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

FORM 10-Q

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from to

Commission file number 000-26422

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

(215) 488-9300
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

As of August 15, 2017, there were outstanding 13,994,960 shares of the registrant's common stock, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Windtree Therapeutics, Inc., and its wholly owned, presently inactive subsidiary, Discovery Laboratories, Inc.

FORWARD-LOOKING STATEMENTS

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

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

Risks Related to Capital Resource Requirements

- the risk that our ability to continue as a going concern is dependent upon our ability to secure additional capital. Our ability to raise such capital was negatively impacted when the top-line results of our AEROSURF phase 2b clinical trial did not meet the planned primary endpoint. Moreover, we believe that our current capital structure, which includes $25 million of long-term secured debt (Deerfield Loan) with affiliates of Deerfield Management L.P. (Deerfield), will likely discourage additional investment until such time as we remove or mitigate the debt overhang. We recently entered into a Loan Agreement with Lee’s Pharmaceuticals (HK), Ltd. (Lee’s) for a potential loan of up to $3.9 million and are in negotiations with Lee’s to complete a $10 million investment with us, and we are negotiating with Deerfield potentially to restructure the Deerfield Loan (*see*, “– Risks Related to Strategic and Other Transactions”). If we are unable to promptly raise additional required capital and close these transactions, we may be unable to continue as a going concern, may have to limit or curtail our development activities and could be forced to cease operations. Moreover, even if we are successful in completing these transactions, we will continue to require significant additional capital to support our research and development activities going forward, including the AEROSURF development program, and our operations;

- the risk that it may be more difficult since our transition to the OTC Markets Group Inc.’s OTCQB® Market (OTCQB) tier in early May 2017, to raise capital through equity-based transactions. For example, we are no longer eligible to register shares using a Form S-3 and will have to register equity securities that we may issue in connection with a strategic transaction or other financing on a Form S-1, which would be time-consuming and expensive; our "at-the-market" equity sales program (ATM Program), which allowed us to efficiently raise additional capital in the public market, is no longer available; our stockholders may not approve a capital transaction for which stockholder approval is required under Delaware law; our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, has made, and in the future is expected to make, it difficult to conduct equity-based financings; and unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution of stockholders' interests. Moreover, our stockholders may find it more difficult to trade our securities on the OTCQB, which may negatively impact the value and liquidity of our common stock, which could have a material adverse effect on our ability to raise the additional capital that we will require;

- risks relating to our pledge of substantially all of our assets to secure our obligations under a $25 million secured loan with Deerfield, which could make it more difficult for us to secure additional capital, including to satisfy our Deerfield debt obligations, with respect to which a principal payment in the amount of $12.5 million is payable in February 2018, and require us to dedicate cash flow to pay debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;

- risks relating to our ability to manage our limited resources effectively and timely modify our business strategy as needed to respond to developments in our research and development activities, as well as in our business, our industry and other factors;

Risks related to Development Activities

- risks related to our AEROSURF clinical development program, which involves significant risks and uncertainties that are inherent in clinical development. Our clinical trials may be delayed, terminated early due to safety or other concerns, subjected to conditions imposed by the FDA or other regulatory body, or fail due to a range of potential factors, including without limitation, issues related to our ADS. We announced in late June 2017 that the top-line results of our AEROSURF phase 2b clinical trial did not meet the primary endpoint of reduction in nCPAP failure at 72 hours due in part, we believe, to device-related dose interruptions; however, when the data from patients with dose interruptions is removed, the results appear to show a potential meaningful effect. We are assessing the results of our trial in the context of our development and regulatory plans and need for additional capital. If we are unable to identify a path forward that would be acceptable to our investors, we may be unable to fund our further development activities, which would have a material adverse effect on our development plan and our business and operations;

- risks related to our AEROSURF development activities for our ADS, with respect to which we are developing and testing a next generation aerosol delivery system (NextGen ADS). We are currently assessing the treatment interruptions that occurred in the phase 2 ADS in our phase 2b clinical trial, which we believe were caused by clogged filters in specific batches of device disposables, and evaluating our design elements for the NextGen ADS to mitigate the chances of such events occurring in the future. Our NextGen ADS could be delayed or fail to perform as expected, which could negatively impact our clinical outcomes. As was the case with clogged filters in our phase 2b clinical trial, unforeseen device issues could arise in the future and could impact the AEROSURF clinical development program, including the planned phase 3 clinical program, and potential future research and development activities, and potentially have a material adverse effect on our development activities and our business and operations;

- risks related to our AEROSURF development activities for our lyophilized KL_4 surfactant, that might arise and also delay or otherwise affect the AEROSURF clinical development program and potential future research and development activities, and potentially have a material adverse effect on our business and operations;

- risks related to our efforts to gain regulatory approval in a timely and successful manner, in the U.S. and in international markets, for our drug products and combination drug/device product candidates, including AEROSURF, including that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or international regulatory approvals for our product candidates; in addition, to respond to the results of our phase 2b clinical trial, the regulatory requirements to secure approval for AEROSURF may have increased and we may be unable to secure the additional required capital to conduct any such additional and potentially time-consuming and expensive development work;

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

Risks Related to Strategic and Other Transactions

- the risk that, although we have recently entered into a Loan Agreement dated as of August 14, 2017 with Lee's to provide us up to a potential $3.9 million loan to support our activities while we seek to negotiate a share purchase agreement with Lee's pursuant to which Lee's potentially, no later than October 31, 2017, would acquire $10 million of our common stock and a controlling interest in our Company, while at the same time negotiating a restructuring agreement with Deerfield to cancel the Deerfield debt in exchange for $2.5 million in cash, plus 2% of our outstanding common stock and up to $15 million in AEROSURF regulatory and commercial milestones, we may be unable to successfully complete these transactions on or before October 31, 2017. Any failure to receive the total loan proceeds and close the transactions with Lee's and Deerfield as currently contemplated likely would have a material adverse effect on our business, operations and financial condition, and could force us to cease operations;

