaction with CVie Therapeutics. The loans accrued interest at a rate per annum of 6% and were collateralized by a security interest in substantially all our assets under a March 2018 Security Agreement.

During 2018, we engaged in active diligence and discussions with CVie Therapeutics Limited, a Taiwan corporation organized under the laws of the Republic of China, to potentially conclude a strategic transaction. At that time, Lee's owned approximately 49% of the outstanding capital stock of CVie Therapeutics, but because of the potential conflict of interest, did not participate in the negotiations and agreed to be bound by the terms otherwise reached between ourselves and CVie Therapeutics, which was represented by James Huang, an independent director. To facilitate the transaction, Lee's committed to maintain in place collateral previously pledged to secure CVie's O-Bank loan and agreed to provide the indemnity agreement to protect our shareholders and holders of certain warrants, as discussed above.

We plan to continue to partner with Lee's and look forward to the development of our KL4 surfactant products in the Asian market under our license agreement and, in the future, potentially other of our product candidates. However, we have no written commitments from Lee's for future transactions and there can be no assurance that Lee's will continue to work with us in the future.

STRATEGIC ALLIANCES AND COLLABORATION ARRANGEMENTS

Battelle Collaboration Agreement

In October 2014, we entered into a Collaboration Agreement with Battelle for the development of our phase 3 ADS. We had previously worked with Battelle, which has expertise in developing and integrating aerosol devices using innovative and advanced technologies, in connection with development of our prototype phase 2 ADS used in the AEROSURF phase 2b clinical trial. Under the Collaboration Agreement, we and Battelle shared the costs of development for a three-stage development plan that included (i) defining the requirements and a detailed project plan for a phase 3 ADS, (ii) executing the project plan, and (iii) completing required testing, verification and documentation, putting us in a position to manufacture a phase 3 ADS for use in the remaining AEROSURF development activities and, if approved, the initial commercial activities. We retained final decision-making authority over all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of the phase 3 ADS. We and Battelle shared equally the costs of the first stage and the planned costs of the remaining two stages. 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. We also agreed that, if Battelle successfully completed the project plan in a timely manner, we would 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, which under the Battelle Payment Restructuring (discussed below) was increased to $35 million. The Collaboration Agreement will end at the time we fulfill our payment obligations to Battelle, unless sooner terminated by a party as provided therein.

In December 2018, we and Battelle entered into a Payment Restructuring Agreement (Battelle Payment Restructuring), which reflected the terms of an October 2017 nonbinding memorandum of understanding, in which we outlined terms to restructure approximately $4.3 million then due to Battelle (at October 18, 2017, the Battelle Payables), under a Research and Development Services Agreement dated as of June 22, 2012 and the Collaboration Agreement. Under the Battelle Payment Restructuring, Battelle Payables accrue interest at a rate of 6% per annum and Battelle participated in our December 2018 private placement equity financing (Private Placement Financing, discussed below) for $1.0 million in a debt-equity exchange for a like amount of Battelle Payables on the same terms as all other investors in the Private Placement Financing. In addition, within 10 days after the Private Placement Financing, or December 31. 2018, we paid Battelle cash in the amount of $972,281, and thereafter initiated payments totaling an aggregate $1,250,000, payable in five equal, consecutive monthly installments of $250,000. In addition, we have agreed to make two milestone payments to Battelle as follow: (i)

upon enrollment of the first patient in the next AEROSURF clinical study, an amount equal to one half of the then-outstanding Battelle Payables (including unpaid interest), and (ii) when we complete the device technology transfer for the phase 3 ADS to Mack, an amount equal to the then-outstanding Battelle Payables, including unpaid interest. In addition, on December 11, 2018, we issued to Battelle warrants to purchase 75,000 shares of common stock, exercisable at a price of $6.50 per share, which expire on the fifth anniversary of the Effective Date.

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 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 $0.5 million upon the initial filing for regulatory approval with the European Medicines Agency and $0.5 million 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).

Università degli Studi di Milano-Bicocca

Effective April 13, 2015, CVie Therapeutics entered into an Agreement for Scientific Collaboration (Agreement) with the Università degli Studi di Milano-Bicocca (Bicocca) in Milan, Italy, focused on defining the role of sarco (endo) plasmic reticulum Ca2+ -ATPase 2a (SERCA2a) and phospholamban (PLN) in modulating cardiac contraction, and discovering new small molecules to modulate SERCA2a activity or new drugs for treating chronic and acute human heart failure. The initial term of the Agreement was three years but the term was extended for approximately an additional year, with option for further renewal. We are currently in discussions potentially to extend this Agreement, although there can be no assurance that we will be able to achieve an extension on acceptable terms, if at all.

Under the Agreement, intellectual property resulting from the collaboration, including patents and know-how, will be jointly owned by the parties. For the development of any new SERCA2a compounds and diagnostic products suitable for further clinical development, we have the option to purchase Bicocca's interest for up to 12 months after the filing of a patent application. If the option is not exercised, then the parties shall remain joint owners and each can use the intellectual property with consent of the other on terms to be defined. If we exercise an option, we have agreed to pay Bicocca (corresponding to stage of development): (i) € 0.1 million (approximately $0.1 million) upon completion and the proof of concept of biological efficacy for new compounds modulating the SERCA2a activity caused by PLN mutations; and (ii) € 1.5 million (approximately $1.7 million) upon obtaining marketing authorization in the US, EU, or China of new compounds with the corresponding companion diagnostic assay. We have also agreed to pay royalties for any purchased intellectual property arising out of the collaboration in the range of a low- to mid-single digit percent of net sales for any products sold in any country for a period of ten years from the date of the first commercial sale.

Also, under the Agreement, we have provided funds aggregating € 0.2 million (approximately $0.2 million) to date to upgrade equipment and pay laboratory expenses for the renewal term expiring in 2019. We also funded several related research contracts for the period covered by the Agreement. In connection with our research activities, Bicocca agreed to provide us exclusive use of a research laboratory for the collaboration work, and nonexclusive access to a physiology laboratory within the university. Bicocca serves as our primary location in Milan.

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 cardiovascular agents including istaroxime, rostafuroxin and potential follow-on compounds, (ii) by protecting our exclusive rights in our lyophilized KL4 surfactant, ADS and aerosol-conducting airway connector technologies through patents that we own or exclusively license, (iii) by seeking regulatory exclusivities, including potential orphan drug and new drug product exclusivities, and (iv) through protecting our trade secrets and proprietary methodologies that support our manufacturing and analytical processes.

Licensing

Lee's Pharmaceutical (HK) Ltd.

In June 2017, we entered into a License, Development and Commercialization Agreement (License Agreement) with Lee's (HK), a company organized under the laws of Hong Kong 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 the FDA in 2012 for 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.

We amended the license in August 2017 to expand certain of Lee's (HK)'s 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.

Under the License Agreement as amended, Lee's (HK) made an upfront payment to us of $1 million. We also may receive up to $35.8 million 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.

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) is 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). Sublicensee rights under the License Agreement do not include the right to further sublicense. In addition, we and Lee's (HK) entered into a technology transfer agreement under which we are transferring 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

In addition to the inventions covered by the patents and patent applications described in this Form 10-K, we have been active in identifying and seeking to identify new patents. We have filed and plan to file patent and provisional patent applications to protect our innovations relating to our current and potential future product candidates, including for composition of matter, new dosage forms, formulations, methods of manufacture, methods of use and related processes. We intend to file for patent protection for select inventions, in such markets that we deem material to our patent strategy, as well as for other new inventions that we may identify.

CVie Therapeutics Patents

CVie Therapeutics holds a patent portfolio of four patent families that include over 100 patents and patent filings directed to compounds, pharmaceutical formulations, methods of manufacturing, methods of delivery, and treatment methods using derivatives of rostafuroxin for the treatment of cardiovascular diseases and related conditions. We plan to continue these patent activities and plan focus on new follow-on compounds, dosage forms, formulations, and treatment methods related to acute heart failure and persistent hypertension. At this time, the patents originally covering istaroxime composition of matter have expired. To benefit from potential non-patent exclusivity within the US, we believe that we may qualify istaroxime as a new chemical entity entitled to market exclusivity for a period of years. *See*, – Government Regulation – Drug Products – The Hatch-Waxman Act – Market Exclusivity.

Rostafuroxin-Related Patents

In November 2006, international patent application PCT/EP2006/068845 was filed and directed to methods of preparing crystalline forms of rostafuroxin. The international patent application entered into the national phase in both the European Patent Office (EP06819722.7, now European Patent No. 1951738 B1) and the US (US 12/094,885, now US Patent No. 9,127,037). US Patent No. 9,127,037 will expire on January 30, 2031, and European Patent No. 1951738 B1 will expire on November 23, 2026.

In June 2008, international patent application PCT/EP2008/056928 was filed and directed to rostafuroxin derivatives useful for the prevention or treatment of restenosis after angioplasty or endarterectomy as well as diseases resulting from organ fibrosis. The international application entered into the national phase in the US, European Patent Office, and several other foreign jurisdictions. In this patent family, multiple foreign counterparts are pending or granted. US Patent Application No. 12/602,827 was abandoned following an unsuccessful appeal of a decision of the US Patent Office examiner. European Patent No. 2160190B1 will expire on June 4, 2028.

In March 2010, international patent application PCT/EP2010/053571 was filed and directed to rostafuroxin derivatives for the treatment of proteinuria, glomerulosclerosis, and renal failure. The international patent application entered into the national phase in the European Patent Office (EP10709529.1, now European Patent No. 2411015B1), US, and multiple other foreign nations. US Patent Application No. 13/258,728 was abandoned on June 2, 2016 in favor of child application US 14/931,083, now US Patent No. 9,868,757. US Patent No. 9,868,757 and European Patent No. 2411015B1 will expire on March 18, 2030.

In October 2010, international patent application PCT/EP2010/065589 was filed covering methods of rostafuroxin administration for the treatment or prevention of cardiovascular conditions in individuals with various single nucleotide polymorphisms (SNPs) associated with improved therapeutic response to rostafuroxin administration. The international patent application entered into the national phase in the European Patent Office (EP10807525.0, now European Patent No. 2490694B1), US (US 13/502,518, now US Patent No. 9,408,854), and multiple other foreign nations. US Patent No. 9,408,854 and European Patent No. 2490694B1 will expire on October 18, 2030.

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) (J&J Patents). All J&J Patents have expired. Under the license agreement, we are obligated to pay the licensors fees of up to $3.0 million 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 $1.0 milliom 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 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. 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 US 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 US and International patent applications (US 11/326,885 which is now US 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. US Patent No 7,541,331 will expire on January 6, 2026. European Patent No. 1841458B1 was revoked on December 11, 2018, following an unsuccessful appeal of a decision of the European Patent Office Opposition Division.

In September 2007, we filed US and International patent applications (US 11/901,866 which is now US 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. US 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 US and EPO) directed to lyophilized pulmonary surfactant and methods of manufacture. In this patent family, two US Patents Nos. 8,748,396 and 8,748,397 were issued on June 10, 2014, European patent 2723323B1 issued on September 23, 2015, another US Patent No. 9,554,999 B2 issued on January 31, 2017 and multiple foreign counterparts are pending or granted. US 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 US (US License Agreement), and, as PMUSA had assigned its ex-US 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 US (together with the US 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 phase 3 ADS potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. Our ADS technology and our phase 3 ADS version are prootected 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.

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, US Patent No. 8,701,658 was issued on April 22, 2014, European patent No. 2265309 was issued on December 16, 2015, US Patent No. 9,352,114 was issued on May 31, 2016, US Patent No. 9,592,361 was issued on March 14, 2017 and several foreign patents have issued during 2011 through 2017. US Patent No. 8,701,658 and US Patent No. 9,352,114 will expire on March 17, 2029. US Patent No. 9,592,361 will expire on September 9, 2033. European Patent No. 2265309 will expire on March 17, 2029.

Trademarks

AEROSURF®, AFECTAIR®, DiscoveryLabs®, DISCOVERYLABS INSPIRED INNOVATION (logo)®, SURFAXIN®, SURFAXIN LS™, 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 the 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

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. *See*, – Government Regulation – Drug Products – Orphan Drugs.

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 US, 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

The FDA has 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) our KL4 surfactant for the treatment of RDS. We believe that other of our products may qualify for Fast Track or Breakthrough Therapy designation or other expedited programs. 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. *See*, – Government Regulation – Drug Products – Fast Track Designation.

COMPETITION

The biotechnology industry is a highly competitive industry. As we work to gain marketing authorization for our product candidates, competition from numerous existing pharmaceutical companies and other companies entering our fields is expected to be intense and expected to increase. In fact, our future competitors are competing with us currently to secure access to development resources, including clinical sites and their patients to advance development programs. We expect that those companies that are successful at being the first to introduce new products and technologies to the market may gain significant advantages over their competitors in the establishment of a customer base and track record for the performance of their products and technologies. Moreover, there are also existing therapies that may compete with the products we are developing. Therefore, as a development stage biotechnology company, our competitors are comprised of other biotechnology firms and pharmaceutical companies that have existing products or are developing products for our primary markets -- respiratory and cardiovascular indications.

GOVERNMENT REGULATION

In the US, drug products, medical devices, and drug/device combination products are subject to extensive regulation by the US 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 US 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 US. 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 US typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which the FDA approval is sought. Satisfaction of the FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

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

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

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

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the 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 the 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 the 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 the FDA. The FDA approval of the NDA is required before marketing of the product may begin in the US. 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 $2,588,000 for fiscal year 2019, and the applicant under an approved new drug application is also subject to an annual program fee, currently exceeding $309,000 per product for fiscal year 2019, which replaced the annual product and establishment fees. These fees are typically increased annually.

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

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee - typically a panel that includes clinicians and other experts - for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The 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 the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

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

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

Orphan Drugs

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

The 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 the 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. The 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 the FDA. In addition, the 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 the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the 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 the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The Hatch-Waxman Act

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

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

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

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

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

Patent Term Extension: After NDA approval, the owner of a relevant drug patent may apply for up to 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 the 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 US 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, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

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

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. the FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted 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 the 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 the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the 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 US 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 the 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 US manufacturers of export-only devices, are required to register their establishments with the FDA and provide the 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 US only if the FDA has: (i) approved a premarket approval application, or PMA, prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because the FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market for certain 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 the FDA has exempted by regulation, a premarket notification is not required before marketing the device in the US. Manufacturers of such devices are required to register their establishments and list the proprietary device name and the generic category or classification regulation into which the device fits. Some 510(k)-exempt devices are also exempt from Quality System Regulation, or QSR, requirements.

Post-market Requirements

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

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

Combination Products

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

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

International Approvals

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

Anti-Kickback, False Claims Laws

In addition to the 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.

Other Federal and State Regulatory Requirements

Pursuant to PPACA, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reports must be submitted on an annual basis and the reported data are posted in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Additional jurisdictions, such as the City of Chicago and the District of Columbia, require pharmaceutical sales representatives to be licensed and meet continuing education requirements. Several additional states are considering similar proposals. Compliance with these laws is difficult and time-consuming, and companies that do not comply with these state laws face civil penalties.

EMPLOYEES

As of April 5, we have 33 employees, including 32 full-time employees.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy or stockholder information statements and other information with the Securities and Exchange Commission (SEC). 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 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 5, 2019, we believe that we have sufficient capital to fund our research and development programs, support our business operations and satisfy existing obligations on a timely basis through October 2019. 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, 2018, we had cash and cash equivalents of $11.2 million and available-for-sale, marketable securities of $13.9 million, current liabilities of $20.6 million, including $8.0 million of Loan payable. Although we believe that the December 2018 merger with CVie and $39 million Private Placement Financing has improved our financial position and may better position us to raise the capital needed to fund our business plans, we expect to continue to incur significant losses and require significant additional capital to advance our istaroxime and AEROSURF® clinical development programs, support our operations and business development efforts, and satisfy existing obligations. As of April 5, 2019, we believe that we will have sufficient resources (including marketable securities) to support our development activities and business operations through October 2019.

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 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. 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.

Our existing and future debt obligations could impair our liquidity and financial condition, and if we are unable to meet our debt obligations, including with respect to any collateral requirements, the lenders could foreclose on our assets or seek a judgment against us and execute against our assets.

We currently have loans in the amount of $3.5 million from an affiliate of Lee's, which is payable on various dates through November 2019, and $4.5 million from O-Bank Co., Ltd in Taiwan that is secured by a pledge of collateral from an affiliate of Lee's. We do not have a written agreement requiring Lee's to maintain the collateral for the term of the loan.

Our debt obligations:

- could impair our liquidity;
- could make it more difficult for us to satisfy our other obligations;
- require us to dedicate cash flow to payments on our debt, 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 US 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 pay our obligations, fail to comply with any covenants contained in any related agreements, including the collateral maintenance agreement under the O-Bank loan, or if Lee's withdraws its pledge of collateral to secure the O-Bank loan, we could be in default regarding that indebtedness and the lender could accelerate payment of the outstanding indebtedness. Moreover, in the future, to secure our obligations under any loans, we may be required to grant to the lender a security interest in some or substantially all of our assets.

We will continue to require significant additional capital to support our research and development activities and operations, and our ability to raise such capital may be impacted by factors impairing or blocking our access to the capital markets at a time when we would like or require, and that would result in an increased cost of capital. Moreover, any equity financings that we undertake could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

Until we are in a position where revenues from commercialization of our product candidates are sufficient to offset our cash requirements, we will continue to require significant additional infusions of capital to execute our business strategy. For the next several years, we do not expect that any of our products will be approved or that we will receive revenues from the sale of approved products, and our cash outflows for development programs, operations and debt service are likely to far outpace the rate at which we may generate revenues and other cash inflows from all available sources.

We 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 without limitation the planned timing and outcomes of our clinical activities, our debt obligations, our status as a smaller reporting company under the SEC regulations, our delisting from The Nasdaq Capital Market in May 2017 and subsequent transfer to the OTC Markets Group Inc.'s OTCQB® market, 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, 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 in a liquidation. No assurance can be given as to the amount of assets, if any, that would be available for common stockholders in the event of a liquidation.

In liquidation, the rights of equity security holders like our common stockholders are subordinate to holders of our debt obligations. 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 US or foreign regulatory policy during the period of product development;
- changes in the US 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 US 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.

We will require significant additional capital to support our research and development activities and operations and may not have sufficient cash resources in the future to pay our vendors, service providers and pay other business expenses. 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.

We have from time to time experienced periods in which our cash resources have been constrained. As such, it is our practice to routinely closely monitor and control our cash resources to assure that investment and spending decisions advance our corporate objectives at any time. To manage our cash, we tightly control purchasing and retention of consultants, closely monitor the release of funds and may defer payment on invoices to conserve cash. This practice of conserving cash may adversely impact our relationships with key vendors and service providers and the pace at which we are able to advance our programs. While we are working closely with our vendors and service providers to preserve our key relationships, there can be no assurance that we will be successful and that our vendor and service providers will continue to work with us, particularly during a period of constrained cash resources. Failure to retain such key relationships could have a material adverse effect on our development activities and our business and operations.

We have a significant amount of intangible assets, including goodwill, recorded on our balance sheet, related to our acquisition of CVie Therapeutics, which may lead to potentially significant impairment charges.

We review long-lived assets, including intangible assets and goodwill, for impairment whenever events or changes in estimates and circumstances indicate that the related carrying amounts may not be recoverable based on the existence of certain triggering events. Intangible assets and goodwill are also subject to an impairment assessment at least annually. The amount of identifiable intangible assets and goodwill in our consolidated balance sheet has increased significantly because of the acquisition of CVie Therapeutics. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development of istaroxime and rostafuroxin. At December 31, 2018, intangible assets and goodwill recorded on our consolidated balance sheet was $77.1 million and $15.7 million, respectively.

If long-lived assets are determined to be impaired in the future, we would be required to record a potentially significant write-off, which would have an adverse effect on our results of operations and financial condition.

Risks Related to our Development Activities

Our clinical development programs involve risks and uncertainties that are inherent in clinical development. Our clinical trials may be delayed, or fail, which will harm our business prospects.

To gain marketing authorization for our product candidates, we will need to successfully complete our clinical trials, including pivotal phase 3 clinical development programs. Such development programs generally take years to complete and may be delayed by a number of factors. We may not reach agreement with the US 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 all markets of interest. Conditions imposed by the FDA and foreign regulators on our clinical development program could significantly increase the time required to complete, and the costs of conducting, and the risks associated with clinical trials. For example, we may not be able to design a study that is acceptable to both the FDA and EMA regulators, which would cause us to limit the scope of our geographical activities or greatly increase our investment. Additionally, we may seek to conduct development activities in competitive clinical locations and therapeutic areas, or design clinical trials with complex requirements, which could adversely affect the rate of enrollment, and our ability to complete our development activities may be impaired and, in turn, require more time and money. 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. Any delay in the results from our clinical trials could force us to make unplanned changes to our clinical trial plan, 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 (or premature infants' 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.