- risks relating to our License, Development and Commercialization Agreement dated as of June 12, 2017 with Lee's, as amended on August 14, 2017 (Lee's License), including the risks related to conducting development activities in the various markets in the licensed territory, risks associated with an international technology transfer of our KL_4 manufacturing processes and device manufacturing, risks related to regulatory filings and protection of intellectual property interests and risks related to the commercialization of our products in international markets;

- the risk that we may be unable to identify and enter into new strategic alliances, collaboration agreements or other strategic transactions that would provide capital to support our AEROSURF development activities and resources and expertise to support the registration and commercialization of AEROSURF in various markets and potentially support the development and, if approved, commercialization, of our other potential KL_4 surfactant pipeline products;

Risks related to Manufacturing

- the risk that we, our contract manufacturing organizations (CMOs) or any of our third-party suppliers and related service providers, including without limitation contract laboratories engaged in release and stability testing activities, most of which are single-source providers, may encounter problems in manufacturing our KL_4 surfactant, the active pharmaceutical ingredients (APIs) used in the manufacture of our KL_4 surfactant, the ADS and related components, and other materials on a timely basis or in an amount sufficient to support our needs and in providing the related services necessary to our manufacturing process and release of drug product for development work;

- risks relating to the transfer of our lyophilized KL_4 surfactant manufacturing technology to our CMOs, and our CMOs' ability to manufacture our lyophilized KL_4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for our research and development activities and, if approved, commercial applications;

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

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

- risks relating to our ability and our design and development partner's ability to complete the development and design verification and validation of our NextGen ADS and related components, which we currently are developing under a Collaboration Agreement with Battelle Memorial Institute for use in our future clinical activities, including our planned phase 3 clinical program for AEROSURF;

Other Risks Affecting our Business

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

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

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

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

- other risks and uncertainties detailed in "Risk Factors" in our most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 31, 2017, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

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

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2017	December 31, 2016
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,528	$ 5,588
Prepaid interest, current portion	1,094	1,094
Prepaid expenses and other current assets	318	512
Total current assets	3,940	7,194
Property and equipment, net	977	1,054
Restricted cash	225	225
Prepaid interest, non-current portion	683	1,226
Total assets	$ 5,825	$ 9,699
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,846	$ 1,813
Collaboration payable	3,930	3,967
Accrued expenses	6,108	7,611
Long-term debt, current portion	12,500	-
Total current liabilities	25,384	13,391
Long-term debt, non-current portion	12,500	25,000
Other liabilities	124	138
Total liabilities	38,008	38,529
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 6,213 and 0 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	-
Common stock, $0.001 par value; 120,00,000 and 60,000,000 shares authorized at June 30, 2017 and December 31, 2016, respectively; 10,569,452 and 8,725,069 shares issued at June 30, 2017 and December 31, 2016, respectively; 10,567,960 and 8,723,577 shares outstanding at June 30, 2017 and December 31, 2016, respectively	11	9
Additional paid-in capital	605,004	592,883
Accumulated deficit	(634,144)	(618,668)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity	(32,183)	(28,830)
Total liabilities & stockholders' equity	$ 5,825	$ 9,699

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Grant revenue	$ 1,147	$ 106	$ 1,366	$ 181
Expenses:				
Research and development	5,483	8,316	11,896	18,676
General and administrative	1,804	1,783	3,726	5,440
Total operating expense	7,287	10,099	15,622	24,116
Operating loss	(6,140)	(9,993)	(14,256)	(23,935)
Change in fair value of common stock warrant liability	-	-	-	223
Other income / (expense):				
Interest income	3	5	6	12
Interest expense	(615)	(637)	(1,226)	(1,259)
Other income	-	1	-	434
Other income / (expense), net	(612)	(631)	(1,220)	(813)
Net loss	$ (6,752)	$ (10,624)	$ (15,476)	$ (24,525)
Deemed dividend on Series A preferred stock	(532)	-	(4,136)	-
Net loss attributable to common shareholders	$ (7,284)	$ (10,624)	$ (19,612)	$ (24,525)
Net loss per common share				
Basic and diluted	$ (0.76)	$ (1.29)	$ (2.10)	$ (2.99)
Weighted average number of common shares outstanding				
Basic and diluted	9,634	8,238	9,317	8,215

See notes to condensed consolidated financial statements

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

(in thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (15,476)	$ (24,525)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	101	140
Stock-based compensation and 401(k) plan employer match	660	971
Fair value adjustment of common stock warrants	-	(223)
Amortization of prepaid interest	543	1,088
Changes in:		
Prepaid expenses and other current assets	194	(92)
Accounts payable	2,231	3,101
Collaboration payable	(37)	1,226
Accrued expenses	(1,077)	(122)
Other liabilities	-	124
Net cash used in operating activities	(12,861)	(18,312)
Cash flows from investing activities:		
Purchase of property and equipment	(24)	(149)
Net cash used in investing activities	(24)	(149)
Cash flows from financing activities:		
Proceeds from Private Placement issuance of securities, net of expenses	8,789	-
Proceeds from ATM Program, net of expenses	1,036	69
Net cash provided by financing activities	9,825	69
Net increase/(decrease) in cash and cash equivalents	(3,060)	(18,392)
Cash, cash equivalents and restricted cash - beginning of year	5,813	38,947
Cash, cash equivalents and restricted cash - end of year	$ 2,753	$ 20,555
Supplementary disclosure of cash flows information:		
Interest paid	$ 514	$ 61

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

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

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that combines our KL4 surfactant with our novel aerosol delivery system (ADS). We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by a deficiency of natural lung surfactant in lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit. By enabling administration of aerosolized KL4 surfactant, AEROSURF may reduce or eliminate the need for invasive endotracheal intubation and mechanical ventilation, which currently are required to administer life-saving surfactant therapy, but which are associated with serious respiratory conditions and other complications. To avoid the risks of surfactant administration, many neonatologists initially delay surfactant therapy and treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)). We believe that AEROSURF, if approved, has the potential to address a serious unmet medical need by enabling earlier KL4 surfactant therapy for infants receiving nCPAP alone, reducing the number of premature infants who are subjected to invasive surfactant administration, and potentially providing transformative clinical and pharmacoeconomic benefits.