Additional risks and uncertainties inherent in the clinical development process include:

- the ability to design a clinical trial that will assure demonstration of improved efficacy over that of a comparator in the primary endpoint of a trial and demonstration of an adequate safety profile;
- the ability of third-party clinical trial consultants and third-party contract research organizations (CROs) to successfully carry out their activities or meet expected deadlines;
- our ability to adequately manage the design, execution and regulatory aspects of our complex and diverse clinical trials;

- the ability of third-party clinical supply organizations (CSO) to timely perform their obligations 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 US and international sites;
- our ability to successfully develop and manufacture our APIs, drug products, medical devices and product candidates in a manner that ensures that they will perform as intended;
- the risk that our clinical trials may be interrupted, delayed or halted because of health and safety concerns (such as patient side effects) or because of matters related to the design of the study or drug availability; and
- the risk that clinical trial design and size is inadequate to assure demonstration of efficacy and meet statistical significance in outcomes, due to variation between clinicians, medical sites and countries in medical practices and procedures associated with treating our targeted diseases.

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 KL4 surfactant. If our phase 3 ADS should fail to perform as designed in our phase 3 clinical program, such failures could adversely affect the results of our clinical development program.

In addition, if for any reason, we abandon or materially limit, geographically or otherwise, our development plans related to drug product candidates, including istaroxime or rostafuroxin, such actions may result in impairment of any related intangible asset and goodwill recorded on our balance sheet, which could have a material adverse effect on our results of operations and financial condition.

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 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.

No assurance can be given 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, other factors or, in the case of AEROSURF, features of the ADS used. We are currently planning to conduct an AEROSURF bridging study to transition in the clinic from the ADS used in the phase 2 clinical program to the phase 3 ADS. 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 our products.

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.

We may conduct clinical development in the US, Canada, the EU, Latin America, and Asia Pacific regions and sell our products in the US 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.

Even if favorable data are generated from nonclinical and clinical studies, 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:

- a regulatory body may disagree with the design or implementation of one or more clinical trials;
- a regulatory body 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;
- a regulatory body 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;
- a regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties;
- a regulatory body may not deem the data collected from clinical trials to be sufficient to support the submission of an NDA or other applicable regulatory filing;
- a regulatory body may require additional preclinical studies or clinical trials;
- a regulatory body may identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- a regulatory body may grant approval contingent on the performance of costly additional post-approval clinical trials;
- a regulatory body also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- a regulatory body may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- a regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or
- a regulatory body 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 obtain marketing approval in the US based on our product dossier, but not obtain approvals from regulatory authorities outside the US 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. 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 outside the US, 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 or analysis that compares the cost-effectiveness of their product candidate to other available therapies. Such trials or other evidence gathering 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 US or the EU, we could be adversely affected. Moreover, failure to secure marketing authorization for any product candidate, including istaroxime and rostafuroxin, in accordance with our development plans, may result in an impairment of any related intangible asset and goodwill recorded on our balance sheet, which could have a material adverse effect on our results of operations and financial condition.

Failure of our phase 3 ADS to perform as intended for our AEROSURF phase 3 development activities and, if approved, initial commercial activities, 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.

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

- the phase 3 ADS that is intended for use in our remaining AEROSURF development activities, may not achieve acceptable 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 have been working with Battelle on certain development initiatives. We currently are working with Mack Molding Company (Mack) to complete a technology transfer of our device manufacturing process and expect to manufacture with Mack a sufficient number of ADS to support our remaining development activities. 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 phase 3 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 AEROSURF development program and 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.

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

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. 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, which generally prevents the FDA from approving an NDA to market a drug containing the same active moiety for the same indication for that period, 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 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. However, we may lose Orphan Drug exclusivity if the FDA determines that the request for designation was materially defective or if we are 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. 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 drug products 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 could potentially delay our research and development activities, as well as eventual regulatory approval and commercialization of our drug product candidates.

Our manufacturing strategy includes manufacturing our drug products 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 US 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, drug products, 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. Any such failure could result in product production and shipment delays or an inability to obtain materials or drug substance supplies.

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 our drug product candidates, we will depend upon third parties to manufacture our drug products and to manufacture and assemble our ADS for AEROSURF. If we are unable to identify and subsequently retain qualified manufacturers and assemblers, our ability to implement our plans for the further development of our product candidates and, if approved, commercialization of our therapies, will be adversely affected and could be severely impacted.

We plan to rely on CMOs to manufacture and assemble the ADS and all subcomponents to support any preclinical experiments, our ongoing and planned clinical trials and, if approved, commercial activities. We are working with Mack to produce our phase 3 ADS to support the remainder of our AEROSURF development activities and, if approved, early commercial supply. Although we expect that we will be able to produce and assemble the ADS for our future development activities with Mack as our CMO, there is a risk that our CMO will be unable to consistently manufacture and assemble the subcomponents of our ADS to our specified standards. In addition, the CMO may not be able to timely comply with 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 phase 3 ADS for use in our Phase 3 program, it will adversely affect our timeline for the development and, if approved, commercialization of AEROSURF.

Risks Related to our Business 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 development programs.

In particular, our planned clinical trials and search for potential strategic partnerships, collaboration arrangements and similar transactions have placed 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. 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

Failure to successfully combine the business of CVie with ours in the expected time frame or realize the expected benefits of such combination may adversely affect our future results.

The success of our acquisition of CVie Therapeutics will depend, in part, on our ability to successfully combine its business with ours. Our management may face significant challenges in consolidating the functions of CVie Therapeutics development programs with ours; integrating the technologies, organizations, procedures, policies and operations; and prioritizing the scientific and clinical programs and retaining key personnel. If we are unable to successfully integrate CVie Therapeutics' operations, the anticipated benefits of the acquisition may not be realized fully or at all, may require significant investment to achieve the benefits or may take longer to realize than expected. The integration process and other disruptions resulting from the acquisition may also disrupt each company's ongoing businesses and/or adversely affect our relationships with employees, regulators and others with whom we have business or other dealings.

The integration of our business with that of CVie Therapeutics may divert our internal resources and management's attention away from our operations.

Successful integration of CVie Therapeutics' operations, products and personnel may be complex, time consuming and place a significant burden on our management and internal resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business, financial condition, operating results and ability to evaluate strategic alliances and collaboration arrangements.

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, we will be exposed to additional risks.

To support our development programs and potentially the commercial introduction of our product candidates, 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, including for AEROSURF, our lyophilized KL4 surfactant technology and rostafuroxin, 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.

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 US. 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 US 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 our products are 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 US 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 US. 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.

Our international operations subject us to additional regulatory oversight in foreign jurisdictions., as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

We are subject to certain risks associated with having assets and operations located in foreign jurisdictions, including our operations in Italy and Taiwan. Our operations in Italy and Taiwan are subject to regulatory agencies, such as the Italian Ministry of Health and the Taiwan Food and Drug Administration. Our operations in foreign jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.

Other Risks Affecting our Business

Healthcare reform measures in the US as well as the general tightening of drug reimbursement pathways and levels of reimbursement globally are expected to add additional pressure to achieve financial expectations for approved products.

If approved, our products are expected to face increasing pricing and reimbursement pressures from payors globally. Such pressures can impair our ability to access patients in geographies or access certain types of patient – regardless of the breadth of our data or approved indications. Pressure from payors, particularly single source government payors and global price referencing, can result in companies being forced to give greater discounts and/or lower pricing than planned resulting in barriers to achieving financial forecasts or even justifying ongoing or additional investment in clinical development programs.

A small group of investors, including Lee's Pharmaceutical Holdings Limited, may be able to exercise significant influence over our business strategy and operations.

As of April 5, 2019, Lee's beneficially owns through its affiliates, approximately 40% of our issued and outstanding shares of common stock and fund affiliates of our Chairman, James Huang, own approximately 28% of our issued and outstanding common stock. These investors could exercise their voting power in a coordinated fashion to approve any matter requiring shareholder approval by written consent without a stockholder meeting. As a result, there is a risk that these investors could cause corporate actions to be approved even if their interests conflict with the interests of our other shareholders. This concentration of voting power could have the effect of deterring or preventing institutional investors interested in us or a change in control that might be beneficial to our other shareholders.

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.

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.

There is uncertainty and risk of noncompliance regarding the use of social media platforms by the biopharmaceutical industry. 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. 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. 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. 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. Such incidents could compromise our intellectual property, expose sensitive business information, cause interruptions in our operations, result in a material disruption of our operations, or require substantial expenditures of resources to remedy.

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.

Our headquarters facilities are located in Warrington, Pennsylvania. We also have a research laboratory in Milan, Italy (Bicocca) and preclinical activities in Taipei, Taiwan. We depend upon third-party manufacturers and laboratories, to manufacture our drug products, our AFECTAIR device and our ADS and perform important API and drug product release testing and stability work. If a catastrophic event occurred at our headquarters facility or our other facilities or the facilities of any of our third-party manufacturers and laboratories, the manufacture of those products would be delayed. 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.

The patent position of biotechnology companies 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 US 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. Certain of such patents related to lyophilized KL4 surfactant have issued in the US, Europe and elsewhere and will expire in March 2033. For our aerosolized KL4 surfactant, we hold worldwide exclusive licenses to our proprietary aerosol delivery systems (ADS) technology for use with pulmonary surfactants alone or in combination with other products for all respiratory diseases and in the US to other (non-surfactant) drugs to treat certain pediatric and adult respiratory indications in hospitals and other health care institutions. The ADS patents have expired or will expire on various dates beginning in May 2016 and ending as late as 2037. For patents related to our cardiovascular drug products owned by CVie Therapeutics are issued in the US, Europe and elsewhere have expired or will expire on various dates between 2026 and 2030.

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. Patent applications in most jurisdictions are not published until 18 months after filing. In certain cases, the USPTO keeps US patent applications confidential for the entire time 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. These agreements require us to make payments and satisfy performance obligations to maintain our rights. 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 development programs for our product candidates. 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. 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. 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.

Many of our competitors 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. 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.

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.

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.

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. 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.

Provisions of our Amended and Restated Certificate of Incorporation (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. 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. Our premises include corporate 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 active pharmaceutical ingredients (APIs) and supportive research for our lyophilized and aerosolized KL4 surfactant. We also maintain a medical device development laboratory that is used by our engineering team to conduct development activities for AEROSURF and our aerosol delivery technologies. In February 2018, we reduced the size of our premises from 30,506 square feet to 21,189 square feet of leased space, which lowered our base rent and security deposit under the related lease agreement. We also maintain a location in Taipei, Taiwan, the former headquarters of CVie Therapeutics, consisting of approximately 2200 square feet of office space, where we perform certain manufacturing development and preclinical activities related to our cardiovascular drug product candidates. We also have access to research laboratories in Milan, Italy under our collaboration agreement with Università degli Studi di Milano-Bicocca, which is expiring. We are in the process of discussing an extension of that arrangement. We believe our current facilities are adequate for our needs in 2019.

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 5, 2019, we had 65 holders of record of shares of our common stock, and there were 32,133,189 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, 2018. The prices set forth below are over-the-counter market quotations that may reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	2018		2017	
	High	Low	High	Low
Period:				
First Quarter	$ 5.81	$ 2.60	$ 36.98	$ 22.40
Second Quarter	$ 4.10	$ 2.56	$ 33.20	$ 4.80
Third Quarter	$ 4.35	$ 3.15	$ 7.00	$ 3.60
Fourth Quarter	$ 5.11	$ 2.53	$ 8.80	$ 3.00

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, 2018 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**
- **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 5 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, 2018 and 2017.
- **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 and medical device company focused on developing drug product candidates and medical device technologies to address acute pulmonary and cardiovascular diseases. Historically, our focus has been on the development of our proprietary KL4 surfactant technology and aerosol delivery system (ADS) technology for the treatment and / or prevention of premature infants with respiratory distress syndrome (RDS). Following our merger with CVie Investments Limited in December 2018 (CVie Acquisition), our four lead development programs are (1) istaroxime for treatment of acute decompensated heart failure (ADHF), (2) AEROSURF® (lucinactant for inhalation) for non-invasive delivery of our lyophilized KL4 surfactant to improve the management of RDS in premature infants, (3) lyophilized KL4 surfactant intratracheal suspension for RDS, and (4) rostafuroxin for genetically associated hypertension.

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business – Company Overview" in this Annual Report on Form 10-K, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development 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 US 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 5 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.

Business Combinations

We follow the acquisition method for an acquisition of a business where the purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values at the dates of acquisition. The excess costs of acquired businesses over the fair values of the assets acquired and liabilities assumed were recognized as goodwill. The valuations of the acquired assets and liabilities will impact the determination of future operating results. In addition to using management estimates and negotiated amounts, we used a variety of information sources to determine the estimated fair values of the assets and liabilities, including a third-party appraisal for the estimated value of identifiable intangible assets. The business and technical judgment of management and third-party experts was also used in determining the value of identifiable intangible assets.

Goodwill and Intangible Assets

We test goodwill for impairment annually and whenever events or circumstances make it more likely than not that impairment may have occurred, such as a significant adverse change in the business climate or a decision to sell or dispose of a significant business.

We test goodwill for impairment by either performing a qualitative evaluation or a two-step quantitative test. The qualitative evaluation is an assessment of factors, including reporting unit specific operating results as well as industry, market, and general economic conditions, to determine whether it is more likely than not that the fair values of reporting unit is less than its carrying amount, including goodwill. Depending on the factors specific to some or all of our reporting units, we may be required to perform a two-step quantitative test.

We test intangible assets with indefinite lives for impairment annually by either performing a qualitative evaluation or a two-step quantitative test. We perform this test whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable, and at a minimum, annually.

For the year-ended December 31, 2018 we performed a qualitative evaluation of both goodwill and intangible assets and did not record any impairment charge for 2018.

Revenue recognition

We account for revenue, including license revenue with affiliate, in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2018. This standard applies to all contracts with customers with the exception of contracts that are within the scope of other standards, such as leases, insurance and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services.

We perform the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer.

We have concluded that our government grants are not within the scope of ASC Topic 606 as they do not meet the definition of a contract with a customer. We have concluded that the grants meet the definition of a contribution and are non-reciprocal transactions, and have also concluded that Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as we are a business entity and the grants are with governmental agencies.

In the absence of applicable guidance under US GAAP, effective January 1, 2018, we developed a policy for the recognition of grant revenue when the related costs are incurred and the right to payment is realized.

We believe this policy is consistent with the overarching premise in ASC Topic 606, to ensure that revenue recognition reflects the transfer of promised goods or services to customers in an amount that reflects the consideration that we expect to be entitled to in exchange for those goods or services, even though there is no exchange as defined in ASC Topic 606. We believe the recognition of revenue as costs are incurred and amounts become realizable is analogous to the concept of transfer of control of a service over time under ASC Topic 606.

Prior to January 1, 2018, we recognized revenue as related costs were incurred under the grants given that 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. Recognized amounts reflected our performance under the grants and equal direct and indirect costs incurred. Revenue and expenses under these arrangements were presented gross. Revenue recognition under this new policy is not materially different than would have been calculated under the old guidance. As a result of the adoption of this policy, there was no change to the amounts we have historically recorded in our financial statements.

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 organizations (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, 2018 and 2017 was $16.2 million and $22.5 million, respectively. The decrease in operating loss from 2017 to 2018 was due to a $6.1 million decrease in operating expenses and a $0.3 million increase in revenue.

The net loss for the years ended December 31, 2018 and 2017 was $20.5 million and $18.4 million, respectively. Included in the net loss is (i) a net loss on debt extinguishment of $3.3 million in 2018; (ii) a gain on debt restructuring of $5.8 million in 2017; (ii) interest expense of $1.4 million and $1.9 million for 2018 and 2017, respectively; and (iv) for 2018, $0.4 million in proceeds from the sale of research and development tax credits.

The net loss attributable to common stockholders for the years ended December 31, 2018 and 2017 was $34.8 million (or $7.74 basic net loss per common share) and $24.8 million (or $24.14 basic net loss per common share), respectively. Included in the net loss attributable to common shareholders for 2018 is a $12.5 million non-cash AEROSURF warrant dividend (*see*, Note 3 – Business Combination). Included in the net loss attributable to common stockholders for 2018 and 2017 is a $1.7 million and $6.4 million, respectively, non-cash deemed dividend on preferred stock (*see*, Note 5 – Accounting Policies and Recent Accounting Pronouncements).

Grant Revenue

We recognized grant revenue of $0.8 million and $1.4 million for the years ended December 31, 2018 and 2017, respectively.

Grant revenue for 2018 includes $0.8 million of funds received and expended under a Phase II Small Business Innovation Research Grant (SBIR) from the NHLBI of the NIH to support the AEROSURF phase 2b clinical trial (AEROSURF Grant).

Grant revenue for 2017 includes $1.1 million of funds received and expended under the 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 KL4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury (Radiation Grant).

As of December 31, 2018, all funding under the AEROSURF Grant and the Radiation Grant has been received and recognized in revenue.

License Revenue with Affiliate

We recognized license revenue with affiliates of $1.0 million and $0.1 million for the years ended December 31, 2018 and 2017, respectively, which had previously been included in deferred revenue – current portion (*see*, – Critical Accounting Policies – License Agreement.)

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, 2018 and 2017 are as follows:

(in thousands)	Year Ended December 31, 2018	2017
Product development and manufacturing	5,334	$ 6,537
Clinical, medical and regulatory operations	4,255	5,758
Direct preclinical and clinical programs	973	5,081
Total Research and Development Expenses	$ 10,562	$ 17,376

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.4 million and $1.0 million for 2018 and 2017, respectively.

For a description of our lead development programs included in research and development expenses, *see*, Item 1 – Business.

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 drug products 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 of our drug product candidates including development of istaroxime, lyophilized KL4 surfactant, and rostafuroxin. 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 $1.2 million from 2017 to 2018, due to (i) our efforts in 2018 to conserve cash and reduce costs and (ii) a 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 2018 to 2017 due to (i) our efforts in 2018 to conserve cash and reduce costs and (ii) a 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 $4.1 million from 2018 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, 2018	2017
Contracted services	$ 4,194	$ 8,214
Salaries & benefits	4,029	5,504
Royalties	800	600
Rents and utilities	683	919
Stock-based compensation	232	837
Raw materials, aerosol devices and supplies	195	138
Depreciation	155	178
Travel	109	390
Contract manufacturing	-	355
Other	165	241
	$ 10,562	$ 17,376

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 2017 to 2018 is due to the completion of enrollment in the AEROSURF clinical trials in the second quarter of 2017.

The decrease in salaries and benefits of $1.5 million from 2017 to 2018 is due to our continuing efforts, beginning in the second quarter of 2017, 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.

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

General and Administrative Expenses

(in thousands)	Year Ended December 31, 2018	2017
General and Administrative Expenses	$ 7,421	$ 6,657

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 for each of the years ended December 31, 2018 and 2017.

General and administrative expenses increased $0.7 million from 2017 to 2018 due to legal and accounting fees related to the CVie Acquisition (*see*, Note 3 – Business Combination).

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.

Other Income / (Expense)

(in thousands)	Year Ended December 31, 2018	2017
Net loss on debt extinguishment	$ (3,345)	$ -
Gain on debt restructuring	-	5,824
Interest income	15	12
Interest expense	(1,409)	(1,863)
Other income	401	129
Other income / (expense), net	$ (4,338)	$ 4,102

Net loss on debt extinguishment

In December 2018, as part of the Private Placement Financing, we converted $6.0 million of existing loan payable obligations to LPH and $1.0 million of existing collaboration and device development payables to Battelle (Battelle Payables) on the same terms as the Investors of the Private Placement Financing. The conversions of the loan payable to LPH and the Battelle Payables are treated as extinguishments of debt and we recorded a loss on debt extinguishment of approximately $3.2 million and $0.5 million, respectively, resulting from the difference between the fair value of the common stock and warrants issued and the carrying value of the obligations. In December 2018, we also repaid our convertible note payable with Panacea in its entirety in cash of $1.5 million. As part of the extinguishment of debt, we recorded a gain on extinguishment of debt of approximately $0.4 million, relating to the reacquisition of the beneficial conversion option.

Gain on debt restructuring

In November 2017, we restructured and retired a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P.(Deerfield) 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 –Restructured Debt Liability).

Interest expense

(in thousands)	Year Ended December 31, 2018	2017
Cash interest expense	$ 546	$ 952
Non-cash amortization of debt discounts	863	-
Non-cash amortization of prepaid interest expense	-	911
Total interest expense	1,409	1,863

Interest expense in 2018 consists of (i) interest expense of $0.3 million related to the Battelle Payables; (ii) interest expense of $0.2 million related to the loan payable obligations to LPH; and (iii) interest expense of $0.1 million related to our convertible note payable with Panacea. Non-cash amortization of debt discounts relates to our convertible note payable with Panacea, which was extinguished in December 2018, and to a discount on Battelle Payables.

Interest expense in 2017 primarily consists of interest expense associated with the Deerfield Loan (*see*, – Liquidity and Capital Resources – Restructured Debt Liability).

Non-cash 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.

Other income

Other income in 2018 consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits, partially offset by $0.1 million of foreign currency losses.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2018, we had cash and cash equivalents of $11.2 million and available-for-sale, marketable securities of $14.0 million, current liabilities of $20.6 million, including $8.0 million of Loan payable (*see*, Note 11 - Loan Payable). As of April 5, 2019, we believe that we have sufficient resources (including marketable securities) available to support our development activities, business operations and debt service through October 2019.