We recently completed an AEROSURF phase 2b clinical trial that was designed to evaluate aerosolized KL4 surfactant administered to premature infants 28 to 32 week gestational age receiving nCPAP, in two dose groups (25 and 50 minutes) with up to two potential repeat doses, compared to infants receiving nCPAP alone. This trial was conducted in approximately 50 clinical sites in the U.S., Canada, the European Union and Latin America. Based on the planned top-line results, data show that AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours, which we believe was due in large part to an unexpected rate of treatment interruptions. Such interruptions occurred in about 24% of active enrollments, predominantly in the 50 minute dose group, and were primarily related to specific lots of disposable cartridge filters in our proprietary ADS that had a tendency to clog. After excluding the patients whose dose was interrupted in the 50 minute dose group, the data show an nCPAP failure rate of 32% compared to 44% in the control 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 targeted outcome.

In addition, in June 2017, we and Lee's Pharmaceutical (HK), Ltd. (Lee's) announced an exclusive license and collaboration agreement (License Agreement) for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets, with a future option to potentially add Japan. The agreement includes AEROSURF as well as the non-aerosol products, SURFAXIN® (approved in the U.S. in 2012) and SURFAXIN LS™ (an improved lyophilized formulation of SURFAXIN). We also granted Lee's an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory and a future option to manufacture the device in the licensed territory. In connection with the Loan Agreement (*see*, "– Note 2 – Liquidity Risks and Management's Plans"), we amended the License Agreement to expand certain of Lee'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 as a party to the License Agreement. We are presently engaged in a technology transfer of our KL4 surfactant manufacturing process to Lee's.

Note 2 – Liquidity Risks and Management's Plans

As of June 30, 2017, we had cash and cash equivalents of $2.5 million, current liabilities of $25.4 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion. Total long-term debt of $25 million is with affiliates of Deerfield Management, L.P. (Deerfield), who hold a security interest in substantially all of our assets (Deerfield Loan).

We expect to continue to incur significant losses and require significant additional capital to further advance our AEROSURF clinical development program, support our operations and meet our debt service obligations for the next several years, and we do not have sufficient existing cash and cash equivalents for at least the next year following the date that these 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 these financial statements are issued.

To potentially alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to seek additional capital through the following: (i) all or a combination of strategic transactions, and other potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through public or private equity offerings. However, there can be no assurance that these alternatives will be available, or if available, that we will be able to raise sufficient capital through such transactions. If we are unable to raise the required capital, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date that these 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 these financial statements.

In connection with the License Agreement with Lee's that we announced in June 2017 (*see*, "– Note 1 – The Company and Description of Business"), we received an upfront license fee of $1.0 million in July 2017 and also are eligible to receive up to $35.8 million in contingent clinical, regulatory and commercialization milestone payments, and royalties at an escalating high single digit to mid-teens percentage across all products. In addition, Lee's will be responsible for all development costs in the licensed territory. In addition to the License Agreement, Lee's also invested $2 million in our February 2017 private placement offering.

Under a Loan Agreement dated as of August 14, 2017, Lee's agreed to lend us up to a potential $3.9 million (Lee's Loan) that will be funded in Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017, and will be used to support our AEROSURF development activities and sustain our operations through October 31, 2017, while we negotiate a potential share purchase agreement (Share Purchase) and related agreements. The Lee's Loan will accrue interest at a rate of 12% per annum. We received the initial installment of $1.3 million from Lee's on August 15, 2017. Under the Share Purchase as currently contemplated, but subject to further negotiation, Lee's would invest $10 million and acquire a controlling interest in our Company. The outstanding principal balance of the Lee's Loan would be applied to the Share Purchase and the Lee's Loan would be discharged in full at the closing. In addition, to facilitate the Share Purchase, we are negotiating with Deerfield to restructure the Deerfield Loan (Loan Restructuring), effective as of the closing of the Share Purchase. Under the Loan Restructuring as currently contemplated, but subject to further negotiation, the notes issued in connection with the Deerfield Loan would be retired in exchange for (i) $2.5 million of cash paid out of the proceeds of the Share Purchase, (ii) a number of newly-issued shares of our common stock equal to 2% of our outstanding common stock on a fully-diluted basis (to be defined) as of the closing date, and (iii) future regulatory and commercial milestones related to the development and commercialization of AEROSURF potentially totaling $15 million. (S*ee*, "– Note 9 – Subsequent Events").

While we believe that we will be able to reach agreement with Lee's and Deerfield and close the Share Purchase and Loan Restructuring, there can be no assurance that we will be successful. At this time, we do not have an alternative source of funding available, such that, if we are unable to complete these transactions for any reason on or before October 31, 2017, we may be forced to curtail all of our activities and, ultimately, cease operations. In addition, if we are unable to finalize and close the Loan Restructuring and thereafter fail to make any required payment under the Deerfield Loan, or fail to comply with any commitments contained in the Deerfield Loan documents, Deerfield would be able to declare a default under the Deerfield Loan agreement, accelerate our payment obligations under all or a portion of our indebtedness, and, since we have pledged substantially all of our assets to secure the Deerfield Loan, foreclose on our assets, which could significantly diminish the market value and marketability of our assets and common stock and render us unable to continue as a going concern. Moreover, even if we are successful in completing these transactions, we will continue to require significant additional capital to support our research and development activities going forward, including the AEROSURF development program, and our operations.

As of August 15, 2017, after receipt of the initial advance under the Lee's Loan, we had cash and cash equivalents of $2.9 million and believe that, assuming receipt of the two additional installments under the Lee's Loan, and before any additional financings, we will have sufficient cash resources to fund our operations through November 2017.

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

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other constraints discussed in this Quarterly Report on Form 10-Q and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to consider transactions on less-than-favorable terms, or limit or cease our development activities. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

In addition, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) our common stock is currently trading on the OTCQB® Market (OTCQB), which is operated by OTC Markets Group Inc., under the symbol "WINT" and may experience periods of illiquidity; (ii) our common stock is currently considered a "penny stock," such that brokers are required to adhere to more stringent market rules, which could result in reduced trading activity and trading levels in our common stock and limited or no analyst coverage; (iii) we are no longer eligible to use a Form S-3 registration statement; (iv) we are no longer able to use our ATM Program; (v) our stockholders may not approve proposals to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, which could impair our ability to conduct equity financings or enter into certain strategic transactions; (vi) our stockholders may not approve, to the extent required under Delaware law, strategic transactions (mergers and acquisitions) recommended by our Board; (vii) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings; and (viii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

We have from time to time collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. In late May 2017, we announced that we have been awarded $0.9 million under a previously announced Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF phase 2b clinical trial. We also have received from time to time grants that support medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

As of June 30, 2017, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance, and 6,213 convertible preferred shares issued in the February 2017 private placement offering. Each preferred share is convertible into 1,000 shares of common stock. Upon exercise of the pre-funded warrants and conversion of the convertible preferred shares, we would issue common shares to the holders and receive no additional proceeds.

As of August 15, 2017, 2.5 million pre-funded warrants and 3,203 convertible preferred shares, convertible into 3.2 million shares of common stock, remained outstanding.

In addition, as of June 30, 2017, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 85.7 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

Note 3 – Basis of Presentation

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. There have been no changes to our critical accounting policies since December 31, 2016. For a discussion of our accounting policies, *see*, "Note 4 – Accounting Policies and Recent Accounting Pronouncements" in the Notes to Consolidated Financial Statements in our 2016 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Note 4 – Stockholders' Equity

February 2017 Private Placement

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units at a price per unit of $1,495, for an aggregate purchase price of approximately $10.5 million, including $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares); and (ii) 1,000 Series A-1 Warrants (Warrants) to purchase one share of common stock at an exercise price equal to $1.37 per share. Each Preferred Share may be converted at the holder's option at any time into 1,000 shares of common stock at a conversion price of $1.37 per share. The Warrants may be exercised beginning August 15, 2017 and through February 15, 2024. The Preferred Shares and the Warrants may not be converted or exercised to the extent that the holder would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of our outstanding shares of common stock. In addition to the offering, the securities purchase agreement also provides that, until February 13, 2018, the investors are entitled to participate in subsequent bona fide capital raising transactions that we may conduct.

As of August 15, 2017, 3,846 Preferred Shares have been converted into 3,846,000 shares of common stock and 3,203 Preferred Shares remain outstanding.

At-the-Market (ATM) Program

During the three and six months ended June 30, 2017, we completed offerings of our common stock under our ATM Program of 41,231 shares and 847,147 shares, respectively. This resulted in an aggregate purchase price of approximately $48,000 ($46,000 net) and $1,082,000 ($1,036,000 net), respectively, for the three and six month periods ended June 30, 2017. During the three months ended June 30, 2016, there were no offerings under our ATM Program. During the six months ended June 30, 2016, we completed offerings of our common stock under our ATM Program of 27,971 shares for an aggregate purchase price of approximately $71,000 ($69,000 net).

Effective May 5, 2017, we were no longer able to make use of our ATM Program (*see*, "–Note 2 – Liquidity Risks and Management's Plans").

Note 5 – Summary of Significant Accounting Policies

Use of Estimates

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

Severance

Effective February 1, 2016, we terminated the Employment Agreement between ourselves and our then-President and Chief Executive Officer (Former CEO). During the first quarter of 2016, we incurred a severance charge of $1.2 million in general and administrative expense under the terms of the Former CEO's employment agreement, including $0.2 million related to stock option expense for certain options that will continue to vest through August 1, 2017. Of the $1.0 million in severance not related to stock-based compensation, $0.9 million was paid as of June 30, 2017.

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

Research and Development Expense

We account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

Net Loss per Common Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period.

As of June 30, 2017 and 2016, the number of shares of common stock potentially issuable upon the conversion of preferred stock or exercise of stock options and warrants was 23.4 million and 9.1 million shares, respectively. For the three and six months ended June 30, 2017 and 2016, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

In accordance with Accounting Standards Codification Topic 260, *Earnings per Share,* when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of these warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of warrants classified as derivative liabilities. For the three and six months ended June 30, 2017 and 2016, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive.

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

Beneficial Conversion Feature

The issuance of our Preferred Shares in the first quarter of 2017 (*see*, "– Note 4 – Stockholders' Equity") resulted in a beneficial conversion feature, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor (or in the money) at inception due to the conversion option having an effective conversion price that is less than the fair value of the underlying stock at the commitment date. We recognized the beneficial conversion feature by allocating the relative fair value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital, resulting in a discount on the Preferred Shares. As the Preferred Shares are immediately convertible by the holders, the discount allocated to the beneficial conversion feature was immediately accreted and recognized as a $3.6 million one-time, non-cash deemed dividend to the preferred shareholders during the first quarter of 2017.