Although we believe that the CVie Acquisition and $39 million Private Placement Financing have improved our financial position and may better position us to raise the capital needed to fund our business plans, we expect to continue to incur significant losses and require significant additional capital to advance our clinical development programs, support our operations and business development efforts, and satisfy our obligations beyond October 2019, 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 a combination of public or private equity offerings and strategic transactions, including but not limited to potential alliances and collaborations focused on various individual markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be able to complete any public or private equity offerings on acceptable terms, or in amounts required to support our operations, if at all, or identify and enter into any strategic transactions that will bring the capital that we will require. 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, 2018, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 72.0 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, 2018 and 2017, we had cash and cash equivalents of $11.2 million and $1.8 million, respectively. Net cash outflows for 2018 consisted of $15.8 million net cash used for ongoing operating activities, $13.7 million of net cash used in investing activities, offset by $38.7 million of net cash provided financing activities.

Operating Activities

Net cash used in operating activities was $15.8 million and $21.0 million for the years ended December 31, 2018 and 2017, respectively. The decrease in net cash used in operating activities from 2017 is attributable to a $6.0 million decrease in operating expenses offset by other changes in working capital.

Investing Activities

Net cash used in investing activities was $13.7 million and $24,000 for the years ended December 31, 2018 and 2017, respectively. The increase in net cash used in investing activities is due to the purchase of $13.9 million of marketable securities with the proceeds from the December 2018 Private Placement (*see*, Private Placement Offerings).

Financing Activities

Net cash provided by financing activities was $38.7 million and $17.3 million for the years ended December 31, 2018 and 2017, respectively, summarized as follows:

(in thousands)	Year Ended December 31, 2018	2017
Proceeds from private placements, net of expenses	32,893	$ 14,860
Proceeds from loan payable, net of expenses	6,160	3,900
Repayment of loan payable	(160)	-
Proceeds from convertible note payable	1,500	-
Repayment of convertible note payable	(1,500)	-
Payments for taxes related to net share settlements of equity awards	(155)	-
Proceeds from ATM Program, net of expenses	-	1,036
Principal payments on debt restructuring	-	(2,500)
Cash flows from financing activities, net	$ 38,738	$ 17,296

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 December 21, 2018, we completed a private placement offering with select institutional investors (Investors), for the purchase of an aggregate of 11,785,540 shares of common stock at a price per share of $3.3132, for an aggregate purchase price of approximately $39.0 million (Private Placement Financing). Included in the purchase price, each of LPH II Investments Limited (LPH II), an affiliate of Lee's Pharmaceutical Holdings Ltd. (Lee's), and Battelle Memorial Institute converted $6.0 million and $1.0 million, respectively, of existing debt obligations on the same terms as the other Investors. In connection with this offering, we issued (i) Series F Warrants to purchase an aggregate of 2,003,541 shares of common stock at an exercise price equal to $3.68 per share, which are exercisable through the 18-month anniversary of the date of issuance (the Series F Warrants), and (ii) Series G Warrants to purchase an aggregate of 3,889,229 shares of common stock at an exercise price equal to $4.05 per share, which are exercisable through the 5-year anniversary of the date of issuance (the Series G Warrants and, together with the Series F Warrants, the December 2018 Warrants). The December 2018 Warrants (i) may not be exercised to the extent that following such exercise, the holder would beneficially own more than 9.99% (or other percent as designated by each holder) of our outstanding shares of common stock, and (ii) contain customary provisions that adjust the exercise price and the number of shares of common stock into which the December 2018 Warrants are exercisable in the event of a corporate transaction.

In April 2018, we completed a private placement with LPH II for the purchase of $2.6 million of our common stock and warrants to purchase our common stock 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 October 2017, we completed a private placement offering with LPH Investments Limited, a company incorporated in the Cayman Islands with limited liability and an affiliate of Lee's (LPH), for the purchase of $10.0 million 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 related agreement, and issued in 2,311,604 shares of our common stock. 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 we had borrowed from Lee's Pharmaceutical (HK) Ltd., a Hong Kong company organized and existing under the laws of Hong Kong (Lee's (HK)) under a Loan Agreement dated August 14, 2017, between ourselves and Lee's (HK).

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 (Preferred Shares); and (ii) 50 Series A-1 Warrants to purchase one share of common stock at an exercise price equal to $27.40. All outstanding Preferred Shares were converted in accordance with their terms in advance of the merger.

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. 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.

Loan Payable

In January 2018 and March 2018, LPH Investments Limited (LPH), an affiliate of Lee's, agreed to lend us $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we sought to identify and advance one or more potential strategic initiatives as defined in the related loan agreements (Funding Event). The loans 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. To secure our obligations under these loans, we granted LPH a security interest in substantially all our assets pursuant to the terms of a Security Agreement with LPH dated March 1, 2018 (LPH Security Agreement).

During the third and fourth quarters of 2018, LPH agreed to lend us funds to sustain our operations while we continued to work on a strategic transaction. The initial loan was funded on August 14, 2018 in the amount of $0.3 million, and subsequent loans on the following dates and in the following amounts: August 29, 2018, in the amount of $0.48 million, September 12, 2018 in the amount of $0.5 million; September 27, 2018 in the amount of $0.5 million; October 19, 2018 in the amount of $0.43 million; November 2, 2018 in the amount of $0.5 million; November 19, 2018 in the amount of $0.35 million; and December 5, 2018 in the amount of $0.6 million. The loans accrued interest at a rate of 6% per annum and matured upon the earlier of (i) the closing date for the strategic transaction (as defined in the related loan agreements), provided that the Company was able to raise a minimum of $30 million in connection with such transaction, or (ii) March 31, 2019. In each case, we granted to LPH a security interest in substantially all of our assets pursuant to the terms of the LPH Security Agreement.

Extinguishment of Loan Payable

On December 21, 2018, as part of the Private Placement Financing, we converted $6.0 million of existing loan payable obligations to LPH on the same terms as those of the Investors of the Private Placement Financing. In connection of the conversion of Lee's debt, we issued: (i) 1,810,938 shares of common stock based at $3.3132 per share, (ii) Series F Warrants to purchase 307,859 shares of common stock, at an exercise price equal to $3.68 per share, and (iii) Series G Warrants to purchase 597,610 shares common stock, at an exercise price equal to $4.05 per share. The Series F Warrants are exercisable at any time after the date of issuance and through the 18-month anniversary of the date of issuance and the Series G Warrants may be exercised through the 5-year anniversary of the date of issuance.

The conversion of the loan payable to LPH is treated as an extinguishment of debt and does not represent a capital transaction as the Private Placement Financing included third-party investors and all investors received identical terms. We recorded a loss on extinguishment of debt approximately $3.2 million. The loss was calculated as the difference between: (i) the aggregate fair value of approximately $9.2 million, based on the fair value of the common stock and Warrants on December 21, 2018, and (ii) the carrying value of the debt liabilities of $6.0 million.

The balance of the loan payable to LPH of $160,000 was paid along with accrued interest of $182,000 on December 27, 2018.

Assumption of bank debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $4.6 million (or NTD $138.0 million) in a bank credit facility due in March 2020.

In September 2016, CVie entered into a 12-month revolving credit facility of approximately $2.9 million (or NTD $90.0 million) with O-Bank Co., Ltd. to finance operating activities. The facility was later renewed and increased to approximately $5.8 million (or NTD $180.0 million) in September 2017. The credit facility was guaranteed by Lee's, which is required to pledge bank deposits in the amount of 110% of the actual borrowing amount. Interest, payable in cash on a monthly basis, is determined based on 90-day TAIBOR (the Taipei Interbank Offer Rate) plus 0.91%. The credit facility will expire on September 11, 2019 and matures six months after the expiration date, on March 11, 2020. Although we reached an understanding with Lee's that it would maintain the bank deposits securing its guaranty obligation under the credit facility, we do not have a written agreement with Lee's requiring it to do so; therefore, the $4.5 million outstanding under the facility has been classified as a current liability on the balance sheet.

As of December 31, 2018, the outstanding principal was approximately $4.5 million (or NTD $138.0 million), due to exchange rate fluctuations.

Assumption of Lee's debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $3.5 million (or NTD $106.2 million) of debt payable to Lee's.

From April 24, 2018 to November 16, 2018, CVie entered into four separate agreements to borrow an aggregate of approximately $3.50 million from Lee's. The terms of the loan agreements are identical where the interest, payable in cash upon maturity, is 4% per annum and each of the four separate loans will mature one year from the effective date as follows: $0.50 million in April 2019; $0.3 million in September 2019; $0.2 million in October 2019; and $2.5 million in November 2019.

As of December 31, 2018, the outstanding principal was approximately $3.5 million (or NTD $106.2 million), due to exchange rate fluctuations.

Convertible Note Payable

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea) a Secured Convertible Promissory Note (the Note) with respect to a loan facility in the aggregate amount of up to $1.5 million, which was funded in two loans of, $1.0 million on the date of the Note and $0.5 million on July 23, 2018. The Note had a maturity date of December 31, 2018 and accrued interest at a rate of 15% per annum until the Note was paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea could deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, participated. In connection with these Loans, we granted to Panacea a security interest in substantially all our assets.

In connection with the Note, we issued to Panacea warrants (the Series D Warrants) to purchase 187,500 shares (the Warrant Shares) at an exercise price of $4.00 per Warrant Share (the Exercise Price). The Warrants may be exercised at any time beginning six months after the date of issuance and through the fifth anniversary of the date of issuance. The Warrants may not be exercised to the extent that the holder thereof would, following such exercise, beneficially own more than 9.99% of the Company's outstanding shares of common stock, which percentage may be increased, decreased or waived by such holder upon sixty-one days' notice to us. The Warrants also contain customary provisions that adjust the Exercise Price and the number of Warrant Shares in the event of a corporate transaction.

We recorded the Note as current debt at its face value of $1.5 million less debt discounts consisting of (i) $0.4 million fair value of the warrants issued in connection with the Note and (ii) a $0.4 million beneficial conversion feature related to an embedded conversion option that had an effective conversion price that was less than the fair value of the underlying stock at the commitment date. The discount is being accreted to the $1.5 million loan over its term using the effective interest method. The Panacea Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815, *Derivatives and Hedging – Contracts in Entity's Own Equity*, and have been classified as equity.

The fair value at issuance of the Panacea Warrants was determined using the Black-Scholes option-pricing model. The input assumptions used in the valuation are the historical volatility of our common stock price, the expected term of the warrants, and the risk-free interest rate based on the five-year treasury bill rate in effect at the measurement date.

Significant Input Assumptions of Warrant Valuation	
Historical volatility	103%
Expected term (in years)	5
Risk-free interest rate	2.75%

The following amounts comprise the convertible note interest expense for the periods presented:

(in thousands)	**Year Ended December 31, 2018**
Non-cash amortization of debt discounts	$ 833
Cash interest expense	106
Total convertible note interest expense	939

Extinguishment of Panacea Convertible Promissory Note

On December 27, 2018, we repaid the Note in its entirety in cash of $1.5 million. As part of the extinguishment of debt, we recorded a gain on extinguishment of debt of approximately $0.4 million, relating to the reacquisition of the beneficial conversion option. The gain was calculated using the intrinsic value of the beneficial conversion option, which is the product of: (i) the difference between the common stock price on the date of extinguishment of $5.11 and the conversion price of $4.00, and (ii) 375,000 shares convertible into common stock.

Restructured Debt Liability

(in thousands)	**December 31, 2018**	**December 31, 2017**
Restructured debt liability - contingent milestone payments	$ 15,000	$ 15,000

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P. (Deerfield Loan) in the aggregate principal amount of $25 million 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) 71,111 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain milestone payments based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. 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 5 – Accounting Policies and Recent Accounting Pronouncements). 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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2018 or 2017, 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, 2018. 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, 2018.

On December 21, 2018, we acquired CVie Investments Limited (CVie). The acquisition of CVie represents a material change in the internal control over financial reporting since management's last assessment of effectiveness. Management has excluded CVie from its assessment of internal control over financial reporting as of December 31, 2018. Total assets of CVie, excluding goodwill and other intangible assets which were included in management's assessment of internal control over financial reporting as of December 31, 2018, are $0.5 million at December 31, 2018. Total operating expenses of CVie were $0.4 million for the year ended December 31, 2018. The total assets and total operating expenses excluded from management's assessment of internal control over financial reporting as of December 31, 2018, represent approximately 0.43% and 2.2%, respectively, of our related consolidated financial statement amounts as of and for the year end December 31, 2018.

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, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors of the Company

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

Name	Position with the Company
James Huang	Director, Chairman of the Board
Craig Fraser	Director, President and Chief Executive Officer
John R. Leone	Director
Joseph M. Mahady	Director
Bruce A. Peacock	Director
Brian D. Schreiber, M.D.	Director

James Huang, age 53, was elected as Chairman of the Board on December 21, 2018. Mr. Huang is a founding and Managing Partner to Panacea Venture. Panacea Venture is a venture capital firm that invests in early and growth stage healthcare and life sciences companies worldwide. Since 2011, Mr. Huang has served as a Managing Partner of Kleiner Perkins Caufield & Byers (KPCB) – China, focusing on the firm's life sciences practice. Mr. Huang has made more than 15 investments in China since 2007. Prior to joining KPCB China, Mr. Huang was a Managing Partner at Vivo Ventures, a venture capital firm specializing in life sciences investments. Prior to joining Vivo in 2007, Mr. Huang was president of Anesiva, a biopharmaceutical company focused on pain-management treatments. During his 20-year career in the pharmaceutical and biotech industry, Mr. Huang also held senior roles in business development, sales, marketing and R&D with Tularik Inc. (acquired by Amgen), GlaxoSmithKline LLC, Bristol-Myers Squibb and ALZA Corp. (acquired by Johnson & Johnson). Mr. Huang is Chairman of Board at Kindstar Global, JHL Biotech and XW Laboratory and Director at ChiralQuest, Zenesis, and CASI Pharmaceuticals. Mr. Huang received an M.B.A. from the Stanford Graduate School of Business in 1992 and a B.S. degree in chemical engineering from the University of California, Berkeley.

Craig Fraser, age 54, has served as President and Chief Executive Officer and a member of the Board since February 1, 2016. He brings over 29 years of experience as a leader in product development, fundraising, business development and commercial operations in building biopharmaceutical and device businesses for startups as well as larger companies. Prior to joining us, Mr. Fraser held executive positions at several biopharmaceutical companies, including Novelion as Chief Operating Officer and President (2014- 2015) and, prior to that, positions of increasing responsibility; as Vice President of Global Disease Areas at Pfizer (2009-2011) and Vice President and Global Business Manager at Wyeth Pharmaceuticals (2007- 2009). Previously, Mr. Fraser served as Vice President, Sales & Marketing and Commercial Operations and as Vice President, Global Strategic Marketing at Johnson & Johnson; and as Gastroenterology Franchise Lead, National Sales Director – Immunology and Acute Cardiovasculars, and Marketing Director – Cardiovasculars and Diagnostics at Centocor. Mr. Fraser is a veteran of both the U.S. Marine Corps and the U.S. Army. Mr. Fraser does not serve on any other public company boards. Mr. Fraser received his B.S. degree in Public Administration from Slippery Rock University of Pennsylvania.

John R. Leone, age 71, has served as a member of our Board of Directors since November 2012, acting as Chairman from January 2013 through December 20, 2018. He currently serves as Chairman of the Board's Nomination and Governance Committee and a member of the Compensation and Audit Committees. With over 30 years of experience, Mr. Leone has built an outstanding track record in pharmaceutical operations, commercial portfolio management, and financing life science companies. His commercial experience includes significant domestic and international executive management roles and direct responsibility for the commercial launch of numerous pharmaceutical products.

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

Joseph M. Mahady, age 65, has served as a member of our Board since January 2013. He also serves as Chairman of the Board's Compensation Committee and a member of the Audit Committee and Nomination and Governance Committees. Mr. Mahady has extensive strategic and operational experience in the biopharmaceutical industry. He has broad international commercial experience, having served in a direct leadership role in more than 30 product launches, and has a successful record of developing profitable businesses based on transformational technologies in both the U.S. and international markets.

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

Bruce A. Peacock, age 67, has served as a member of our Board since September 2010. Mr. Peacock brings to our Board extensive biotech and pharmaceutical experience, including financial expertise in debt, equity capital and alliance transactions. He also has significant experience in drug development, having led the effort to gain regulatory approval for several drug candidates in the United States and in other major markets worldwide. Mr. Peacock also has had responsibility for marketing, commercial and manufacturing operations.

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

Brian Schreiber, M.D., age 65, has served as a member of our Board since December 21, 2018 and in March 2019 became a member of the Compensation Committee. Dr. Schreiber is a Board-Certified Nephrologist and Internist with extensive industry and clinical experience, specializing in rare diseases. Dr. Schreiber is currently the Chief Medical Officer for Cerium Pharmaceuticals, a company who leverages the basic drug discovery work performed by others and moves drug candidates through the clinical and regulatory development processes. Since 2015, Dr. Schreiber has also served as President and Managing Partner for Metabolism Disease Consultants, focusing on drug development, clinical trial design and in-licensing clinical guidance. Dr. Schreiber also served as Vice President of Medical Development at Relypsa and spent 14 years at Sigma-Tau Pharmaceuticals as consultant medical director and Vice President of its Medical Affairs Department. Dr. Schreiber's clinical experience includes his role as Chief Medical Director of Dialysis Care Inc., a multi-center dialysis chain providing services in the Northeast and Central Wisconsin and Chairman of Nephrology at LaSalle Clinic, Affinity Medical System, serving as its first president until 2001. Dr. Schreiber has also continued his activities in academia as Assistant Clinical Professor of Medicine, Department of Medicine, Division of Nephrology, Medical College of Wisconsin since 2001, and has published numerous academic papers, given a variety of lectures, and ran various symposia.

Executive Officers and Key Officers and Employees

The following table sets forth the names and positions of our executive officers:

Name	Position with the Company
Craig Fraser	President and Chief Executive Officer
Steven G. Simonson, M.D.	Senior Vice President and Chief Medical Officer
John A. Tattory	Senior Vice President and Chief Financial Officer
Mary B. Templeton, Esq.	Senior Vice President, General Counsel and Corporate Secretary

Mr. Fraser's biographical information appears above.

Steven G. Simonson, M.D., age 60, was appointed our Senior Vice President and Chief Medical Officer in April 2017, having previously served as our Senior Vice President and Chief Development Officer since October 2014, and our Vice President, Clinical Development, upon joining the Company in May of 2014. Dr. Simonson brings to us over 25 years of medical practice and pharmaceutical industry clinical trial experience with a significant background in pulmonary critical care and developing respiratory drugs, including preclinical, first time into man and phases 1-4, and IND, NDA and sNDA experience. Dr. Simonson spent 15 years at AstraZeneca Pharmaceuticals in areas of medical and clinical leadership primarily in the pulmonary and infection therapeutic areas. He has been involved in or led several successful IND and NDA filings including the Pulmicort® Turbuhaler® M3 NDA, which was approved for treatment of asthma. He spent the next two years as Vice President of Clinical Development at Agennix, Inc., a biopharmaceutical company primarily focused in oncology and sepsis, leading programs including studies of talactoferrin in necrotizing enterocolitis, the second most common cause of morbidity in premature neonates. Most recently, Dr. Simonson was an Executive Director in the Molecule Development Group at Covance, a biopharmaceutical development services company, where he applied his experience to developing clinical development programs for small and mid-size biotech and pharmaceutical companies. Dr. Simonson completed training in internal medicine followed by a fellowship in pulmonary and critical care medicine at Duke University Medical Center. He then held several faculty appointments at Duke in the departments of Anesthesiology and Medicine, including the divisions of Pulmonary and Critical Care Medicine. He is a Fellow of the American College of Chest Physicians, and author or co-author of multiple peer reviewed publications, abstracts, posters and chapters. Dr. Simonson received his medical degree from the Medical College of Wisconsin, and his Master of Health Sciences degree in Biometry from the Duke University School of Medicine.

John A. Tattory, age 53, was appointed our Senior Vice President and Chief Financial Officer in March 2014, having previously served as our Vice President, Finance and Chief Accounting Officer (March 2013 - March 2014), and our Vice President, Finance, and Controller and the designated principal accounting officer (July 2010 - March 2013), and Vice President, Finance (January 2008 – July 2010). He brings more than 25 years of financial management and leadership experience, including directing U.S. and international financial operations, strategic transactions, licensing and collaboration arrangements, and equity and debt financings. Prior to joining us, Mr. Tattory held financial management positions at Tyco International, where he served as Director, Financial Planning & Analysis for Tyco Flow Control, an operating unit that included the majority of business operations in international markets; and Bristol-Myers Squibb (BMS), where he held financial roles of increasing responsibility, most recently as Finance Director, U.S. Primary Care, with responsibility for the financial matters of various BMS pharmaceutical businesses, including international operations. Previously, Mr. Tattory served as an Audit Manager with Ernst & Young LLP. Mr. Tattory is a certified public accountant (CPA) and holds a B.S. degree in Commerce from Rider University.