An additional discount to the Preferred Shares of $4.5 million was created due to the allocation of proceeds to the Warrants which were issued with the Preferred Shares. This discount is amortized proportionately as the Preferred Shares are converted. For the three months ended June 30, 2017, we recognized a non-cash deemed dividend to the preferred shareholders of $0.5 million related to the Preferred Shares converted during the period.

Recently Adopted Accounting Standards

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). We adopted ASU 2014-15 effective December 31, 2016. Management has concluded that substantial doubt exists with respect to our ability to continue as a going concern through one year after the issuance of these financial statements (*see*, " – Note 2 – Liquidity Risks and Management's Plans").

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

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

Recent Accounting Pronouncements

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

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. Early adoption is permitted. We are currently evaluating the effect that ASU 2017-09 may have on our consolidated financial statements and related disclosures.

Note 6 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

(in thousands)	Fair Value June 30, 2017	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 2,528	$ 2,528	$ -	$ -
Certificate of deposit	225	225	-	-
Total Assets	$ 2,753	$ 2,753	$ -	$ -

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

The following table summarizes changes in the fair value of common stock warrant liability measured on a recurring basis using Level 3 inputs for the six months ended June 30, 2016 representing the write-off of the remaining liability upon expiration of the underlying warrants in February 2016.

(in thousands)	
Balance at January 1, 2016	**$ 223**
Change in fair value of common stock warrant liability	(223)
Balance at June 30, 2016	**$ -**

Fair Value of Long-Term Debt

At June 30, 2017, the estimated fair value of the Deerfield Loan (*see*, "– Note 7 – Long-term Debt") was $22.4 million, compared to a carrying value for current and non-current portions of $25.0 million. The estimated fair value of the Deerfield Loan is based on discounting the future contractual cash flows to the present value at the valuation date. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts that could be realized in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value. The methodology and assumptions do not take into consideration the potential restructuring of the Deerfield Loan (*see*, "– Note 9 – Subsequent Events").

Note 7 – Long-term Debt

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

(in thousands)	June 30, 2017	December 31, 2016
Current portion	$ 12,500	$ -
Non-current portion	12,500	25,000
Total Deerfield Loan	$ 25,000	$ 25,000

The principal amount of the loan is payable in two equal annual installments of $12.5 million, payable in each of February 2018 and 2019. *See*, "Note 9 – Long-term Debt" in the Notes to Consolidated Financial Statements in our 2016 Form 10-K.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2017	2016	2017	2016
Amortization of prepaid interest expense	$ 273	$ 544	$ 543	$ 1,088
Cash interest expense	257	-	511	-
Total interest expense	$ 530	$ 544	$ 1,054	$ 1,088

Amortization of prepaid interest expense represents non-cash amortization of $5 million of units purchased by Deerfield in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Loan. Cash interest expense represents interest at an annual rate of 8.25% on the outstanding principal amount, paid in cash on a quarterly basis.

Note 8 – Stock Options and Stock-Based Employee Compensation

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

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

(in thousands, except for weighted-average data) Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2017	1,142	$ 14.66	
Granted	822	1.23	
Forfeited or expired	(53)	33.52	
Outstanding at June 30, 2017	1,911	$ 8.36	7.4
Vested and exercisable at June 30, 2017	488	$ 26.89	5.4
Vested and expected to vest at June 30, 2017	1,257	$ 8.45	8.3

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

	Six Months Ended June 30,	
	2017	2016
Weighted average expected volatility	79%	79%
Weighted average expected term (years)	6.6	5.7
Weighted average risk-free interest rate	2.22	1.4
Expected dividends	-	-

The table below summarizes the total stock-based compensation expense included in the statements of operations for the periods presented:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 124	$ 140	$ 283	$ 322
General and administrative	130	110	271	531
Total	$ 254	$ 250	$ 554	$ 853

Note 9 – Subsequent Events

On July 13, 2017, we implemented a reduction in workforce by 20 employees, representing approximately 42% of our total workforce, from 48 to 28 employees. The reduction was across all functions of the Company. Affected employees are eligible for certain severance and other benefits. In addition, the Company expects to record a one-time charge of approximately $0.2 million in the third quarter of 2017.

Effective as of August 14, 2017, we entered into a loan agreement with Lee's, pursuant to which Lee's has agreed to lend us up to a potential $3.9 million that will be funded in Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017, and will be used to support our AEROSURF development activities and sustain our operations through October 31, 2017, while we negotiate the potential Share Purchase and related agreements. The Lee's Loan will accrue interest at a rate of 12% per annum. We received the initial installment of $1.3 million from Lee's on August 15, 2017. Under the Share Purchase as currently contemplated, but subject to further negotiation, Lee's would invest $10 million in our Company and acquire a controlling interest of a majority of the outstanding shares of our common stock at a price per share based on the average 10-day volume-weighted average price per share (VWAP) up to and including the closing date, plus a premium up to, but not exceeding 15%, but in no event greater than $0.25 per share. As partial consideration for the Share Purchase, the outstanding principal balance of the Lee's Loan would be applied in full satisfaction of a like amount of cash consideration payable by Lee's at the closing of such Share Purchase, and the Lee's Loan would be discharged in full. In connection with the Lee's Loan, Deerfield, which holds a security interest in substantially all of our assets to secure its $25 million Deerfield Loan, entered into a Subordination Agreement, dated as of August 14, 2017, with us and Lee's generally granting Lee's a first right through October 31, 2017, to any cash payments (other than regularly scheduled interest payments under the Deerfield Loan) and to the proceeds of sales of assets in a bankruptcy proceeding for up to $3.9 million principal amount plus related interest and expenses, subject to the exceptions set forth in the Subordination Agreement.

As partial consideration for the Lee's Loan, we and Lee's also entered into Amendment No. 1 to the License Agreement (Amendment) pursuant to which reductions have been made to certain of the milestone and royalty payments. As a result, we may receive up to $35.8 million (previously, $37.5 million) in potential clinical, regulatory and commercial milestone payments. The options to add Japan to the Licensed Territory (as defined in the License Agreement) and to manufacture our aerosol delivery device in and for the Licensed Territory have been made effective immediately. In addition, Zhaoke Pharmaceutical (Hefei) Co. Ltd., an affiliate of Lee's, has been made a party to the License Agreement. Except as set forth in the Amendment, all other terms and conditions of the License Agreement shall remain in full force and effect.

In addition, to facilitate the Share Purchase, we are negotiating with Deerfield to restructure the Deerfield Loan (Loan Restructuring), effective as of the closing of the Share Purchase. Under the Loan Restructuring as currently contemplated, but subject to further negotiation, the notes issued in connection with the Deerfield Loan would be retired in exchange for (i) $2.5 million of cash, which would be paid out of the proceeds of the Share Purchase, and (ii) a number of newly-issued shares of our common stock that equals 2% of our outstanding common stock on a fully-diluted basis (to be defined) as of the closing of the Share Purchase and Loan Restructuring. In addition, Deerfield would be entitled to receive future regulatory and commercial milestones related to the development and commercialization of AEROSURF potentially totaling $15 million.

The Share Purchase and Loan Restructuring agreements are expected to include such customary representations, warranties, covenants, conditions and indemnities for certain losses and other terms as are acceptable to the parties. While we believe that we will be able to reach agreement with Lee's and Deerfield and close the Share Purchase and Loan Restructuring agreements in a timely manner, there can be no assurance that we will be successful.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. The reader should review the "Forward-Looking Statements" section, and risk factors discussed elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2016 that we filed with the Securities and Exchange Commission (SEC) on March 31, 2017 (2016 Form 10-K,) and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q. The disclosure in this Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) of this Quarterly Report on Form 10-Q includes information on preclinical studies supported in part from funds from the National Institutes of Health (NIH). Such information is solely our responsibility and does not necessarily represent the official views of the NIH.

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

OVERVIEW

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

Our lead development program is AEROSURF® (lucinactant for inhalation), an investigational combination drug/device product that combines our KL4 surfactant with our novel aerosol delivery system (ADS). We are developing AEROSURF to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by a deficiency of natural lung surfactant in lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit. By enabling administration of aerosolized KL4 surfactant, AEROSURF may reduce or eliminate the need for invasive endotracheal intubation and mechanical ventilation, which currently are required to administer life-saving surfactant therapy, but which are associated with serious respiratory conditions and other complications. To avoid the risks of surfactant administration, many neonatologists initially delay surfactant therapy and treat premature infants with noninvasive respiratory support (such as nasal continuous positive airway pressure (nCPAP)). We believe that AEROSURF, if approved, has the potential to address a serious unmet medical need by enabling earlier KL4 surfactant therapy for infants receiving nCPAP alone, reducing the number of premature infants who are subjected to invasive surfactant administration, and potentially providing transformative clinical and pharmacoeconomic benefits.

We recently completed an AEROSURF phase 2b clinical trial that was designed to evaluate aerosolized KL4 surfactant administered to premature infants 28 to 32 week gestational age receiving nCPAP, in two dose groups (25 and 50 minutes) with up to two potential repeat doses, compared to infants receiving nCPAP alone. This trial was conducted in approximately 50 clinical sites in the U.S., Canada, the European Union and Latin America. Based on the planned top-line results, data show that AEROSURF did not meet the primary endpoint of a reduction in nCPAP failure at 72 hours, which we believe was due in large part to an unexpected rate of treatment interruptions. Such interruptions occurred in about 24% of active enrollments, predominantly in the 50 minute dose group, and were primarily related to specific lots of disposable cartridge filters in our proprietary ADS that had a tendency to clog. After excluding the patients whose dose was interrupted in the 50 minute dose group, the data show an nCPAP failure rate of 32% compared to 44% in the control 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 targeted outcome.

Business and Pipeline Program Updates

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business – Company Overview" and "– Business Strategy," in the 2016 Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

The following are updates to our business and development programs since filing the 2016 Form 10-K on March 31, 2017:

- On August 14, 2017, we announced that we entered into a Loan Agreement with Lee's Pharmaceutical (HK), Ltd. (Lee's) under which Lee's agreed to lend us up to a potential $3.9 million (Lee's Loan) to be paid in Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017. We received the first installment on August 15, 2017. The loan will be used to support our activities through October 31, 2017, while we and Lee's negotiate a potential share purchase agreement (Share Purchase) under which Lee's would purchase a controlling interest in our Company. In addition, we are negotiating with affiliates of Deerfield Management Company L.P. (Deerfield) to restructure (Loan Restructuring) the outstanding $25 million long-term loan (Deerfield Loan) effective as of the closing of the Share Purchase. Under the Loan Restructuring as currently contemplated, but subject to further negotiation, the notes issued in connection with the Deerfield Loan would be retired in exchange for $2.5 million in cash, common stock equal to 2% of our outstanding shares, plus potential future milestones payments. (*See*, "Note 9 – Subsequent Events").

- We have implemented various cost-cutting measures and evaluated the needs of our Company going forward. Among other things, on July 13, 2017, following completion of our AEROSURF phase 2b clinical trial, we implemented a reduction in our workforce from 48 to 28 employees affecting all functions of our Company. Affected employees are eligible for certain severance and other benefits. In addition, the Company expects to record a one-time charge of approximately $0.2 million in the third quarter of 2017.

- On June 29, 2017, we announced the top line results for our AEROSURF phase 2b clinical trial evaluating aerosolized KL4 surfactant for the treatment of respiratory distress syndrome (RDS) in premature infants, 28 to 32 week gestational age, receiving nCPAP for RDS (*see*, "– Overview").