Mary B. Templeton, Esq., age 72, has served as Senior Vice President, General Counsel and Corporate Secretary since September 2011, having previously served as Senior Vice President and Deputy General Counsel since joining us in March 2006. Ms. Templeton brings to us 40 years of legal and senior management experience. Prior to joining us, Ms. Templeton held senior executive positions in the financial services industry, including as Senior Vice President and General Counsel of The Charles Schwab Corporation and as Senior Vice President and General Counsel of The Sequor Group Inc. (securities subsidiaries of Security Pacific Corporation) and was in private practice in Philadelphia and New York. Previously, at Charles Schwab & Co., Ms. Templeton led development of the first mutual fund marketplace, and, at Bradford Trust Company (New York), the first for-profit clearing corporation registered with the SEC. Ms. Templeton received a B.A. degree from Chatham University, where she is a member of the Board of Trustees, and a J.D. with High Honors from Rutgers Law School, Camden NJ, where she was Editor-in-Chief of the Law Journal. She is a member of the Bar Associations of Pennsylvania and New York.

Family Relationships

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our directors, officers (including a person performing a principal policy-making function) and persons who beneficially own more than 10% of a registered class of our equity securities (collectively, "Reporting Persons") to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Reporting Persons are required by SEC regulations to furnish us with copies of all filings they make under Section 16(a) and we are required to identify those Reporting Persons who failed to make such filings timely. Except as noted below, based solely on a review of the copies of any such filings made available to us and written representations from our officers and directors, we believe that all Reporting Persons complied with the filing requirements under Section 16(a) of the Exchange Act during the year ended December 31, 2018.

Effective with the closing of the CVie Acquisition and Private Placement Financing, Bioengine Capital Inc. (Bioengine) became a holder of 10% of our outstanding common stock effective December 21, 2018. Bioengine filed a Form 3 with the SEC on March 21, 2019.

Procedures for Recommending Nominees to our Board

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board since we described those procedures in our proxy statement for our 2017 Annual Meeting of Stockholders, which we filed with the SEC on May 18, 2017.

Audit Committee

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

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

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

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

Code of Business Conduct and Ethics

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

ITEM 11. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

Named Executive Officers

The following table summarizes, for the years 2018 and 2017, the compensation of (1) each individual who served as our principal executive officer at any time during 2018 and (2) the two most highly-compensated executive officers (other than the principal executive officer) who were serving as executive officers on December 31, 2018 ranked by their total compensation for the fiscal year ended December 31, 2018, to whom we collectively refer herein as our "Named Executive Officers."

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

Name and Principal Position	Year	Salary ($)	Bonus ($) (1)(2)	Stock Awards ($)(3)	Option Awards ($)(4)	All Other Compensation ($)(5)	Total ($)
Craig Fraser							
President and Chief Executive Officer	2018	$ 437,068	$ 226,038	$ 274,359	$ 4,287,110	$ -	$ 5,224,575
	2017	425,375	-	121,396	90,720	3,164	640,655
Steven G. Simonson, M.D.							
Senior Vice President and Chief Medical Officer	2018	346,704	149,420	130,581	2,500,814	-	3,127,519
	2017	337,563	-	57,778	49,896	3,375	448,612
John A. Tattory							
Senior Vice President, Chief Financial Officer and Treasurer	2018	325,538	151,522	122,609	2,500,814	-	3,100,483
	2017	313,646	-	54,251	49,896	3,150	420,943

(1) On November 16, 2018, the Compensation Committee approved a Strategic and Retention Bonus Program (the Strategic Bonus). The program provides for payment of a bonus to certain key employees, including our Named Executive Officers, upon completion of an eligible transaction, which is defined under the program to include a (i) strategic transaction (which includes the CVie Acquisition) and (ii) one or more financings within a nine-month period that results in proceeds of at least $30 million. The bonus amount for each executive varies under the program based on the following criteria; (i) to the extent that the amount raised in the financing(s) is less than $45 million, then the amount of the bonus to be paid is reduced in a stepped-down fashion as outlined in the program; (ii) the individual bonus amount is determined by application of a multiplier to the executive’s base salary. The individual multiplier varies based on (a) the executive’s position, and (b) the amount raised in a financing between $30 million and $45 million, which for Messrs. Fraser, Tattory and Dr. Simonson, is between 0.2 and 1.5, 0.27 and 1.35, and 0.25 and 1.25, respectively; and (ii) once determined, the bonus is payable in two equal installments, the first within five business days of the closing of the strategic transaction, and the second on the nine-month anniversary of the closing of the strategic transaction, provided that the executive is actively employed with us at the time of the payment. With respect to the CVie Acquisition and Private Placement Financing (*see*, “Item 1 – Company Overview – Acquisition of CVie Therapeutics and Private Placement Financing”), based on an aggregate raise of $39 million, on December 31, 2018, we paid the first installment of a Strategic Bonus to Messrs. Fraser, Tattory and Dr. Simonson in the amounts of $226,038, $151,522 and $149,420 respectively. The second installment is expected to be paid effective September 21, 2019, provided the executive remains employed with us at that time. Through September 21, 2019, the executives will be eligible for incremental Strategic Bonus amounts until the aggregate amount raised in the period equals $45 million.

(2) In October 2017, in connection with the purchase of a controlling interest in our common stock by Lee’s Pharmaceutical Holdings Ltd (Lee’s) through a subsidiary, each Named Executive Officer agreed to amend his Employment Agreement with us to waive a change in control provision that otherwise would have required payment of the executives’ annual target bonuses in each of the next two fiscal years following the closing of the change in control. As such, Messrs. Fraser and Tattory and Dr. Simonson waived bonuses in 2017 of $213,725, $95,512 and $101,723, respectively, and in 2018, of $220,137, $98,378, and $104,774, respectively. The Strategic and Retention Bonus was the only cash bonus paid to the named executive officers in 2017 and 2018. *See also*, footnote 3 to this table.

(3) Represents the ratable amount expensed for the year under Accounting Standards Codification (ASC) Topic 718 "Stock Compensation" (“ASC Topic 718”) for grants of restricted stock units (2017 RSUs) made in connection with the October 2017 change in control transaction with Lee’s. This amount is not the amount paid to, or realized by, the Named Executive Officer. The assumptions that we utilized are described in Note 15, Stock Options and Stock-based Employee Compensation, to our consolidated financial statements for the year ended December 31, 2018. The 2017 RSUs were granted in lieu of waived cash bonuses (*see*, footnote 2 to this table) and initially vested in two equal tranches on March 15, 2018 and March 15, 2019. However, the 2017 RSUs were amended multiple times to (i) change the initial vesting date from March 15, 2018 to December 28, 2018 and, (ii) effective March 15, 2018, cause the initial tranche of the 2017 RSUs to become non-forfeitable in the event of termination of employment of the executive for other than cause (as defined in the executive’s employment agreement). Except as provided in the RSU amendment, the 2017 RSUs were non-transferable and subject to cancellation upon termination of an executive’s employment. The ASC Topic 718 value as of the grant date for the 2017 RSU was spread over the number of months of service required for the grant to become non-forfeitable.

In February 2019, we determined that issuance of certain of the 2017 RSUs exceeded the limit that no more than 750,000 RSUs per person per year could be issued under the 2011 Long-Term Incentive Plan. Since the common shares underlying the RSUs had not yet been delivered to the executives following the December 28, 2018 vesting date, we canceled the first and second tranche of the original 2017 RSUs issued to Mr. Fraser because each tranche exceeded the limit; we also canceled the second tranche of the original 2017 RSUs issued to Mr. Tattory and Dr. Simonson because the total grant was in excess of the limit but the initial tranche was within the limit. Concurrently with the cancellations, we issued equivalent replacement grants for Mr. Fraser’s entire 2017 RSU and the second tranche of Mr. Tattory's and Dr. Simonson’s 2017 RSUs, which, following a reverse-split in December 2017, no longer exceeded the plan limit. The replacement grants were issued with a vesting date of March 15, 2019.

(4) Represents the grant date fair value of the stock options computed in accordance with ASC Topic 718. The assumptions that we utilized are described in Note 15, "– Stock Options and Stock-based Employee Compensation," to our consolidated financial statements for the year ended December 31, 2018. The amounts reported in this column have not been paid to, nor realized by, the Named Executive Officer. The Compensation Committee approved grants to Messrs. Fraser and Tattory and Dr. Simonson on December 24, 2018 for 1,265,717, 738,335 and 738,335 shares, respectively, each with an exercise price of $4.22. The Compensation Committee approved grants to Messrs. Fraser and Tattory and Dr. Simonson on March 1, 2017 for 5,000, 2,750 and 2,750 shares, respectively, each with an exercise price of $24.60. All options vest in three equal annual installments beginning with the first-year anniversary of the date of grant. All options have a term of 10 years.

(5) The reported amount reflects any Company match under our 401(k) Plan, which was made in shares of our common stock through the second quarter of 2017, and thereafter suspended for the period reported. During 2018 and 2017 as applicable, the aggregate perquisites and other personal benefits afforded to each Named Executive Officer was less than $10,000, calculated as the incremental cost of providing such benefits to each Named Executive Officer, in accordance with SEC disclosure rules. This amount does not include the cost of medical and health benefits, as such benefits are available to all of our employees. In 2018, the Compensation Committee authorized payment of a company match in cash, subject to there being sufficient cash resources as determined in the sole discretion of the Compensation Committee at any time, in an amount per participant equal to 50% of a participant's contribution (up to a maximum of 6% of the participant's base salary) to the Plan. The match was not made in 2018 but we plan to reinstitute it in 2019.

Outstanding Equity Awards at Fiscal Year-End 2018

The following table shows the number of shares covered by exercisable and unexercisable options held by the Named Executive Officers on December 31, 2018. To improve readability, the following columns have been removed from the table as there is no reportable information with respect to these items: "Option Awards – Equity Incentive Plan Awards: No. of Securities Underlying Unexercised Unearned Options," "Units of Stock That Have Not Vested," and "– Market Value of Shares or Units of Stock That Have Not Vested."

	Option Awards				Stock Awards Equity Incentive Plan Awards	
Named Executive Officer	No. of Securities Underlying Unexercised Options - Exercisable	No. of Securities Underlying Unexercised Options - Unexercisable	Option Exercise Price ($)	Option Expiration Date	No. of Unearned Shares, Units or Other Rights That Have Not Vested	Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
Craig Fraser	6,829 (1)	3,414 (1)	$ 46.60	02/02/26	49,405 (6)	$ 213,725
	1,334 (2)	666 (2)	35.40	07/28/26		
	1,667 (3)	3,333 (3)	24.60	03/01/27		
		1,265,717 (4)	4.22	12/24/28		
Steven G. Simonson, M.D.	429		476.00	05/19/24	23,514 (6)	$ 101,722
	982		327.60	03/27/25		
	1,191 (5)	595 (5)	46.60	02/02/26		
	833 (2)	417 (2)	35.40	07/28/26		
	917 (3)	1,833 (3)	24.60	03/01/27		
		738,335 (4)	4.22	12/24/28		
John A. Tattory	268		512.40	10/07/21	22,078 (6)	$ 95,512
	143		758.80	05/04/22		
	286		660.80	03/26/23		
	322		722.40	03/06/24		
	536		327.60	03/27/25		
	774 (5)	387 (5)	46.60	02/02/26		
	833 (2)	417 (2)	35.40	07/28/26		
	917 (3)	1,833 (3)	24.60	03/01/27		
		738,335 (4)	4.22	12/24/28		

(1) In connection with the hiring of Mr. Fraser on February 1, 2016, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 10,243 shares of our common stock, representing 2.5% of our outstanding shares. These options vested in equal installments on the first three anniversaries of the February 1, 2016 grant date, assuming that Mr. Fraser continues to be employed with us through each vesting date. These options expire on the tenth anniversary of the grant date.

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

(3) These options vest and become exercisable in equal installments on the first three anniversaries of the March 1, 2017 grant date, assuming that the officer continues to be employed with us through each vesting date. These options expire on the tenth anniversary of the grant date.

(4) These options vest and become exercisable in equal installments on the first three anniversaries of the December 24, 2018 grant date, assuming that the officer continues to be employed with us through each vesting date. These options expire on the tenth anniversary of the grant date.

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

(6) The 2017 RSUs vested in two equal tranches on December 28, 2018 and March 15, 2019.

Retirement Benefits

During 2018, none of our Named Executive Officers participated in any plan that provides for the payment of retirement benefits, or benefits that will be paid primarily following retirement, other than our 401(k) savings plan ("401(k) Plan"). Under the 401(k) Plan, eligible employees (as defined in the 401(k) Plan) may elect to make pre-tax deferrals or Roth deferrals up to the maximum amount allowed by law (which was limited for this purpose in 2018 to $18,500). The 401(k) Plan also permits (i) rollover contributions and (ii) catch up contributions by employees age 50 and over (which was limited for this purpose in 2018 to $6,000). Under the 401(k), we historically made employer matching contributions on a quarterly basis by matching employee regular and catch-up contributions with shares of our common stock determined by reference to the lower of (i) the average closing price of shares of our common stock on all trading days in the applicable quarter, or (ii) the closing price of our common stock on the last trading day of the quarter. However, in 2017, based on management's recommendation, the Compensation Committee determined to cease the share match. In 2018, the Compensation Committee approved a company match to be made in cash, subject to there being sufficient cash resources as determined in the sole discretion of the Compensation Committee, in an amount per participant equal to 50% of each participant's contribution (up to a maximum of 6% of the participant's base salary) to the Plan. There was no cash match in 2018. We plan to initiate the Company match during the 2019 plan year.

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

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

Executive Employment Agreements

On March 26, 2013, the Compensation Committee approved a form of executive employment agreement (the "Executive Agreements") for senior executive officers, including Mr. Tattory and Dr. Simonson. The following describes the key terms of the Executive Agreements Messrs. Fraser and Tattory and Dr. Simonson as presently in effect.

- The effective dates of the Executive Agreements for Messrs. Fraser, Tattory and Dr. Simonson was February 1, 2016, April 1, 2014 and December 19, 2014, respectively. Mr. Fraser's agreement was based on the then-current form of Executive Agreement, with changes and updates that thereafter were incorporated into the other Executive Agreements by amendment dated March 13, 2018. As amended, the agreements remain in effect until terminated, and are governed by Pennsylvania law, with arbitration to be held in the Philadelphia PA. In addition, in March 2018, Mr. Fraser's agreement was amended to correct an apparent scrivener's error and conform the period of extended benefits in the event of a change of control with the other agreements (18 months).

- All Executive Agreements include a 12-month post-employment noncompetition agreement and non-solicitation agreement and provide for confidentiality and the assignment to us of all intellectual property. Effective February 1, 2019 the base salaries of Mr. Fraser, Mr. Tattory and Dr. Simonson were increased from $440,274 to $453,482, from $327,926 to $337,764, and from $349,247 to $380,000 respectively. Each executive has a target annual bonus (Annual Bonus Amount), which may be awarded at the discretion of the Compensation Committee and expressed as a percent of base salary. The Annual Bonus Amounts in 2018 for Messrs. Fraser, Mr. Tattory and Dr. Simonson were 50%, 30% and 30% of base salary, respectively. On March 19, 2019 the Compensation Committee approved an increase of the Annual Bonus Amount for each of Mr. Tattory and Dr. Simonson to 40% of their respective base salaries.

- Upon termination by us without Cause or by the executive for Good Reason (in each case as defined therein), in addition to any amounts or benefits that are due under any of our vested plans or other policy, and on the condition that the executive enters into a separation agreement containing a final and effective plenary release of claims in a form acceptable to us, and, with respect to termination by the Executive for Good Reason, the executive asserts his right within 30 days after having actual knowledge of the acts or omissions giving rise to Good Reason and provides for a 30-day cure period, each executive will be entitled to: (i) a pro rata bonus equal to a percentage of the executive's Annual Bonus Amount determined by dividing the total actual bonuses paid to other contract executives for the year in which the termination occurs by the aggregate of such other contract executives' total target bonuses for that year, and further prorated for the number of days the executive was employed in the year of termination, payable at the time that other contract executives are paid bonuses with respect to the year of termination; (ii) a severance amount equal to the sum of the executive's base salary then in effect (determined without regard to any reduction constituting Good Reason) and the Annual Bonus Amount, payable in equal installments from the date of termination to the date that is 12 months after the date of termination (the "Severance Period"); and (iii) all vested stock options, restricted stock grants and other similar equity awards held by the executive ("Executive Equity Awards") shall continue to be exercisable during the Severance Period. In addition, during the Severance Period, if the executive elects to continue medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), we will continue to pay our costs of the executive's and his or her dependents' benefits as in effect on the date of termination as such benefits are provided to active employees. If COBRA coverage is unavailable, we will reimburse the executive an amount which, after taxes, is sufficient to purchase medical and dental coverage substantially equivalent to that which the executive and his dependents were receiving immediately prior to the date of termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under our plans, and provided further, that our obligation to provide benefits will cease or be reduced to the extent that a subsequent employer provides substantially similar coverage. All of our obligations to an executive shall cease if at any time during the Severance Period the executive engages in a material breach of the Executive Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach.

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

- Upon a Change of Control, for a period of 24 months after the date of the Change of Control (the "Effective Period"), and provided that the executive is employed on the last day of a fiscal year ending in that period, the executive will be entitled to an annual bonus at least equal to such executive's Annual Bonus Amount, payable no later than March 15 in the next succeeding fiscal year. *See also*, "– 2017 Change of Control."

2017 Change of Control

Effective October 27, 2017, a subsidiary of Lee's invested $10 million in us and acquired 73% of our issued and outstanding shares of common stock, which constituted a change of control under the Executive Agreements. The purchase agreement also amended our Named Executive Officers' Executive Agreements to provide. solely with respect to Lee's purchase, Messrs. Fraser, Tattory and Dr. Simonson waived payment of the target Annual Bonus Amounts that otherwise would have been payable in the 24-month period immediately following the closing. *See*, footnote 2 to the Executive Compensation Table. In addition, each executive was awarded 2017 RSUs, having a value when issued equal to the combined total value of such executive's waived 2017 and 2018 Annual Bonus Amounts, and initially vesting in two equal installments on March 15, 2018 and March 15, 2019. Through amendments, (i) the March 15, 2018 vesting date was changed to December 28, 2018 and, (ii) effective March 15, 2018, the initial tranche of the 2017 RSUs became non-forfeitable in the event of termination of employment of the executive for other than cause (as defined in such executive's employment agreement).

DIRECTOR COMPENSATION

Directors who are also employees are not compensated separately for serving on the Board or any of its committees. Each of our non-employee directors receives cash compensation for his services. On June 9, 2015, the Compensation Committee and Board approved cash compensation for non-employee directors as follows: (i) $8,750 per quarter for all directors other than the Chairman of the Board, and $15,000 per quarter for the Chairman of the Board; (ii) $3,750 per quarter for the director who served as Chairman of the Audit Committee; (iii) $2,500 per quarter for the director who served as Chairman of the Compensation Committee; (iv) $1,875 per quarter for the director who served as Chairman of the Nomination and Governance Committee; (v) $1,750 per quarter for each director who served as a non-Chairman member of the Audit Committee; (vi) $1,250 per quarter for each director who served as a non-Chairman member of the Compensation Committee; and (vii) $1,000 per quarter for each director who served as a non-Chairman member of the Nomination and Governance Committee. In addition, to better align the interests of our Board with our stockholders, the Compensation Committee considers and recommends to the Board long-term equity compensation. On December 24, 2019, the Compensation Committee approved an award to each non-employee director of options to purchase our common stock and restricted stock units as set forth in the table below. These awards were issued pursuant to our 2011 Plan and were approved after due consideration of the practices of other similarly situated biotechnology companies in providing equity compensation to their non-employee directors. The Compensation Committee plans to conduct a review of peer company director compensation practices periodically, including before considering changes to our director compensation policy and amounts in the future.

The following chart summarizes the cash and non-cash compensation earned or paid to our non-employee directors during the year ended December 31, 2018. To improve readability, the following columns have been removed from the table, as there is no reportable information with respect to these items: “Non-Equity Incentive Compensation” and “Change in Pension Value and Nonqualified Deferred Compensation Earnings.”

Name	Fees Earned or Paid in Cash *	Stock Awards (1)	Option Awards (2)	Total
John R. Leone	$ 69,000	$ 63,300	$ 108,387	$ 240,687
Joseph M. Mahady	52,000	63,300	108,387	223,687
Bruce A. Peacock	59,000	63,300	108,387	230,687
Marvin E. Rosenthale, Ph.D. †	37,125	48,530	72,823	158,478

† In August 2018, we announced the passing of Marvin E. Rosenthale, Ph.D., a long-standing member of our Board, at the age of 84. Dr. Rosenthale served as a valued member of our Board from 1998 until his death and throughout his tenure was an enthusiastic supporter of our management team and our Company. The payments and equity awards to Dr. Rosenthale have been prorated to the date of his death and delivered to his estate.

(1) Represents the grant date fair value of the stock award, equivalent to the closing stock price on the grant date, computed in accordance with ASC Topic 718. On December 24, 2018 15,000 RSUs were awarded each to Mr. Leone, Mr. Mahady, and Mr. Peacock and 11,250 RSUs were delivered to the estate of Dr. Rosenthale. The RSUs vest on the first anniversary of the date of grant.

(2) Represents the grant date fair value of the stock options computed in accordance with ASC Topic 718. The assumptions utilized are described in Note 15, “Stock Options and Stock-based Employee Compensation,” to our consolidated financial statements for the year ended December 31, 2018, which are included in this Form 10-K. On December 24, 2018 32,000 options were awarded each to Mr. Leone, Mr. Mahady and Mr. Peacock, and 21,500 options to the estate of Dr. Rosenthale, each with a strike price of $4.22, which was the closing price of our common stock on the date of grant. The options vest in full on the first anniversary of the date of grant and have a term of 10 years.

* Due to cash resource constraints, we delayed payment of accrued director fees from mid-2017 and through 2018. The amounts due were paid to each director on January 13, 2019, including amounts related to 2018, as follows: Mr. Leone - $69,000, Mr. Mahady - $52,000, Mr. Peacock - $59,000, and to the estate of Dr. Rosenthale - $37,125.

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

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

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table describes as of December 31, 2018 the number of shares of our common stock issuable upon exercise of outstanding awards under our 2011 Plan. Except as described in footnote 2 to the table, there are no equity incentive plans not approved by security holders (other than our 401(k) Plan under which we matched in shares of our common stock to mid-2017), and that line of the table has been omitted.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) ©
Equity compensation plans approved by security holders				
2011 Long-Term Incentive Plan	4,557,662	$	6.54	1,452,807
2007 Long-Term Incentive Plan (1)	50	$	1,926.12	-
Equity compensation plans not approved by security holders				
Inducement Grant (2)	10,243	$	46.60	-
Total	4,567,955	$	6.65	1,452,807

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

(2) In connection with the hiring of Mr. Fraser on February 1, 2016, Mr. Fraser was awarded an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4) in the form of an option to purchase 10,243 shares of our common stock, representing 2.5% of our outstanding shares.

Security Ownership of Certain Beneficial Owners

The following table sets forth information regarding the beneficial ownership of our common stock, unless otherwise noted as of April 5, 2019, (i) by each current director and each Named Executive Officer , (ii) as of April 5, 2019, by all directors and executive officers as a group, and (iii) as of the date noted in each related footnote, by the entities known by us to be the beneficial owners of more than five percent of the outstanding shares of our common stock.

Name and Address of Beneficial Owner (1)	Common Stock	Common Stock Equivalents (2)	Total Beneficial Ownership	Percentage of Class Beneficially Owned (1)
Non-Executive Directors				
James Huang (3)	4,641,760	2,451,173	7,092,933	*
John R. Leone	1,212	1,848	3,060	*
Joseph M. Mahady	1,160	1,869	3,029	*
Bruce A. Peacock	1,160	1,986	3,146	*
Brian D. Schreiber, M.D.	-	-	-	*
Named Executive Officers				
Craig Fraser	62,931	15,261	78,192	*
Steven G. Simonson, M.D.	30,888	6,074	36,962	*
John A. Tattory	26,635	5,414	32,049	*
Executive Officers and Directors as a group (9 persons)	**4,766,837**	**2,487,418**	**7,254,255**	**0.86%**
5% Security Holders				
Name and Address				
Lee's Pharmaceutical Holdings Limited (4) 1/F, Building 20E, Phase 3 Hong Kong Science Park Shatin, Hong Kong	12,193,953	1,107,786	13,301,739	40.02%
Panacea Venture Healthcare Fund I L.P. (5) #6 Lane 1350 Middle Fuxing Rd. Xuhui District Shanghai, China 200319	4,527,345	2,451,173	6,978,518	14.09%
Bioengine Capital (6) Bioengine Technology Development, Inc.	3,551,750	1,131,836	4,683,586	14.08%

7F, No. 3-2 Park St.				
Nangang District Taipei City 1 15				
Taiwan				
Republic of China				
Ivy Blue Holding Limited (7)	4,336,790	-	4,336,790	13.50%
(KPCB China II)				
No. 6 Lane 1350 Middle Fuxing Rd.				
Xuhui District				
Shanghai, China 200319				
Tyrus-DA Global Healthcare No. 1 (8)	2,530,137	1,265,068	3,795,205	9.99%
Tyrus Holdings				
#1904 Trade Tower				
Yeongdongdaero 511				
Gangnam-gu, Seoul, Korea (06164)				

* Less than 1%.

(1) Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended ("Exchange Act") and includes voting and investment power with respect to shares of common stock. Shares of common stock and shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days after April 6, 2018 held by each person or group named above, are deemed outstanding for computing the percentage ownership of the person or group holding any options or warrants but are not deemed outstanding for purposes of computing the percentage ownership of any other person or group. As of April 5, 2019, there were 32,133,189 shares of common stock issued and outstanding. The address of each individual person is c/o Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622.

(2) Except where noted, Common Stock Equivalents include shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days after April 5, 2019 held by each person or group named above.

(3) This information is based on a Form 3 filed with the SEC by Mr. Huang, and Mr. Huang disclaims beneficial ownership of the shares held by the fund, except to the extent of his pecuniary interest therein.

(4) This information is based on the following: a Form 4/A filed with the SEC by Lee's, a Form 3 filed with the SEC by China Cardiovascular Focus Limited (China Cardiovascular) and Pharmaceutical International Limited (Lee's International), and a Form 4/A filed by LPH II Investments Limited (LPH II) on December 26,2018; and a Schedule 13D/A filed with the SEC by Lee's and LPH, a Schedule 13 D filed with the SEC by Lee's International and China Cardiovascular, and a Schedule 13D/A filed by LPH II on December 31, 2018, including with respect to the following: (i) Lee's holds directly a beneficial ownership interest in 66,900 shares of common stock and 1,338 Series A-1 Warrants to purchase 66,900 shares of common stock at an exercise price per share of $27.40, which were acquired on February 13, 2017 in a unit offering consisting of Series A Convertible Preferred Stock and Series A-1 Warrants at a unit price of $1495; on November 8, 2018, Lee's converted its Preferred Stock into 66,900 shares of common stock pursuant to an Exchange Agreement with us. Lee's ability to exercise the Series A-1 warrants is initially restricted (which restriction may be adjusted on 61 days' notice to us) to the extent that, upon exercise, the number of shares then beneficially owned by Lee's and its affiliates and any other person or entities with which Lee's would constitute a group under §13(d) of the Exchange Act would exceed 9.99% of the total number of shares then outstanding (the "Ownership Cap"); as a result of the Ownership Cap, Lee's is currently unable to exercise its Series A-1 Warrants; (ii) on December 21, 2018, LPH II, a wholly-owned subsidiary of Lee's, converted $6.0 million of existing debt obligations in the Private Placement Financing on the same terms as other investors and received 1,810,938 shares of common stock, 307,859 Series F Warrants to purchase 307,859 shares of common stock at an exercise price per share of $3.68, and 597,610 Series G Warrants to purchase 597, 610 shares of common stock at an exercise price per share of $4.05. In addition, on March 30, 2018, LPH II invested $2.6 million in us and acquired 541,667 shares of common stock and 135,417 Series C Warrants to purchase 135,417 shares of common stock. The Series C Warrants are not currently exercisable due to an ownership cap restriction. As a result of the foregoing, LPH II holds directly 2,352,605 shares of common stock, 307,859 Series F Warrants to purchase 307,859 shares of common stock, 597,610 Series G Warrants to purchase 597,610 shares of common stock, and 135,417 Series C warrants to purchase 135,417 shares of common stock. LPH II is currently unable to exercise the Series C, F and G warrants due to an ownership cap restriction. Lee's holds an indirect beneficial interest in these securities based upon its ownership of 100% of LPH II; (iii) in connection with the CVie Acquisition, China Cardiovascular, a wholly-owned subsidiary of Lee's International and a former shareholder of CVie Therapeutics, received 8,063,861 shares of common stock in the merger at an exchange ratio of .3512 share of our common stock for each share of CVie common stock. Of this amount, 984,000 shares are held in escrow with our transfer agent for a one-year period to secure the performance of Lee's under an indemnification letter agreement indemnifying the holders of our common stock as of December 20, 2018 for losses incurred by us in connection with any material inaccuracy in any representation or warranty made by CVie in the merger agreement to which CVie is a party (notwithstanding any lack of survival after closing of the representations and warranties made by CVie therein).] China Cardiovascular holds its beneficial interest in such shares directly. The beneficial interest of Lee's International is indirect and is based on its ownership of 100% of China Cardiovascular, and the beneficial interest of Lee's is indirect and is based on Lee's ownership of 100% of Lee's International; (iv) effective October 27, 2017, LPH, at the time a wholly-owned subsidiary of Lee's, invested $10.0 million in us and acquired 2,311,604 shares of common stock. Following a transaction in which a passive investor acquired from Lee's a 26% interest in LPH, Lee's holds a 74% interest in LPH and LPH holds shared voting power with respect to 2,311,604 shares of common stock, all of which may be attributed to Lee's

(5) This information is based on a Schedule 13D filed with the SEC by Panacea Venture Healthcare Fund I, L.P. (the Fund), Panacea Venture Healthcare Fund GP I, L.P. the general partner of the Fund (the Immediate GP), Panacea Venture Healthcare Fund GP Company, Ltd., the general partner of the Immediate GP (the Parent GP) and Panacea Venture Management Company Ltd. (the Management Company and together with Parent GP, Immediate GP and the Fund, the Panacea Entities), on December 21, 2018 with respect to 6,791,018 of our shares owned by the Panacea Entities, which includes 769,649 shares issuable upon exercise of Series F Warrants and 1,494,024 shares issuable upon exercise of Series G Warrants. Mr. Huang serves as a director of the Fund, the Parent GP and the Management Company. In addition, the Management Company owns 187,500 Series D Warrants to purchase 187,500 shares of our common stock. The Panacea Entities may be deemed to constitute a "group" within the meaning of Section 13(d)(3) of the Exchange Act.

(6) This information is based on a Form 3 and a Schedule 13G filed with the SEC on March 21, 2019, with respect to 3,551,750 shares of common stock owned by the following persons: Center Laboratories, Inc. (Center) and Bioengine Capital Inc. (Bioengine). The beneficial ownership for Bioengine is based on 3,551,750 shares of common stock issued directly to Bioengine. The beneficial ownership percentage of Center is indirect and is based on Center's ownership of 58.6% of the equity interest in Bioengine.

(7) This information is based on a Form 3 and Schedule 13D filed with the SEC on December 31, 2018, with respect to 4,336,790 shares of common stock owned by Ivy Blue Holding Limited (Ivy Blue) and KPCB China Fund II, L.P. and affiliates. The beneficial ownership for Ivy Blue is based on 4,336,790 shares of common stock owned directly by Ivy Blue. The indirect beneficial ownership of KPCB China Fund II, L.P. is based on its ownership of 100% of Ivy Blue. In addition, KPCB China Associates II, L.P. is the general partner of KPCB China Fund II, L.P. KPCB China Holdings II, Ltd. is the general partner of KPCB China Associates II, L.P. The directors of KPCB China Holdings II, Ltd. are Brook Byers, Wen Hsieh, James Huang and Theodore Schlein. By virtue of these relationships, Brook Byers, Wen Hsieh, James Huang and Theodore Schlein may be deemed to indirectly beneficially own the securities held by Ivy Blue Holdings Limited; however each disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.

(8) With respect to the Private Placement Financing on December 21, 2018, we issued to Tyrus-DA Global Healthcare No. 1 – 2,530,137 shares of common stock, 430,123 Series F Warrants to purchase 430,123 shares of common stock, and 834,945 Series G Warrants to purchase 834,945 shares of common stock.

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

Except as noted below, there were no reportable transactions between us and any person that is a related party to us since the beginning of our fiscal year ended December 31, 2017 through December 31, 2018. Any proposed transaction between us and any related party that involves an amount in excess of approximately $120,000 (the lower of $120,000 and one percent of the average of our total assets at year end for the last two completed fiscal years) must be submitted to, and reviewed and approved by, the Audit Committee of the Board. The Audit Committee will make its determination based on the particular circumstances of the proposed transaction, including whether the proposed transaction is in our best interest and does not involve an expense in excess of that which would likely be incurred in an arms' length transaction. In reviewing such transactions, the Audit Committee refers to our written corporate policies related to conflicts of interest and related party transactions.

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

For a discussion of our related party transactions with Lee's Pharmaceutical Holdings Limited and affiliates, please refer to "Item 1 – Lee's Pharmaceutical Holdings Limited And Affiliates."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

The following table sets forth all fees paid or accrued by us for professional services rendered by Ernst & Young LLP, our independent registered public accounting firm, during the years ended December 31, 2018 and 2017:

Fee Category	2018	% of Total	2017	% of Total
Audit fees	$ 475,000	52%	$ 375,000	75%
Audit-related fees	445,000	48%	123,000	25%
Total fees	$ 920,000	100%	$ 498,000	100%

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

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

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

Pre-Approval Policies

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

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

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

ITEM 16. FORM 10-K SUMMARY.

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

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	Incorporated by reference to Exhibit 3.1 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 17, 2018
3.2	Amended and Restated By-Laws	Incorporated by reference to Exhibit 3.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 18, 2016
4.1	Form of Warrant dated October 10, 2014	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
4.6	Form of Series D Warrant dated July 2, 2018	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 6, 2018
4.7	Form of Series E Warrant dated December 11, 2018	Incorporated by reference to Exhibit 4.7 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
4.8	Form of Series F Warrant dated December 24, 2018	Incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
4.9	Form of Series G Warrant dated December 24, 2018	Incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
4.10	Form of Series H Warrant dated February 14, 2019	Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
10.1+	Sublicense Agreement dated 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 dated March 28, 2008, between Windtree and Philip Morris USA Inc.,	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 dated March 28, 2008, between Windtree and Philip Morris Products S.A.	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 dated 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 December 3, 2004, 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 June 12, 2017, 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 August 14, 2017 to the License Development and Commercialization Agreement between Windtree and Lee's Pharmaceutical (HK) Ltd. dated 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 2011 Long-Term Incentive Plan, as amended	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 31, 2018
10.9*	Form of Employee Option Agreement under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012
10.10*	Form of Non-Employee Director Option Agreement under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012
10.11*	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.11 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015
10.12*	Form of Restricted Stock Unit Award Agreement for Employees under Windtree's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.14 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on April 17, 2018
10.13*	Employment Agreement dated February 1, 2016, 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
10.14*	Inducement Stock Option Award Agreement dated February 1, 2016, between Windtree and Craig Fraser	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016

10.15*	Amendment dated March 13, 2018, to Employment Agreement dated February 1, 2016, 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
10.16*	Employment Agreement dated December 19, 2014, 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
10.17*	Amendment dated December 29, 2014 to Employment Agreement dated December 19, 2014, effective as of April 1, 2015, 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
10.18*	Amendment dated March 13, 2018, to Employment Agreement dated December 19, 2014 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
10.19*	Employment Agreement dated March 21, 2014, 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
10.20*	Amendment dated December 29, 2014 to Employment Agreement dated March 21, 2014, effective as of April 1, 2015, 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
10.21*	Amendment dated March 13, 2018 to Employment Agreement dated March 21, 2014 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
10.22*	Form of Indemnification Agreement between Windtree and certain 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
10.23*	Form of Indemnification Agreement between Windtree and certain named directors	Incorporated by reference to Exhibit 10.23 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.24	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, 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
10.25	Second Amendment to Lease Agreement dated January 3, 2013 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
10.26	Fourth Amendment to Lease Agreement dated April 29, 2016, 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
10.27	Fifth Amendment to Lease Agreement dated February 23, 2018, 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
10.28+	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

10.29+	Supply Agreement dated December 22, 2010 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
10.30	Exchange and Termination Agreement dated 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
10.31	Registration Rights Agreement dated 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
10.32	Registration Rights Agreement dated 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
10.33	Payment Restructuring Agreement effective December 7, 2018, 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 December 7, 2018
10.34	Loan Agreement dated October 25, 2018, between CVie Therapeutics, Lee's Pharmaceutical Holdings Limited, and O-Bank Co., Ltd.	Incorporated by reference to Exhibit 10.34 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.35	Shareholder Loan Agreement dated April 24, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics	Incorporated by reference to Exhibit 10.35 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.36	Shareholder Loan Agreement dated September 20, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics	Incorporated by reference to Exhibit 10.36 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.37	Shareholder Loan Agreement dated October 26, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics	Incorporated by reference to Exhibit 10.37 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.38	Shareholder Loan Agreement dated November 16, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics	Incorporated by reference to Exhibit 10.38 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
10.39	Merger Agreement dated December 21, 2018, between Windtree, WT Acquisition Corp., and CVie Investments Limited	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
10.40	Indemnification Letter Agreement dated December 21, 2018, between Windtree and Lee's Pharmaceutical Holdings Limited	Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
10.41	Securities Purchase Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto	Incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
10.42	Registration Rights Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto	Incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018
21.1	Subsidiaries of Windtree	Incorporated by reference to Exhibit 21.1 to the Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019

23.1	Consent of Ernst & Young LLP, independent registered public accounting firm	Incorporated by reference to Exhibit 23.1 to the Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
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
99.1	Rule 201c Temporary Hardship Exemption for XBRL files	Incorporated by reference to Exhibit 99.1 to the Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019
101.1	The following consolidated financial statements from the Windtree Therapeutics, Inc. Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2018 and December 31, 2017, (ii) Statements of Operations for the years ended December 31, 2018 and December 31, 2017, (iii) Statements of Changes in Equity for the years ended December 31, 2018 and December 31, 2017, (iv) Statements of Cash Flows for the years ended December 31, 2018 and December 31, 2017, 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.

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 23, 2019

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 Officer)	April 23, 2019
/s/ John Tattory	John Tattory Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	April 23, 2019
/s/ James Huang	James Huang Director (Chairman of the Board)	April 23, 2019
/s/ John R. Leone	John R. Leone Director	April 23, 2019
/s/ Joseph M. Mahady	Joseph M. Mahady Director	April 23, 2019
/s/ Bruce A. Peacock	Bruce A. Peacock Director	April 23, 2019
/s/ Brian D. Schreiber	Brian D. Schreiber, M.D. Director	April 23, 2019

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

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Consolidated Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

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

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,187	$ 1,815
Available-for-sale marketable securities	13,959	-
Prepaid expenses and other current assets	507	422
Total current assets	25,653	2,237
Property and equipment, net	802	885
Restricted cash	171	225
Intangible assets	77,090	-
Goodwill	15,682	-
Total assets	$ 119,398	$ 3,347
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,420	$ 2,324
Collaboration and device development payable, net	2,576	4,418
Accrued expenses	6,465	4,134
Deferred revenue - current portion	198	884
Loan payable	7,974	-
Total current liabilities	20,633	11,760
Restructured debt liability - contingent milestone payments	15,000	15,000
Deferred revenue - non-current portion	-	407
Deferred tax liabilities	15,476	
Other liabilities	175	100
Total liabilities	51,284	27,267
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares and 2,701 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at December 31, 2018 and December 31, 2017; 32,133,263 and 3,227,495 shares issued at December 31, 2018 and December 31, 2017, respectively; 32,133,189 shares and 3,227,421 shares outstanding at December 31, 2018 and December 31, 2017, respectively	32	3
Additional paid-in capital	728,783	616,245
Accumulated deficit	(657,647)	(637,114)
Treasury stock (at cost); 74 shares	(3,054)	(3,054)
Total stockholders' equity	68,114	(23,920)
Total liabilities & stockholders' equity	$ 119,398	$ 3,347

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

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

	Year Ended December 31,	
	2018	**2017**
Revenues:		
Grant revenue	$ 765	$ 1,383
License revenue with affiliate	1,023	102
Total revenues	1,788	1,485
Expenses:		
Research and development	10,562	17,376
General and administrative	7,421	6,657
Total operating expense	17,983	24,033
Operating loss	(16,195)	(22,548)
Other income / (expense):		
Net loss on debt extinguishment	(3,345)	-
Gain on debt restructuring	-	5,824
Interest income	15	12
Interest expense	(1,409)	(1,863)
Other income, net	401	129
Other income / (expense), net	(4,338)	4,102
Net loss	$ (20,533)	$ (18,446)
AEROSURF warrant dividend	(12,505)	-
Deemed dividend on Series A preferred stock	(1,718)	(6,370)
Net loss attributable to common shareholders	$ (34,756)	$ (24,816)
Net loss per common share		
Basic and diluted	$ (7.74)	$ (24.14)
Weighted average number of common shares outstanding		
Basic and diluted	4,493	1,028