- In June 2017, we and Lee's announced an exclusive license and collaboration agreement (License Agreement) for the development and commercialization of KL4 surfactant products in China, Hong Kong and other select Asian markets, with a future option to potentially add Japan. The agreement includes AEROSURF as well as the non-aerosol products, SURFAXIN® (approved in the U.S. in 2012) and SURFAXIN LS™ (an improved lyophilized formulation of SURFAXIN). We also granted Lee's an exclusive license to manufacture KL4 surfactant in China for use in non-aerosol surfactant products in the licensed territory. In connection with the Lee's Loan, we amended the License Agreement to reduce or eliminate certain of the milestone and royalty payments and add an affiliate of Lee's as a party to the License Agreement. We also expanded certain of Lee's rights by making effective immediately options to add Japan to the licensed territory and to manufacture the aerosol delivery device in the licensed territory (*see*, "Note 9 –Subsequent Events"). We are presently engaged in a technology transfer of our KL4 surfactant manufacturing process to Lee's.

- On May 3, 2017, we were notified by The Nasdaq Stock Market LLC (Nasdaq) that the Nasdaq Qualifications Hearings Panel had determined to delist our common stock from The Nasdaq Capital Market® (Nasdaq Market). Trading in our common stock on the Nasdaq Market was suspended and our shares began trading on the OTCQB® Market (OTCQB), which is operated by OTC Markets Group Inc., under the symbol "WINT" effective Friday, May 5, 2017. On July 21, 2017, after all appeal periods had expired, Nasdaq filed a Form 25 announcing the removal of our stock from the Nasdaq Market.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2016. For a discussion of our accounting policies, *see*, "Note 4 – Accounting Policies and Recent Accounting Pronouncements" in the Notes to Consolidated Financial Statements (Notes) in our 2016 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended June 30, 2017 and 2016 was $6.1 million and $10.0 million, respectively. The decrease in operating loss from 2016 to 2017 was due to a $1.0 million increase in grant revenue and a $2.8 million decrease in operating expenses.

The operating loss for the six months ended June 30, 2017 and 2016 was $14.3 million and $23.9 million, respectively. The decrease in operating loss from 2016 to 2017 was due to a $1.2 million increase in grant revenue and an $8.5 million decrease in operating expenses.

The net loss for the three months ended June 30, 2017 and 2016 was $6.8 million and $10.6 million, respectively. Included in the net loss is (i) interest expense of $0.6 million in both 2017 and 2016; and (ii) for 2016, $1.2 million for a severance charge related to the termination of our Former CEO.

The net loss for the six months ended June 30, 2017 and 2016 was $15.5 million and $24.5 million, respectively. Included in the net loss is (i) interest expense of $1.2 million and $1.3 million for 2017 and 2016, respectively; and (ii) for 2016, $1.2 million for a severance charge related to the termination of our Former CEO, $0.4 million for a severance charge related to our May 2016 workforce reduction, and the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million.

The net loss attributable to common shareholders for the three and six months ended June 30, 2017 was $7.3 million (or $0.76 basic net loss per common share) and $19.6 million (or $2.10 basic net loss per common share), respectively. The net loss attributable to common shareholders for the three and six months ended June 30, 2016 was $10.6 million (or $1.29 basic net loss per common share) and $24.5 million (or $2.99 basic net loss per common share), respectively. Included in the net loss attributable to common shareholders for the three and six months ended June 30, 2017 is a $0.5 million and a $4.1 million non-cash deemed dividend on preferred stock, respectively (*see*, "Note 5 – Summary of Significant Accounting Policies").

Grant Revenue

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

For the three months ended June 30, 2017 and 2016, we recognized grant revenue of $1.1 million and $0.1 million, respectively. For the six months ended June 30, 2017 and 2016, we recognized grant revenue of $1.4 million and $0.2 million, respectively.

Grant revenue for the three months ended June 30, 2017 includes $0.9 million of funds received and expended under a Phase II Small Business Innovation Research Grant (SBIR) from the National Heart, Lung, and Blood Institute (NHLBI) of the NIH to support the AEROSURF phase 2b clinical trial.

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 three and six months ended June 30, 2017 and 2016 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2017**	**2016**	**2017**	**2016**
Product development and manufacturing	$ 1,830	$ 2,353	$ 3,707	$ 6,134
Clinical, medical and regulatory operations	1,569	1,998	3,377	4,063
Direct preclinical and clinical programs	2,084	3,965	4,812	8,479
Total Research and Development Expenses	$ 5,483	$ 8,316	$ 11,896	$ 18,676

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.2 million for both the three months ended June 30, 2017 and 2016, and of $0.4 million and $0.5 million for the six months ended June 30, 2017 and 2016, respectively.

Product Development and Manufacturing

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

Product development and manufacturing expenses decreased $0.5 million for the three months ended June 30, 2017 compared to the same period in 2016 due to our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures.

Product development and manufacturing expenses decreased $2.4 million for the six months ended June 30, 2017 compared to the same period in 2016 due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures, (ii) a $0.8 million decrease in costs related to development activities under our collaboration agreement with Battelle Memorial Institute (Battelle), and (iii) a $0.5 million decrease in costs associated with the technology transfer of our lyophilized surfactant manufacturing facility process to a new facility at our CMO.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses decreased $0.4 million and $0.7 million, respectively, for the three and six months ended June 30, 2017 compared to the same period in 2016 due to our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures.

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 $1.9 million and $3.7 million, respectively, for the three and six months ended June 30, 2017 compared to the same period in 2016 due to a decrease in AEROSURF phase 2 clinical development program costs as many upfront site initiation costs and manufacturing costs related to ADS delivery, site set-up and training were completed during the three and six months ended June 30, 2016 and are not ongoing clinical trial costs.