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

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, 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
Preferred stock conversions	(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	-	-	142	-	-	-	-	-	-
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)**
Net Loss			-	-	-	(20,533)	-	-	(20,533)
Preferred stock conversions	(3)	-	135	-	-	-	-	-	-
Issuance of common stock, Share Purchase Agreement, April 2018	-	-	542	1	2,540	-	-	-	2,541
Issuance of common stock and warrants, Share Purchase Agreement, December 2018, net of issuance costs	-	-	11,786	12	41,101	-	-	-	41,113
Issuance of common stock, placement agent	-	-	114	-	-	-	-	-	-
Issuance of common stock, CVie Acquisition	-	-	16,265	16	67,484	-	-	-	67,500
Vesting of restricted stock units	-	-	95	-		-	-	-	-
Withholding tax payments related to net share settlements of restricted stock units	-	-	(31)	-	(155)	-	-	-	(155)
Issuance of warrants, equity consideration in debt issuance	-	-	-	-	417	-	-	-	417
Issuance of warrants, equity consideration in payable restructuring	-	-	-	-	196	-	-	-	196
Stock-based compensation expense	-	-	-	-	955	-	-	-	955
Balance - December 31, 2018	**-**	**$ -**	**32,133**	**$ 32**	**$ 728,783**	**$ (657,647)**	**-**	**$ (3,054)**	**$ 68,114**

See notes to consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (20,533)	$ (18,446)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	160	192
Amortization of debt discount	863	-
Stock-based compensation	955	1,655
Amortization of prepaid interest	-	912
Net loss on extinguishment of debt	3,345	
Gain on debt restructuring	-	(5,824)
Gain on sale of equipment	(9)	
Changes in:		
Prepaid expenses and other current assets	302	90
Accounts payable	997	2,433
Collaboration and device development payable	(510)	(343)
Accrued expenses	(276)	(2,995)
Deferred revenue - current	(686)	884
Deferred revenue - non-current	(407)	407
Other liabilities	18	(10)
Net cash used in operating activities	(15,781)	(21,045)
Cash flows from investing activities:		
Cash acquired in CVie acquisition	223	-
Purchase of marketable securities	(13,959)	-
Proceeds from sale of property and equipment	9	-
Purchase of property and equipment	-	(24)
Net cash used in investing activities	(13,727)	(24)
Cash flows from financing activities:		
Proceeds from private placement issuance of securities, net of expenses	32,893	14,860
Proceeds from loan payable, net of expenses	6,160	3,900
Repayment of loan payable	(160)	-
Proceeds from convertible note payable	1,500	-
Repayment of convertible note payable	(1,500)	-
Payment for taxes related to net share settlements of restricted stock units	(155)	-
Proceeds from ATM Program, net of expenses	-	1,036
Principal payments on debt restructuring	-	(2,500)
Net cash provided by financing activities	38,738	17,296
Effect of exchange rates on cash	88	-
Net increase/(decrease) in cash, cash equivalents and restricted cash	9,318	(3,773)
Cash, cash equivalents and restricted cash - beginning of year	2,040	5,813
Cash, cash equivalents and restricted cash - end of year	$ 11,358	$ 2,040
Supplementary disclosure of cash flows information:		
Interest paid	$ 288	$ 1,088

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 and medical device company focused on developing drug product candidates and medical device technologies to address acute pulmonary and cardiovascular diseases. Historically, our focus has been on the development of our proprietary KL4 surfactant technology and aerosol delivery system (ADS) technology for the treatment and or prevention of respiratory distress syndrome (RDS) in premature infants. Following our merger with CVie Investments Limited in December 2018 (*see*, Note 3 – Business Combination), we are also focusing on therapies for acute heart failure and hypertension and associated organ dysfunction.

Our four lead development programs are (1) istaroxime for treatment of acute decompensated heart failure (ADHF), (2) AEROSURF® (lucinactant for inhalation) for non-invasive delivery of our lyophilized KL4 surfactant to treat RDS in premature infants, (3) lyophilized KL4 surfactant intratracheal suspension for RDS, and (4) rostafuroxin for genetically associated hypertension.

Heart failure is a chronic, progressive disease resulting from structural or functional cardiac abnormalities and is characterized by inadequate pumping function of the heart that results in fluid accumulation manifesting as pulmonary congestion, peripheral edema and congestion in other parts of the body. Insufficient cardiac output can result in inadequate peripheral perfusion that increases the risk of other organ dysfunction such as renal failure. Heart failure commonly but episodically worsens to a point of decompensation, a condition called ADHF. We are developing istaroxime for the treatment of ADHF. Istaroxime has a dual mechanism of action referred to as luso-inotropic, that may result in improvement in cardiac function to reduce congestion and edema and preserve other organ function while avoiding the side effects associated with other classes of heart failure therapies. Istaroxime has been evaluated in two phase 2 clinical trials, the results of which suggest that istaroxime may improve cardiovascular physiology as assessed by parameters of pump function, decreases in pulmonary capillary wedge pressure, decreases in heart rate, increases in blood pressure without adverse events such as arrhythmias, cardiac damage (as indicated by elevated troponin values) or adverse impact on kidney function. Based on preclinical and clinical studies performed to date, we believe that istaroxime, if approved, could potentially improve patients' heart failure symptoms and reduce complications and the length of hospital stays when compared to current therapeutic regimens for ADHF. In 2019, we plan to work with heart failure experts to review the program and engage with the FDA and regulators in the EU to determine next steps in clinical development for this potential novel therapy for ADHF.

AEROSURF (lucinactant for inhalation) is an investigational combination drug/device product that we are developing to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. Surfactants in the US are animal-derived and must be administered using endotracheal intubation, frequently with mechanical ventilation, invasive procedures that may result in serious respiratory conditions and other complications. AEROSURF is designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary aerosol delivery systems (ADS) technology, without invasive procedures. In 2017, we completed a phase 2b clinical trial, which based on the planned top-line results, did not meet the primary endpoint of reduction in nCPAP failure at 72 hours, due in large part, we believe, to an unexpected rate of treatment interruptions, which occurred in about 24% of active enrollments, predominantly in the 50-minute dose group. We believe the interruptions were primarily related to certain of the prototype phase 2 ADS with specific lots of disposable cartridge filters that had a higher tendency to clog. After excluding patients in the 50-minute dose group whose dose was interrupted, in accordance with the predesignated statistical plan, we observed 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 a result of these events, in 2019, we are planning to initiate an additional AEROSURF clinical bridging study that is designed, among other things, to clinically evaluate the design and performance of our new phase 3 ADS. This trial will not be powered to establish statistical significance but will generate additional higher dose treatment data to augment the higher dose data obtained in the phase 2b clinical trial. We believe that AEROSURF, if approved, has the potential to reduce the number of premature infants who are subjected to invasive surfactant administration, and potentially provide transformative clinical and pharmacoeconomic benefits. The FDA has granted Fast Track designation for our KL4 surfactant (including AEROSURF) to treat RDS.

We are also assessing potential development pathways to secure marketing approval for lyophilized KL4 surfactant as an intratracheal instillate for the treatment and/or prevention of RDS. Lyophilized KL4 surfactant is the drug product component of AEROSURF and a lyophilized dosage form of a liquid KL4 surfactant that was approved by the FDA in 2012 (SURFAXIN®). We previously discussed with the FDA a potential approach and plan potentially to re-engage with the FDA in the second half of 2019. If we can define an acceptable development plan that is achievable from a cost, timing and resource perspective, we may seek approval to treat premature infants who, because they are unable to breathe on their own or other reason, are not candidates for AEROSURF.

We also believe that our lyophilized KL4 surfactant may potentially support a product pipeline to address a broad range of serious respiratory conditions in children and adults. We are pursuing a number of early exploratory research efforts to identify potential product candidates, including a collaboration with Eleison Pharmaceuticals, Inc., a specialty pharmaceutical company developing life-saving therapeutics for rare cancers, to assess the feasibility of using our ADS potentially to deliver Eleison's inhaled lipid cisplatin (ILC), and with support from the National Institutes of Health (NIH), to address respiratory conditions.

Our fourth product candidate is rostafuroxin for the treatment of genetically associated hypertension. Rostafuroxin targets resistant hypertensive patients with a specific genetic profile, which is found in approximately 20% – 25% of the adult hypertensive population. We believe that rostafuroxin may reduce or normalize blood pressure in this genetically identified subset of patients and may reduce the risk of hypertension-related sequelae beyond the level normally associated with the absolute reduction of blood pressure, per se, because the molecular mechanism blocked by rostafuroxin may also be involved in organ damage. CVie Therapeutics completed three clinical trials assessing rostafuroxin, including a phase 2b clinical trial which was conducted in two parts, one in Caucasian patients in Italy and one in Chinese patients in Taiwan. While the blood pressure reduction in Caucasians was notable, there was no blood pressure response in Chinese patients. We are analyzing the results of these studies potentially to understand the reasons for the limited response in Chinese patients. In 2019, we plan to focus on finalizing the drug formulation and defining drug product analytical methods. We then to engage in business development activities potentially to out-license rostafuroxin to a larger company that has interest in and/or operates in the very large and broad antihypertension market.

The reader is referred to, and encouraged to read in its entirety, “Item 1 – Business – Company Overview” in this Annual Report on Form 10-K, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Note 2 – Basis of Presentation

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the US (US GAAP) and include accounts of Windtree and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. When necessary, prior year’s consolidated financial statements have been reclassified to conform to the current year presentation.

Note 3 – Business Combination

On December 21, 2018 (the Acquisition Date), we completed the acquisition of all the capital stock of CVie Investments Limited (CVie Investments), an exempted company with limited liability incorporated under the laws of the Cayman Islands, by issuing 16,256,060 shares of its common stock (CVie Acquisition). The preliminary purchase price for the CVie Acquisition was approximately $67.5 million. We plan to operate CVie and its wholly-owned subsidiary, CVie Therapeutics Limited (CVie Therapeutics, and together with CVie Investments, CVie), a Taiwan corporation organized under the laws of the Republic of China and CVie Investments' operating company, as a business division focused on development of drug product candidates in cardiovascular diseases. The CVie Acquisition was undertaken as part of a strategic initiative to create stockholder value and resulted from a multi-year process focused on identifying strategic opportunities, including potential strategic alliances, collaborations (primarily outside the United States), joint development opportunities, acquisitions, technology licensing arrangements, as well as potential combinations (including by merger or acquisition) or other corporate transactions.

In connection with the CVie Acquisition, our board of directors declared a dividend to the holders of record of outstanding shares of common stock, and holders of certain warrants to purchase common stock, that were outstanding on December 20, 2018 of 0.6148 Series H AEROSURF Warrant, for each share of common stock held by a shareholder or each warrant held by a warrant holder, as applicable, on the record date (AEROSURF Warrants). The AEROSURF Warrants are exercisable for an aggregate of 2,963,167 shares of common stock. Each AEROSURF Warrant has a term of five years and provides for automatic exercise into one share of common stock, without any exercise price, upon our public announcement of the dosing of the first human subject enrolled in our phase 3 clinical trial for AEROSURF. The AEROSURF Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815, Derivatives and Hedging – Contracts in Entity’s own Equity, and have been classified as equity. The $12.5 million fair value at issuance of the AEROSURF Warrants was determined using the Black-Scholes option-pricing model. The input assumptions used in the valuation are the historical volatility of our common stock price, the expected term of the warrants of two and a half years based on the expected date of the first human subject enrollment in our phase 3 clinical trial for AEROSURF, and the risk-free interest rate based on the average two-year and three-year treasury bill rate in effect at the measurement date.

Significant Input Assumptions of Warrant Valuation	
Historical volatility	116%
Expected term (in years)	2.5
Risk-free interest rate	2.62%

On the Acquisition Date, we entered into an indemnification letter agreement (the Indemnification Letter Agreement) with Lee’s Pharmaceutical Holdings Limited (Lee’s), pursuant to which Lee’s agreed to indemnify the holders of issued and outstanding shares of common stock on December 20, 2018 (the Indemnitees) for any loss, liability, damage or expense, including reasonable attorney’s fees and expenses incurred by us in connection with or, as a result of, any material inaccuracy in any representation or warranty made by CVie in the Merger Agreement (notwithstanding that the representations and warranties made by CVie do not survive after the closing of the merger). To secure Lee’s performance of this indemnity obligation, 984,000 of the shares issued to Lee’s affiliate in the Merger are being placed in escrow with our transfer agent, Continental Stock Transfer & Trust Company for one year. A portion of the escrowed shares will be transferred to the Indemnitees as the sole and exclusive remedy for a successful indemnity claim.

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The aggregate purchase price has been allocated based on the fair value of assets acquired and liabilities assumed as of the acquisition date. The excess of the $67.5 million acquisition consideration over the acquired net assets was recorded as goodwill. The goodwill recorded is not deductible for tax purposes. The following table summarizes the initial allocation of the purchase price to the estimated fair value of the net assets acquired and liabilities assumed.

(in thousands)		
Cash and cash equivalents	$	193
Restricted cash		31
Prepaid expenses and other current assets		387
Property and equipment, net		76
Intangible assets		77,090
Total identifiable assets acquired	$	77,777
Current liabilities	$	(2,590)
Loan payable, current		(3,453)
Loan payable, non current		(4,491)
Deferred tax liabilities, noncurrent		(15,418)
Other liabilities, noncurrent		(7)
Net identifiable assets acquired		51,818
Goodwill		15,682
Net assets acquired	$	67,500

The acquired identifiable intangible assets consist of in-process research and development (“IPR&D”) of approximately $77.1 million with an indefinite useful life. *See*, Note 5 for further discussion.

From the Acquisition Date to December 31, 2018, we recorded net loss from the CVie Acquisition of approximately $0.5 million.

The following table presents unaudited consolidated pro forma results of operations based on our historical financial statements and adjusted for the acquisition of CVie as if it occurred on January 1, 2017. The unaudited pro forma amounts were prepared for comparative purposes only and are not indicative of what actual consolidated results of our operations would have been, nor are they indicative of the consolidated results of operations in the future.

	Year Ended December 31,	
(in thousands, except per share data)	**2018**	**2017**
Pro forma net loss attributable to common shareholders	$ (38,082)	$ (34,616)
Pro forma EPS - basic and diluted	$ (1.20)	$ (1.19)

For the year ended December 31, 2018, net loss excludes the impact of transaction costs related to the CVie Acquisition. For the years ended December 31, 2018 and 2017, net loss excludes the impact of interest expense related to liabilities that were converted into common stock as part of the private placement.

Note 4 – Liquidity Risks and Management’s Plans

As of December 31, 2018, we had cash and cash equivalents of $11.2 million and available-for-sale, marketable securities of $14.0 million, current liabilities of $20.6 million, including $8.0 million of Loan payable (*see*, Note 11 - Loan Payable). As of April 5, 2019, we believe that we have sufficient resources (including marketable securities) available to support our development activities, business operations and debt service through October 2019.

Although we believe that the December 2018 CVie Acquisition and $39 million Private Placement Financing have improved our financial position and may better position us to raise the capital needed to fund our business plans, we expect to continue to incur significant losses and require significant additional capital to advance our istaroxime and AEROSURF clinical development programs, support our operations and business development efforts, and satisfy our obligations beyond October 2019, 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 a combination of public or private equity offerings and strategic transactions, including but not limited to potential alliances and collaborations focused on various individual markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be able to complete any public or private equity offerings on acceptable terms, or in amounts required to support our operations, if at all, or identify and enter into any strategic transactions that will bring the capital that we will require. 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.

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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, 2018, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Certificate of Incorporation, and approximately 72.0 million shares of common stock and 5.0 million shares of preferred stock available for issuance and not otherwise reserved.

Note 5 – Accounting Policies and Recent Accounting Pronouncements

Principles of consolidation

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the US (US GAAP) and include accounts of Windtree Therapeutics, Inc. and its wholly-owned subsidiaries, CVie Investments Limited and its wholly-owned subsidiary, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

Business combinations

We follow the acquisition method for an acquisition of a business where the purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values at the dates of acquisition. The excess of the fair value of purchase consideration over the fair value the assets acquired and liabilities assumed is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Management's estimate of fair value is based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and as such, actual results may differ materially from estimates.

Goodwill and intangible assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development ("IPR&D") assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. The following table represents identifiable intangible assets as of December 31, 2018:

(in thousands)		**Estimated Fair Value**
Istaroxime drug candidate	$	22,340
Rostafuroxin drug candidate		54,750
Total	$	77,090

Goodwill represents the excess of the purchase price over the fair value assets acquired and liabilities assumed in a business combination and is not amortized. We perform an annual impairment test for goodwill and evaluates the recoverability whenever events or changes in circumstances indicate that the carrying value of goodwill may not be fully recoverable. In making such assessment, qualitative factors are used to determine whether it is more likely than not that our fair value is less than our carrying value. If the estimated fair value is less than our carrying value, then an impairment loss is recorded.

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Foreign currency transactions

The functional currency for our foreign subsidiaries is US Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income (expense). Foreign currency transactions resulted in losses of approximately $0.1 million for the year ended December 31, 2018. There were no foreign currency transaction gains or losses for the year ended December 31, 2017.

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 at domestic and foreign financial institutions 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.

Marketable securities

Marketable securities consist of investments in US Treasury securities. Management determines the appropriate classification of these securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. We classify investments as available-for-sale pursuant to Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) 320, Investments—Debt and Equity Securities. Investments are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders’ equity and a component of total comprehensive loss in the consolidated statements of comprehensive loss, until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the years ended December 31, 2018 and 2017. There were no unrealized gains or losses on investments for the years ended December 31, 2018 and 2017.

We review investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment’s carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if we have experienced a credit loss, have the intent to sell the investment, or if it is more likely than not that we will be required to sell the investment before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

Available-for-sale marketable securities are classified as marketable securities, current or marketable securities, non-current depending on the contractual maturity date of the individual available-for-sale security.

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, 2018 and 2017, respectively. We determine the fair value of marketable securities on quoted market prices or other relevant information generated by market transactions involving identical or comparable assets. Accounts payable and accrued expenses are carried at cost, which approximates fair value because of their short maturity. The carrying amount of loan payable (including current installments) approximates fair value based on a comparison of interest rates on the loan to current market rates considering our credit risk.

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 principally of a $140,000 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 and $31,000 in deposits held by our landlord for our offices in Taipei, Taiwan, the former headquarters of CVie Therapeutics (*see,* – Note 18 – Commitments, for further discussion on our leases).

Long-lived assets

Our long-lived assets, primarily consisting of intangible assets, 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, 2018 and 2017 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 16 – Collaboration, Licensing and Research Funding Agreements.

Restructured debt liability – contingent milestone payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*see,* – Note 13 – 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.

Deferred revenue

Deferred revenue represents amounts received prior to satisfying the revenue recognition criteria (*see*, Revenue recognition) and are recognized as deferred revenue in our balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as Deferred revenue – current portion. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as Deferred revenue – non-current portion.

Deferred revenue primarily consists of amounts related to an upfront license fee received in July 2017 in connection with the License Agreement with Lee's. The revenue will be recognized as our performance obligations under the contract are met (*see*, Note 16 – Collaboration and Device Development Payment Restructuring, Licensing and Research Funding Agreements).

Revenue recognition

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, we recognize the cumulative effect of initially adopting ASC Topic 606, if any, as an adjustment to the opening balance of retained earnings. Additionally, under this method of adoption, we apply the guidance to all incomplete contracts in scope as of the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

In accordance with ASC Topic 606, we recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC Topic 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, we assess the goods or services promised within a contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We have concluded that our government grants are not within the scope of ASC Topic 606 as they do not meet the definition of a contract with a customer. We have concluded that the grants meet the definition of a contribution and are non-reciprocal transactions, and have also concluded that Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition does not apply, as we are a business entity and the grants are with governmental agencies.

In the absence of applicable guidance under US GAAP, effective January 1, 2018, we developed a policy for the recognition of grant revenue when the related costs are incurred and the right to payment is realized.

We believe this policy is consistent with the overarching premise in ASC Topic 606, to ensure that revenue recognition reflects the transfer of promised goods or services to customers in an amount that reflects the consideration that we expect to be entitled to in exchange for those goods or services, even though there is no exchange as defined in ASC Topic 606. We believe the recognition of revenue as costs are incurred and amounts become realizable is analogous to the concept of transfer of control of a service over time under ASC Topic 606.

Prior to January 1, 2018, we recognized revenue as related costs were incurred under the grants given that 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. Recognized amounts reflected our performance under the grants and equal direct and indirect costs incurred. Revenue and expenses under these arrangements were presented gross. Revenue recognition under this new policy is not materially different than would have been calculated under the old guidance. As a result of the adoption of this policy, there was no change to the amounts we have historically recorded in our financial statements.

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 15 – 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

A beneficial conversion feature 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.

Preferred Stock

The issuance of Series A Convertible Preferred Stock (Preferred Shares) in the first quarter of 2017 (see, "– Note 14 – Stockholders' Equity") resulted in a beneficial conversion feature. We recognized this feature by allocating the intrinsic value of the beneficial conversion feature, 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 years ended December 31, 2018 and December 31, 2017, we recognized a non-cash deemed dividend to the preferred shareholders of $1.7 million and $2.8 million, respectively, related to the Preferred Shares converted during the period. As of December 31, 2018, there were no Preferred Shares remaining to be converted.

Convertible Note

The issuance on July 2, 2018 of a Secured Convertible Promissory Note (the Note) to Panacea Venture Management Company Ltd. (Panacea) with respect to a loan facility in the aggregate amount of $1.5 million resulted in a beneficial conversion feature. We recognized this 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, resulting in a discount on the Note. We recorded the Note as current debt at its face value of $1.5 million less debt discount consisting of (i) $0.4 million related to the beneficial conversion feature and (ii) $0.4 million in fair value of the warrants issued in connection with the Note. The discount was accreted to the $1.5 million loan over its term using the effective interest method (*see*, – Note 11 – Loan Payable). On December 27, 2018, we repaid the Note in its entirety in cash of $1.5 million. As part of the extinguishment of debt, we recorded a gain on extinguishment of debt of approximately $0.4 million, relating to the reacquisition of the beneficial conversion option. The gain was calculated using the intrinsic value of the beneficial conversion option, which is the product of: (i) the difference between the common stock price on the date of extinguishment of $5.11 and the conversion price of $4.00, and (ii) 375,000 shares convertible into common stock.

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, 2018 and 2017, 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 14.4 million and 1.0 million shares, respectively. As of December 31, 2018 and 2017, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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.

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Business segments

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

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was subsequently amended by several other ASUs related to Topic 606 to, among other things, defer the effective date and clarify various aspects of the new revenue guidance including principal versus agent considerations, identifying performance obligations, licensing, and other improvements and practical expedients. We adopted ASU 2014-09, as amended, effective January 1, 2018 using the modified retrospective transition method. In June 2017, we entered into a License Agreement with Lee's Pharmaceutical (HK) Ltd. (Lee's (HK)), granting Lee's (HK) rights to develop and commercialize our products in a specific Asian territory. The consideration we are eligible to receive under this agreement includes an upfront payment, contingent revenues in the form of regulatory and commercial milestones, and sales-based milestone and royalty payments. We evaluated the License Agreement under ASU 2014-09 and determined that there was no material impact to revenues for any of the years presented upon adoption. Additionally, there were no revisions to any balance sheet components of revenues such as deferred revenues or beginning retained earnings as a result of using the modified retrospective method. The primary impact on our financial statements is related to revised or additional disclosures with respect to revenues and cash flows arising from contracts with customers (*See,* "– Note 16 – Collaboration, Licensing and Research Funding Agreements).

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 adopted ASU 2017-09 effective January 1, 2018 and the adoption did not have a material impact on our annual 2018 financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*. This ASU clarifies clarify how entities should classify certain cash receipts and cash payments related to eight specific cash flow issues, including debt prepayment or extinguishment costs, with the objective of reducing diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The ASU also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The ASU is effective retrospectively for the annual period ending December 31, 2018 and interim periods within that annual period. We adopted ASU 2016-15 effective January 1, 2018 and the adoption did not have a material impact on our annual 2018 financial statements.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. The FASB changed its definition of a business in an effort to help entities determine whether a set of transferred assets and activities is a business. The guidance requires an entity to first evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the set of transferred assets and activities is not a business. If the threshold is not met, the entity evaluates whether the set meets the requirements of a business, which includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The ASU is effective for the annual period ending December 31, 2018 and interim periods within that annual period. We adopted ASU 2017-01 effective January 1, 2018 and the adoption did not have a material impact on our annual 2018 financial statements.

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Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). 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 January 1, 2019. Early adoption is permitted. The standard requires a modified retrospective approach; however, the FASB recently added a transition option to the leases standard that allows entities to apply the new guidance in the year of transition rather than at the beginning of the earliest period presented. We have not elected to early adopt this standard. While we continue to assess all the effects of adoption, we believe the most significant effect relates to the recognition of right-of-use assets and corresponding liabilities on our consolidated balance sheet, primarily related to existing facility operating leases, and providing new disclosures with regards to our leasing activities.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment*. ASU 2017-04 simplifies the subsequent measurement of goodwill by removing the second step of the two-step impairment test and specifies that goodwill impairment should be measured by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. ASU 2017-04 is effective for annual or interim goodwill impairment tests performed in fiscal years beginning after December 15, 2019; early adoption is permitted. We currently anticipate that the adoption of ASU 2017-04 will not have a material impact on our financial statements.

Note 6 – License Revenue with Affiliate

(in thousands)	Year Ended December 31, 2018	2017
License revenue with affiliate	$ 1,023	$ 102

License revenue with affiliate for years ended December 31, 2018 and 2017 represents revenue from a License Agreement with Lee's (HK) and constitutes a contract with a customer accounted for in accordance with ASC Topic 606, which we adopted effective January 1, 2018 (*see*, Note 5 – Accounting Policies and Recent Accounting Pronouncements, and Note 16 – Collaboration, Licensing and Research Funding Agreements). There was no impact to License revenue with affiliate previously recognized as a result of the adoption of ASC Topic 606.

Note 7 – 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, 2018 and 2017:

(in thousands)	Fair Value December 31, 2018	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 5,234	$ 5,234	$ -	$ -
U.S. Treasury notes	19,912	$ 19,912		
Certificate of deposit	171	171	-	-
Total Assets	$ 25,317	$ 25,317	$ -	$ -

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(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	$ -	$ -

Note 8 – Property and Equipment

Property and equipment is comprised of the following:

(in thousands)	December 31, 2018	2017
Manufacturing, laboratory & office equipment	$ 4,359	$ 4,965
Furniture & fixtures	390	615
Leasehold improvements	2,469	2,458
Subtotal	7,218	8,038
Accumulated depreciation and amortization	(6,416)	(7,153)
Property and equipment, net	$ 802	$ 885

Depreciation expense on property and equipment for the years ended December 31, 2018 and 2017 was $0.2 million and $0.2 million, respectively.

Note 9 – Collaboration and Device Development Payable

Collaboration and device development payable represents amounts due to Battelle under a collaboration agreement related to the development of our phase 3 ADS (*see*, Note 16 – Collaboration, Licensing and Research Funding Agreements) and a Research and Development Services Agreement (RDSA) dated June 2012 for our prototype phase 2 ADS. As of December 31, 2018 and 2017, collaboration and device development payable was $2.6 million and $4.4 million, respectively, including accrued interest.

Restructuring of the Battelle Payables

On December 7, 2018, we entered into a payment restructuring agreement with Battelle Memorial Institute ("Battelle") in which we agreed to the following: (i) the outstanding amounts owing under the Collaboration Agreement and RDSA (such amounts, the Battelle Payables) will continue to accrue interest at a rate of 6.0% per annum and shall be payable on a monthly basis or any unpaid interest shall be added to the balance of the Battelle Payables, (ii) we and Battelle will continue the development activities relating to AEROSURF under the RDSA, and we will prepay for services to be provided by Battelle until we have repaid $3.0 million of the Battelle Payables, after which time, services incurred shall be payable upon 30 days of receipt of the invoice, (iii) Battelle participated in the December 2018 Private Placement Financing for $1.0 million in a debt-equity exchange for a like amount of Battelle Payables (*see*, Note 14 – Stockholders' Equity), (iv) upon the closing of the Private Placement Financing, we paid Battelle cash in the amount of $972,281, and thereafter initiated payments totaling an aggregate $1,250,000, payable in five equal, consecutive monthly installments of $250,000, and (v) increased the royalty cap previously set forth in the collaboration agreement from $25.0 million to $35.0 million. In addition, we have agreed to make two milestone payments to Battelle as follow: (i) upon enrollment of the first patient in the next AEROSURF clinical study, an amount equal to one half of the then-outstanding Battelle Payables (including unpaid interest), and (ii) when we complete the device technology transfer for the phase 3 ADS to Mack, an amount equal to the then-outstanding Battelle Payables, including unpaid interest. If any amounts of the Battelle Payables remain unpaid by December 31, 2019, then all unpaid Battelle Payables will be due on January 7, 2020.

Management determined the payment restructuring agreement of the Battelle Payables do not represent a troubled debt restructuring as Battelle did not grant us a concession. Further, the payment restructuring agreement constitutes a debt modification as the restructured terms do not result in a substantially different instrument.

In connection with the payment restructuring agreement, we also issued to Battelle Series E Warrants ("Series E Warrants") to purchase 75,000 shares of common stock, at an exercise price equal to $6.50 per share ("the Exercise Price"). The Series E Warrants may be exercised after the date of issuance through the 5-year anniversary of the date of issuance on December 11, 2023. The Series E Warrants may not be exercised to the extent that the holder thereof would, following such exercise or conversion, beneficially own more than 9.99% (or other percent as designated by each holder) of our outstanding shares of common stock. The Series E Warrants contain customary provisions that adjust the Exercise Price and the number of shares of common stock into which the Series E Warrants are exercisable in the event of a corporate transaction.

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The Series E Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815, Derivatives and Hedging – Contracts in Entity's own Equity, and have been classified as equity. The fair value at issuance of the Series E Warrants was determined using the Black-Scholes option-pricing model. The input assumptions used in the valuation are the historical volatility of our common stock price, the expected term of the warrants, and the risk-free interest rate based on the five-year treasury bill rate in effect at the measurement date.

Significant Input Assumptions of Warrant Valuation	
Historical volatility	103%
Expected term (in years)	5
Risk-free interest rate	2.70%

As of December 31, 2018, we had accrued interest expense relating to the Battelle Payables of $0.3 million.

Extinguishment of Collaboration and Device Development Payable

On December 21, 2018, as part of the Private Placement Financing, we converted $1.0 million of existing Battelle Payables on the same terms as the Investors of the Private Placement Financing. In connection with the conversion of the Battelle Payables, we issued: (i) 301,823 shares of common stock based at $3.3132 per share, (ii) Series F Warrants to purchase 51,310 shares of common stock, at an exercise price equal to $3.68 per share, and (iii) Series G Warrants to purchase 99,602 shares common stock, at an exercise price equal to $4.05 per share. The Series F Warrants are exercisable at any time after the date of issuance and through the 18th month anniversary of the date of issuance and the Series G Warrants may be exercise through the 5-year anniversary of the date of issuance.

The conversion of the Battelle Payables is treated as an extinguishment of outstanding liabilities. We recorded a loss on extinguishment of debt of approximately $0.5 million. The loss was calculated as the difference between: (i) the aggregate fair value of approximately $1.5 million, based on the fair value of the common stock and Warrants on December 21, 2018 and (ii) the carrying value of the Battelle Payables of $1.0 million.

Note 10 – Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	December 31, 2018	December 31, 2017
Professional fees	$ 2,473	$ 412
Research and development	2,361	1,778
Salaries, bonus & benefits	815	1,008
Manufacturing operations	212	537
Other	604	399
Total accrued expenses	$ 6,465	$ 4,134

Note 11 – Loan Payable

In January 2018 and March 2018, LPH Investments Limited ("LPH"), an affiliate of Lee's, agreed to lend us $1.5 million and $1.0 million, respectively, to support our AEROSURF development activities and sustain our operations while we sought to identify and advance one or more potential strategic initiatives as defined in the related loan agreements (Funding Event). The loans 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. To secure our obligations under these loans, we granted LPH a security interest in substantially all our assets pursuant to the terms of a Security Agreement with LPH dated March 1, 2018 (LPH Security Agreement).

During the third and fourth quarters of 2018, LPH agreed to lend us funds to sustain our operations while we continued to work on a strategic transaction. The initial loan was funded on August 14, 2018 in the amount of $0.3 milliopn, and subsequent loans on the following dates and in the following amounts: August 29, 2018, in the amount of $0.48 million; September 12, 2018 in the amount of $0.5 million; September 27, 2018 in the amount of $0.5 million; October 19, 2018 in the amount of $0.43 million; November 2, 2018 in the amount of $0.5 million; November 19, 2018 in the amount of $0.35 million; and December 5, 2018 in the amount of $0.6 million. The loans accrued interest at a rate of 6% per annum and matured upon the earlier of (i) the closing date for the strategic transaction (as defined in the related loan agreements), provided that the we were able to raise a minimum of $30 million in connection with such transaction, or (ii) March 31, 2019. In each case, we granted to LPH a security interest in substantially all of our assets pursuant to the terms of the LPH Security Agreement.

Extinguishment of Loan Payable

On December 21, 2018, as part of the Private Placement Financing, we converted $6.0 million of existing loan payable obligations to LPH on the same terms as those of the Investors of the private placement. In connection with the conversion of Lee's debt, we issued: (i) 1,810,938 shares of common stock based at $3.3132 per share, (ii) Series F Warrants to purchase 307,859 shares of common stock, at an exercise price equal to $3.68 per share, and (iii) Series G Warrants to purchase 597,610 shares common stock, at an exercise price equal to $4.05 per share. The Series F Warrants are exercisable at any time after the date of issuance and through the 18-month anniversary of the date of issuance and the Series G Warrants may be exercised through the 5-year anniversary of the date of issuance.

The conversion of the loan payable to LPH is treated as an extinguishment of debt and does not represent a capital transaction as the Private Placement Financing included third-party investors and all investors received identical terms. We recorded a loss on extinguishment of debt approximately $3.2 million. The loss was calculated as the difference between: (i) the aggregate fair value of approximately $9.2 million, based on the fair value of the common stock and Warrants on December 21, 2018, and (ii) the carrying value of the debt liabilities of $6.0 million.

The balance of the loan payable to LPH of $160,000 was paid along with accrued interest of $182,000 on December 27, 2018.

Assumption of bank debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $4.5 million (or NTD $138.0 million) in a bank credit facility due in March 2020.

In September 2016, CVie entered into a 12-month revolving credit facility of approximately $2.9 million (or NTD $90.0 million) with O-Bank Co., Ltd. to finance operating activities. The facility was later renewed and increased to approximately $5.84 million (or NTD $180.0 million) in September 2017. The credit facility was guaranteed by Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. The guaranty was part of the facility; however, we do not have a written commitment from Lee's to maintain the collateral. Interest, payable in cash on a monthly basis, is determined based on 90-day TAIBOR (the Taipei Interbank Offer Rate) plus 0.91%. The credit facility will expire on September 11, 2019 and matures six months after the expiration date, on March 11, 2020. Although we reached an understanding with Lee's that it would maintain the bank deposits securing its guaranty obligation under the credit facility, we do not have a written agreement with Lee's requiring it to do so; therefore, the $4.5 million outstanding under the facility has been classified as a current liability on the balance sheet.

As of December 31, 2018, the outstanding principal was approximately $4.5 million (or NTD $138.0 million), due to exchange rate fluctuations.

Assumption of Lee's debt as part of the CVie Acquisition

As part of the CVie Acquisition, we assumed approximately $3.5 million (or NTD $106.2 million) of debt payable to Lee's Pharmaceutical International Limited (Lee's International).

From April 24, 2018 to November 16, 2018, CVie entered into four separate agreements to borrow an aggregate of approximately $3.5 million from Lee's International. The terms of the loan agreements are identical where the interest, payable in cash upon maturity, is 4% per annum and each of the four separate loans will mature one year from the effective date as follows: $0.5 million in April 2019; $0.3 million in September 2019; $0.2 million in October 2019; and $2.5 million in November 2019.

As of December 31, 2018, the outstanding principal was approximately $3.5 million (or NTD $106.2 million), due to exchange rate fluctuations.

Note 12 – Convertible Note Payable

On July 2, 2018, we issued to Panacea Venture Management Company Ltd. (Panacea) a Secured Convertible Promissory Note (the Note) with respect to a loan facility in the aggregate amount of up to $1.5 million, which was funded in two loans of, $1.0 million on the date of the Note and $0.5 million on July 23, 2018. The Note had a maturity date of December 31, 2018 and accrued interest at a rate of 15% per annum until the Note was paid in full or converted into shares of our common stock at a price per share of $4.00. In addition, in lieu of converting the Note, Panacea could deliver the Note into a private placement in which Panacea Venture Healthcare Fund I L.P., an affiliate of Panacea, participated. In connection with these Loans, we granted to Panacea a security interest in substantially all our assets.

In connection with the Note, we issued to Panacea warrants (the "Series D Warrants") to purchase 187,500 shares (the "Warrant Shares") at an exercise price of $4.00 per Warrant Share (the "Exercise Price"). The Warrants may be exercised at any time beginning six months after the date of issuance and through the fifth anniversary of the date of issuance. The Warrants may not be exercised to the extent that the holder would, following such exercise, beneficially own more than 9.99% of our outstanding shares of common stock, which percentage may be increased, decreased or waived by such holder upon sixty-one days' notice to us. The Warrants also contain customary provisions that adjust the Exercise Price and the number of Warrant Shares in the event of a corporate transaction.

We recorded the Note as current debt at its face value of $1.5 million less debt discounts consisting of (i) $0.4 million fair value of the warrants issued in connection with the Note and (ii) a $0.4 million beneficial conversion feature related to an embedded conversion option that had an effective conversion price that was less than the fair value of the underlying stock at the commitment date. The discount is being accreted to the $1.5 million loan over its term using the effective interest method. The Panacea Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815, *Derivatives and Hedging – Contracts in Entity's Own Equity*, and have been classified as equity.

The fair value at issuance of the Panacea Warrants was determined using the Black-Scholes option-pricing model. The input assumptions used in the valuation are the historical volatility of our common stock price, the expected term of the warrants, and the risk-free interest rate based on the five-year treasury bill rate in effect at the measurement date.

Significant Input Assumptions of Warrant Valuation	
Historical volatility	103%
Expected term (in years)	5
Risk-free interest rate	2.75%

The following amounts comprise the convertible note interest expense for the periods presented:

(in thousands)	Year Ended December 31, 2018
Non-cash amortization of debt discounts	$ 833
Cash interest expense	106
Total convertible note interest expense	$ 939

Extinguishment of Panacea Convertible Promissory Note

On December 27, 2018, we repaid the Note in its entirety in cash of $1.5 million. As part of the extinguishment of debt, we recorded a gain on extinguishment of debt of approximately $0.4 million, relating to the reacquisition of the beneficial conversion option. The gain was calculated using the intrinsic value of the beneficial conversion option, which is the product of: (i) the difference between the common stock price on the date of extinguishment of $5.11 and the conversion price of $4.00, and (ii) 375,000 shares convertible into common stock.

Note 13 – Restructured Debt Liability

(in thousands)	December 31, 2018	December 31, 2017
Restructured debt liability - contingent milestone payments	$ 15,000	$ 15,000

On November 1, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P. (Deerfield Loan) in the aggregate principal amount of $25 million 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) 71,111 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain milestone payments based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. 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 5 – Accounting Policies and Recent Accounting Pronouncements). 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.

Note 14 – Stockholders' Equity

Private Placement Offerings

December 2018 Private Placement Financing

On December 21, 2018, we completed a private placement offering and entered into a Registration Rights Agreement with select institutional investors (Investors), for the purchase of an aggregate of 11,785,540 shares of common stock at a price per share of $3.3132, for an aggregate purchase price of approximately $39.0 million (Private Placement Financing). Included in the purchase price, each of LPH II Investments Limited (LPH II), an affiliate of Lee's Pharmaceutical Holdings Ltd. (Lee's), and Battelle, converted $6.0 million and $1.0 million, respectively, of existing debt obligations on the same terms as the other Investors. In connection with the offering, we issued (i) Series F Warrants to purchase an aggregate of 2,003,541 shares of common stock at an exercise price equal to $3.68 per share, which are exercisable through the 18-month anniversary of the date of issuance (the Series F Warrants), and (ii) Series G Warrants to purchase an aggregate of 3,889,229 shares of common stock at an exercise price equal to $4.05 per share, which are exercisable through the 5-year anniversary of the date of issuance (the Series G Warrants and, together with the Series F Warrants, the December 2018 Warrants). The December 2018 Warrants (i) may not be exercised to the extent that following such exercise, the holder would beneficially own more than 9.99% (or other percent as designated by each holder) of our outstanding shares of common stock, and (ii) contain customary provisions that adjust the exercise price and the number of shares of common stock into which the December 2018 Warrants are exercisable in the event of a corporate transaction.

Under the Registration Rights Agreement, we agreed to file by May 1, 2019 a resale registration statement with the SEC to register for subsequent resale the shares of common stock issued in the Private Placement Financing and the shares of common stock to be issued upon exercise of the December 2018 Warrants.

April 2018 Private Placement

On April 4, 2018, we completed a private placement offering and entered into a Registration Rights Agreement with LPH II for the purchase of $2.6 million of our common stock at a purchase price per share of $4.80, and issued 541,667 shares of common stock and warrants to purchase 135,417 shares of our 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. Under the Registration Rights Agreement, we agreed to file 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.

Share Purchase Agreement

Effective October 27, 2017, we entered into a Share Purchase Agreement (SPA) with LPH, an affiliate of Lee’s. Under the agreement, LPH invested $10 million (the Investment) in our common stock and acquired 2,311,604 shares (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). Although the SPA granted LPH the right to appoint up to two individuals to serve on our Board of Directors, and LPH was permitted to designate such individuals on or prior to the 30th day following the closing of the transactions contemplated by the SPA (the Closing) no such appointments were made. 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.

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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 consisted of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares); and (ii) Series A-1 Warrants to purchase 50 shares of common stock at an exercise price equal to $27.40 per share. Each Preferred Share was convertible at the holder's option at any time into 50 shares of common stock. The Series A-1 Warrants may be exercised through February 15, 2024. The Preferred Shares and Series A-1 Warrants may not be converted or exercised to the extent that the holder would, following such exercise or conversion, would 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 would have had 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 received in the aggregate up to three times its original investment. In addition to the offering, the securities purchase agreement also provided that, until February 13, 2018, the investors were entitled to participate in subsequent bona fide capital raising transactions.

To facilitate consummation of the Share Purchase Agreement in October 2017 (see – Share Purchase Agreement), Battelle, which held 1,095 Preferred Shares, 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, 2018, all outstanding Preferred Shares have been converted into shares of common stock.

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). We were not required to sell any shares at any time during the term of the ATM Program.

If we issued a sale notice to Stifel, we may have designated 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 was 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.

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, 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 SEC. For the year ended December 31, 2017, the match resulted in the issuance of 7,561 shares of common stock. Expense associated with the 401(k) match for the year ended December 31, 2017 was $0.1 million. During 2018, we did not have a company match.

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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, 2018	December 31, 2017	Exercise Price	Expiration Date
Investors - Aerosurf	2,963	-	$ -	02/14/24
Investors - December 2018 financing - long-term	3,889	-	$ 4.05	12/04/23
Investors - December 2018 financing - short-term	2,004	-	$ 3.68	06/24/20
Battelle - 2018 payables restructuring agreement (1)	75	-	$ 6.50	12/07/23
Panacea Venture Management Company Ltd.	188	-	$ 4.00	07/02/23
LPH II Investments Limited	135	-	$ 5.52	04/04/25
Investors - February 2017 financing	352	352	$ 27.40	02/15/24
Investors - July 2015 financing	240	240	$ 196.00	07/22/22
Battelle - 2014 collaboration agreement (1)	4	4	$ 1,400.00	10/10/24
Total	9,850	596		

(1) *See*, – Note 16 – 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 shareholders dated as of November 13, 2017. On December 24, 2018, the Compensation Committee of our Board of Directors approved an increase in the number of shares available for issuance under the Plan by approximately 4.2 million shares, which increase was also approved by an action by written consent without a meeting of holders of a majority of our outstanding shares of common stock.

As of December 31, 2018 and 2017, we had 1.5 million and 1.6 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, 2018 and 2017, we had 807 common shares reserved for potential future issuance under the 401(k) Plan.

Note 15 – 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.

There are 6.1 million shares of our common stock authorized under the 2011 Plan, of which 1.5 million shares remain available for issuance. 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.

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

(in thousands)	December 31, 2018	December 31, 2017
Stock Options and RSUs Outstanding		
2011 Plan	4,558	263
Non-Plan	10	10
Total Outstanding	4,568	273
Available for Future Grants under 2011 Plan	1,453	1,623

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 vests in a series of three successive, equal installments beginning with the first anniversary of the grant date, and has a 10-year term.

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

(in thousands, except for weighted-average data) Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2018	84	$ 163.20	
Granted	4,337	4.22	
Forfeited or expired	(4)	617.75	
Outstanding at December 31, 2018	4,417	$ 6.73	9.9
Vested and exercisable at December 31, 2018	63	$ 171.87	6.5
Vested and expected to vest at December 31, 2018	4,243	$ 6.78	9.9

(in thousands, except for weighted-average data) Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2018	190	$ 4.33
Awarded	56	4.22
Vested	(95)	4.33
Unvested at December 31, 2018	151	$ 4.29

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, 2018 and 2017 was $3.39 and $17.44, respectively. The weighted-average grant-date fair value of RSUs granted during the years ended December 31, 2018 and 2017 was $4.22 and $4.33, respectively. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2018 are each $0.

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Stock-Based Compensation

We recognized stock-based compensation expense in accordance with ASC Topic 718 of $1.0 million and $1.6 million, respectively, for each of the years ended December 31, 2018 and 2017.

Stock-based compensation expense was classified as follows:

(in thousands)	Year Ended December 31, 2018	2017
Research and development	$ 232	$ 837
Selling, general and administrative	723	724
Total	$ 955	$ 1,561

Under the 2011 Plan, except as may be provided in an award agreement or an employment agreement, outstanding awards fully vest upon a change in control. Concurrent with the execution of the share purchase agreement with LPH in October 2017 (*see*, Note 14 – Stockholders' Equity – Private Placement Offerings) and the resulting change in control, all outstanding awards under the 2011 Plan, except as provided for in agreements for 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 US Treasury yield curve in effect at the time of the grant.

	Year Ended December 31, 2018	2017
Weighted average expected volatility	93%	79%
Weighted average expected term (in years)	7.0	6.6
Weighted average risk-free interest rate	2.7%	2.2%
Expected dividends	-	-

The total fair value of the underlying shares of the options vested during 2018 and 2017 equals $0.6 million and $1.9 million, respectively. As of December 31, 2018, there was $13.9 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 2.9 years.

Note 16 – Collaboration, Licensing and Research Funding Agreements

Collaboration Agreement

Battelle Memorial Institute

In October 2014, we entered into a Collaboration Agreement with Battelle Memorial Institute (Battelle) for the development of our phase 3 ADS. We had previously worked with Battelle, which has expertise in developing and integrating aerosol devices using innovative and advanced technologies, in connection with development of our prototype phase 2 ADS used in the AEROSURF phase 2b clinical trial. Under the Collaboration Agreement, we and Battelle shared the costs of development for a three-stage development plan that included (i) defining the requirements and a detailed project plan for a phase 3 ADS, (ii) executing the project plan, and (iii) completing required testing, verification and documentation, putting us in a position to manufacture a phase 3 ADS for use in the remaining AEROSURF development activities and, if approved, the initial commercial activities. We retained final decision-making authority over all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of the phase 3 ADS. We and Battelle shared equally the costs of the first stage and the planned costs of the remaining two stages. 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. We also agreed that, if Battelle successfully completed the project plan in a timely manner, we would 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, which under the Battelle Payment Restructuring (discussed below) was increased to $35 million. The Collaboration Agreement will end at the time we fulfill our payment obligations to Battelle, unless sooner terminated by a party as provided therein.

In December 2018, we and Battelle entered into a Payment Restructuring Agreement. *See*, Note 9 – Collaboration and Device Development Payable, regarding the December 2018 Payment Restructuring Agreement.

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 (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 the FDA in 2012 for 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 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 common stock 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 KL4 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.

Accounting Analysis under ASC 606

In evaluating the License Agreement in accordance with ASC Topic 606, we concluded that the contract counterparty, Lee's (HK), is a customer. We identified the following performance obligations: (i) a bundled performance obligation consisting of licensing rights to develop and commercialize our KL4 surfactant products and a technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS; and (ii) a technology transfer process for the manufacture of our ADS. We determined that participation in the Joint Steering Committee (and other committees under its authority) and our ongoing product development, regulatory, and commercialization activities under the License Agreement were deemed immaterial in the context of the contract. Consistent with the guidance under ASC 606-10-25-16A, we disregarded immaterial promised goods and services when determining performance obligations.

We concluded that the licensing rights were not distinct within the context of the contract (i.e. separately identifiable) because the licensing rights do not have stand-alone value from other promised goods and services as Lee's (HK) could not benefit from the licensing rights without the completion of the technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS. The ADS manufacturing right and the technology transfer process for the manufacture of our ADS are distinct within the context of the contract because each has stand-alone value from other promised goods and services as Lee's (HK) could benefit from each of these rights on a stand-alone basis. However, we determined that the ADS manufacturing right and the ADS technology transfer process have nominal stand-alone selling prices as the ADS is not yet verified and there is uncertainty with regard to the commercial value of the ADS given that the AEROSURF combination drug/device product is currently in clinical development.

With respect to Amendment No. 1, we elected to use the practical expedient for contract modifications that occur prior to the adoption of ASU 2014-09, and we determined that the impact was immaterial. Allocable arrangement consideration under the practical expedient comprised the upfront payment of $1 million and $0.3 million related to reductions in royalties and milestones in connection with Amendment No. 1. The $1.3 million was attributed in its entirety to the bundled performance obligation of licensing rights to develop and commercialize our KL4 surfactant products and a technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS. Revenue associated with the bundled performance obligation was recognized beginning in November 2017 with the initiation of the technology transfer process for the manufacture of SURFAXIN and SURFAXIN LS and will be recognized over time as services are performed and based on the input method related to the level of effort expended. The expected completion date for the technology transfer is June 2019.

Regulatory and commercialization milestones were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. As part of our evaluation of the constraint, we considered a number of factors in determining whether there is significant uncertainty associated with the future events that would result in the milestone payments. Those factors include: our financial position; ongoing delays in our development activities and with initiating our phase 3 clinical trial; our limited experience with successful drug development; our limited experience with clinical trials; our recent failure to achieve primary endpoints in our phase 2b clinical trial; our limited experience with commercialization; our decision in 2015 to cease manufacturing and commercializing of SURFAXIN; and the fact that the uncertainty about the related consideration is not expected to be resolved for a long period of time (*see*, Item 1A – Risk Factors).

Consideration related to sales-based milestones and royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Lee's (HK) and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

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 US 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 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. For 2018, we paid the minimum royalty of $400,000 to each of PMUSA and to PMPSA.

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 $1.0 million to date for milestones that have been achieved including a $0.5 million 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.

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Università degli Studi di Milano-Bicocca

Effective April 13, 2015, CVie Therapeutics, entered into an Agreement for Scientific Collaboration with the Università degli Studi di Milano-Bicocca (Bicocca) in Milan, Italy, focused on defining the role of sarco (endo) plasmic reticulum Ca2+ -ATPase 2a (SERCA2a) and phospholamban (PLN) in modulating cardiac contraction, and discovering new small molecules to modulate SERCA2a activity or new drugs for treating chronic and acute human heart failure. The term of the collaboration agreement would have expired after three years but was extended for approximately an additional year, with option for further renewal. We are currently in discussions potentially to extend this agreement, although there can be no assurance that we will be able to achieve an extension on acceptable terms, if at all.

Under the collaboration agreement, intellectual property resulting from the collaboration, including patents and know-how, will be jointly owned by the parties. For the development of any new SERCA2a compounds and diagnostic products suitable for further clinical development, we have the option to purchase Bicocca's interest for up to 12 months after the filing of a patent application. If the option is not exercised, then the parties shall remain joint owners and each can use the intellectual property with consent of the other on terms to be defined. If we exercise an option, we have agreed to pay Bicocca (corresponding to stage of development): (i) € 0.1 million (approximately $0.1 million) upon completion and the proof of concept of biological efficacy for new compounds modulating the SERCA2a activity caused by PLN mutations; and (ii) € 1.5 million (approximately $1.7 million) upon obtaining marketing authorization in the US, EU, or China of new compounds with the corresponding companion diagnostic assay. We have also agreed to pay royalties for any purchased intellectual property arising out of the collaboration in the range of a low- to mid-single digit percent of net sales for any products sold in any country for a period of ten years from the date of the first commercial sale.

Also, under the collaboration agreement, we have provided funds aggregating € 0.2 million (approximately $0.2 million) to date to upgrade equipment and pay laboratory expenses for the renewal term expiring in 2019. We also funded several related research contracts for the period covered by the collaboration agreement. In connection with our research activities, Bicocca agreed to provide us exclusive use of a research laboratory for the collaboration, and nonexclusive access to a physiology laboratory within the university. Bicocca serves as our primary location in Milan.

Note 17 – Related Party Transactions

Lee's Pharmaceutical Holdings Limited

As of December 31, 2018 and 2017, Lee's beneficial ownership of our issued and outstanding shares of common stock was 40% and 73%, respectively.

From June 2017 through December 2018 we entered into transactions with Lee's as follows:

- In June 2017, we entered into a licensing agreement with an affiliate of Lee's (*see*, Note 16 – Collaboration, Licensing and Research Funding Agreements)
- In October 2017, we completed a $10 million Share Purchase Agreement with an affiliate of Lee's (*see*, Note 14 – Stockholders Equity)
- During 2018, we entered into multiple loan agreements with an affiliate of Lee's (*see*, Note 11 – Loan Payable)
- In April 2018, we completed a $2.6 million private placement with an affiliate of Lee's (*see*, Note 14 – Stockholders Equity)
- In conjunction with the CVie Acquisition in December 2018, we issued shares of common stock to Lee's as a 49% shareholder in CVie Investment and entered into an indemnification letter agreement with Lee's (*see*, Note 3 – Business Combination)
- In December 2018, as part of the Private Placement Financing, we converted $6.0 million of existing loan payable obligations to the Lee's affiliate on the same economic terms as those of the other investors (*see*, Note 11 – Loan Payable)
- Our $4.5 million bank credit facility is guaranteed by Lee's (*see*, Note 11 – Loan Payable)

Panacea Venture and KPCB-China

Mr. James Huang, who in connection with the CVie Acquisition in December 2018 was appointed as a director and Chairman of our Board, is a founding and Managing Partner to Panacea Venture (Panacea) and, since 2011, has served as a Managing Partner of Kleiner Perkins Caufield & Byers (KPCB) – China. During 2018 we had the following transactions with Panacea and KCPB:

- In July 2018, we issued a $1.5 million secured convertible promissory note (Note) to an affiliate of Panacea. The Note was paid in full in December 2018 (*see*, Note 12 – Convertible Note Payable)
- In December 2018, we issued 114,415 shares of our common stock to Rui Jin (HK) Consulting Management Company Limited, an affiliate of Panacea, for services rendered before Panacea and Mr. Huang became related parties to us.
- In December 2018, conjunction with the CVie Acquisition, we issued shares of common stock to an investment fund managed by KPCB that was a 27% shareholder in CVie (*see*, Note 3 – Business Combination). Mr. Huang disclaims any beneficial interest in this KPCB investment fund.
- In December 2018, Panacea was an investor in the Private Placement Financing (*see*, Note 14 – Stockholders Equity)

As of December 31, 2018, Panacea and KPCB each had a 14% beneficial ownership of our issued and outstanding shares of common stock.

Note 18 – Commitments

Operating Leases

Our operating leases consist primarily of a facility leases for our operations in Warrington, Pennsylvania and Taipei, Taiwan.

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. We also maintain offices in Taipei, Taiwan, the former headquarters of CVie Therapeutics, where we perform certain manufacturing development and preclinical activities related to our cardiovascular drug product candidates.

In February 2018, we amended our Warrington, Pennsylvania lease 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 leases as of December 31, 2018 are approximately $2.1 million.

Rent expense under these leases was $0.8 million and $0.7 million for the years ended December 31, 2018 and 2017, respectively.

Strategic and Retention Bonus

In November 2018, the Compensation Committee of our Board of Directors approved an Executive Strategic and Retention Bonus Program ("Strategic and Retention Bonus") that was intended to provide incentives to, and retain, certain key personnel while they focused on completing the CVie Acquisition and, if successful, integrating and executing an expanded business plan.

Under the terms of the Strategic and Retention Bonus, an Eligible Transaction (as that term is defined under the program) means either (a) a strategic transaction consisting of a merger that would advance our strategic needs, including by potentially allowing for diversification of our product candidates, or (b) an acquisition; and, in addition, one or more financings within a nine-month period that in the aggregate results in gross proceeds to us of at least $30 million. The Strategic and Retention Bonus payments could vary depending upon the aggregate amount raised in the financings. The maximum bonus amount would be determined by application of a multiplier to participants' 2018 base salary and would be payable only if we were to complete an Eligible Transaction with gross proceeds of at least $45 million, while the minimum bonus amount would equal 20% of the maximum bonus amount and would be payable if we were to raise at least $30 million. For other amounts raised, the maximum bonus amount would be reduced in a stepped-down fashion as provided under the program. The bonus payments, if earned, would be paid in two equal installments to support retention with the first installment due within five business days after the closing of the Eligible Transaction, and the second installment due on the nine-month anniversary of the closing of the Eligible Transaction, provided that the recipient is actively employed by us at the time of payment.

With completion of the CVie Acquisition and the $39 million Private Placement Financing on December 21, 2018, the participants became eligible to receive a total bonus of $1.4 million, of which the first installment of $0.7 million was paid in December 2018. The balance of $0.7 million will be due on the nine-month anniversary of the closing of the Eligible Transaction in September 2019.

Note 19 – 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.

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Note 20 – 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, 2018 and 2017 is as follows:

(in thousands)	December 31, 2018	2017
Income tax benefit, statutory rates	$ (4,312)	$ (6,272)
State taxes on income, net of federal benefit	(535)	(398)
Impact of tax reform	5	71,151
Research and development tax credit	(351)	(797)
Foreign rate differential	24	-
Employee related	2,875	953
Interest related	186	(147)
Income tax expense / (benefit), statutory rates	(2,108)	64,490
Valuation allowance	2,108	(64,490)
Income tax benefit, net	$ -	$ -

During 2017, we recorded tax charges for the impact of the 2017 Tax Cuts and Jobs Act (the 2017 Tax Act) effects using the current available information and technical guidance on the interpretations of the 2017 Tax Act. As permitted by SEC Staff Accounting Bulletin 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, we recorded provisional estimates and have subsequently finalized our accounting analysis based on the guidance, interpretations, and data available as of December 31, 2018. Adjustments made in the fourth quarter of 2018 upon finalization of our accounting analysis were not material to our Consolidated Financial Statements.

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2018 and 2017, are as follows:

(in thousands)	December 31, 2018	2017
Long-term deferred assets:		
Net operating loss carryforwards (federal and state)	$ 176,759	$ 168,263
Research and development tax credit	16,718	16,813
Compensation expense on stock	1,121	1,191
Charitable contribution carryforward	-	5
Other accrued	1,016	2,547
Deferred revenue	57	317
Depreciation	309	297
Total long-term deferred tax assets	195,980	189,433
Long-term deferred liabilities:		
IPR&D	(15,476)	-
Total long-term deferred tax liabilities	(15,476)	-
Valuation allowance	(195,980)	(189,433)
Deferred tax liabilities, net	$ (15,476)	$ -

We are in a net deferred tax liability position at December 31, 2018. We are in a net deferred tax asset position at December 31, 2017 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, 2018 or 2017, nor were any incurred in 2018 or 2017.

At December 31, 2018 and 2017, we had available carryforward net operating losses for federal tax purposes of $606.6 million and $590.0 million, respectively, and a research and development tax credit carryforward of $16.7 million and $16.8 million, respectively. The Federal net operating loss and research and development tax credit carryforwards will continue to expire through 2037.

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At December 31, 2018 and 2017, we had available carryforward losses of approximately $584.8 million and $567.7 million , respectively, for state tax purposes. Of the $583.9 million state tax carryforward losses, $570.2 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.

Note 21 – Selected Quarterly Financial Data (Unaudited)

The following tables contain unaudited statement of operations information for each quarter of 2018 and 2017. The operating results for any quarter are not necessarily indicative of results for any future period.

2018 Quarters Ended:

(in thousands, except per share data)	**Mar. 31**	**June 30**	**Sept. 30**	**Dec. 31**	**Total Year**
Revenues:					
Grant revenue	$ -	$ 695	$ 70	$ -	$ 765
License revenue with affiliate	204	356	159	304	1,023
Total revenues	204	1,051	229	304	1,788
Expenses:					
Research and development	3,118	2,879	2,197	2,368	10,562
Selling, general and administrative	1,926	1,208	1,500	2,787	7,421
Total expenses	5,044	4,087	3,697	5,155	17,983
Operating loss	(4,840)	(3,036)	(3,468)	(4,851)	(16,195)
Other income / (expense), net	328	(16)	(459)	(4,191)	(4,338)
Net (loss) / income	$ (4,512)	$ (3,052)	$ (3,927)	$ (9,042)	$ (20,533)
AEROSURF warrant dividend	-	-	-	(12,505)	(12,505)
Deemed dividend on preferred stock	-	-	-	(1,718)	(1,718)
Net (loss) / income attributable to common shareholders	$ (4,512)	$ (3,052)	$ (3,927)	$ (23,265)	$ (34,756)
Net (loss) / income per common share - basic	$ (1.40)	$ (0.81)	$ (1.04)	$ (3.24)	$ (7.74)
Net (loss) / income per common share - diluted	$ (1.40)	$ (0.81)	$ (1.04)	$ (3.24)	$ (7.74)
Weighted average number of common shares outstanding - basic	3,227	3,751	3,769	7,191	4,493
Weighted average number of common shares outstanding - diluted	3,227	3,751	3,769	7,191	4,493

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARY

2017 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues:					
Grant revenue	$ 219	$ 1,147	$ 17	$ -	$ 1,383
License revenue with affiliate	-	-	-	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)
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

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

1. I have reviewed this Amendment No. 1 on Form 10-K/A of Windtree Therapeutics, Inc. for the year ended December 31, 2018; and

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.

Date: April 23, 2019

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

Exhibit 31.1

CERTIFICATIONS

I, John Tattory, certify that:

1. I have reviewed this Amendment No. 1 on Form 10-K/A of Windtree Therapeutics, Inc.; and

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.

Date: April 23, 2019

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

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, 2018 ("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 23, 2019

/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.