General and Administrative Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2017**	**2016**	**2017**	**2016**
General and Administrative Expenses	$ 1,804	$ 1,783	$ 3,726	$ 5,440

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

General and administrative expenses decreased $1.7 million for the six months ended June 30, 2017 compared to the same period in 2016 due to (i) our efforts in the second quarter of 2016 to initiate cash conservation and other cost reduction measures and (ii) $1.6 million of severance charges during the six months ended June 30, 2016 (*see*, "Note 5 – Summary of Significant Accounting Policies").

Other Income and (Expense)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2017**	**2016**	**2017**	**2016**
Interest income	$ 3	$ 5	$ 6	$ 12
Interest expense	(615)	(637)	(1,226)	(1,259)
Other income	-	1	-	434
Other income / (expense), net	$ (612)	$ (631)	$ (1,220)	$ (813)

Interest expense consists of interest expense associated with the Deerfield Loan (*see*, "Note 7 – Long-term Debt") and under our collaboration agreement with Battelle (*see*, "Note 7 – Collaboration Payable and Accrued Expenses" in the Notes to Consolidated Financial Statements in our 2016 Form 10-K).

Other income / (expense) primarily consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits. The decrease in tax credits for the six months ended June 30, 2017 to the same period in 2016 is due to the timing of the sale of the tax credits. The 2015 tax credits were sold in the first quarter of 2016 while the 2016 tax credits were sold in the fourth quarter of 2016.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2017**	**2016**	**2017**	**2016**
Amortization of prepaid interest expense	$ 273	$ 544	$ 543	$ 1,088
Cash interest expense	257	-	511	-
Total interest expense	$ 530	$ 544	$ 1,054	$ 1,088

Amortization of prepaid interest expense represents non-cash amortization of $5 million of units that Deerfield purchased in our July 2015 public offering and accepted in satisfaction of $5 million of future interest payments calculated at an interest rate of 8.75% under the Deerfield Loan. Cash interest expense represents interest at an annual rate of 8.25% on the outstanding principal amount, paid in cash on a quarterly basis.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2017, we had cash and cash equivalents of $2.5 million, current liabilities of $25.4 million (including $12.5 million of long-term debt, current portion) and $12.5 million of long-term debt, non-current portion. Total long-term debt of $25 million is with Deerfield, who hold a security interest in substantially all of our assets related to the Deerfield Loan.

We expect to continue to incur significant losses and require significant additional capital to further advance our AEROSURF clinical development program, support our operations and meet our debt service obligations for the next several years, and we do not have sufficient existing cash and cash equivalents for at least the next year following the date that the accompanying 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 accompanying financial statements are issued.

To potentially alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to seek additional capital through the following: (i) all or a combination of strategic transactions, including other potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions; and (ii) through public or private equity offerings. However, there can be no assurance that these alternatives will be available, or if available, that we will be able to raise sufficient capital through such transactions. If we are unable to raise the required capital, 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 accompanying 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.

In connection with the License Agreement with Lee's that we announced in June 2017 (see, "Note 1 – The Company and Description of Business"), we received an upfront license fee of $1.0 million in July 2017 and also are eligible to receive up to $35.8 million in contingent clinical, regulatory and commercialization milestone payments, and royalties at an escalating high single digit to mid-teens percentage across all products. In addition, Lee's will be responsible for all development costs in the licensed territory. In addition to the License Agreement, Lee's also invested $2 million in our February 2017 private placement offering.

Under a Loan Agreement dated as of August 14, 2017, Lee's agreed to lend us up to a potential $3.9 million (Lee's Loan) that will be funded in Lee's sole discretion in three equal installments on August 15, September 10 and October 10, 2017, and will be used to support our AEROSURF development activities and sustain our operations through October 31, 2017, while we negotiate the potential Share Purchase and related agreements. The Lee's Loan will accrue interest at a rate of 12% per annum. We received the initial installment of $1.3 million from Lee's on August 15, 2017. Under the Share Purchase as currently contemplated, but subject to further negotiation, Lee's would invest $10 million and acquire a controlling interest in our Company. The outstanding principal balance of the Lee's Loan would be applied to the Share Purchase and the Lee's Loan would be discharged in full at the closing. In addition, to facilitate the Share Purchase, we are negotiating the Loan Restructuring with Deerfield to restructure the Deerfield Loan, effective as of the closing of the Share Purchase. Under the Loan Restructuring as currently contemplated, but subject to further negotiation, the notes issued in connection with the Deerfield Loan would be retired in exchange for (i) $2.5 million of cash paid out of the proceeds of the Share Purchase, (ii) a number of newly-issued shares of our common stock equal to 2% of our outstanding common stock on a fully-diluted basis (to be defined) as of the closing date, and (iii) future regulatory and commercial milestones related to the development and commercialization of AEROSURF potentially totaling $15 million. (S*ee*, "Note 9 – Subsequent Events").

While we believe that we will be able to reach agreement with Lee's and Deerfield and close the Share Purchase and Loan Restructuring, there can be no assurance that we will be successful. At this time, we do not have an alternative source of funding available, such that, if we are unable to complete these transactions for any reason on or before October 31, 2017, we may be forced to curtail all of our activities and, ultimately, cease operations. In addition, if we are unable to finalize and close the Loan Restructuring and thereafter fail to make any required payment under the Deerfield Loan, or fail to comply with any commitments contained in the Deerfield Loan documents, Deerfield would be able to declare a default under the Deerfield Loan agreement, accelerate our payment obligations under all or a portion of our indebtedness, and, since we have pledged substantially all of our assets to secure the Deerfield Loan, foreclose on our assets, which could significantly diminish the market value and marketability of our assets and common stock and render us unable to continue as a going concern. Moreover, even if we are successful in completing these transactions, we will continue to require significant additional capital to support our research and development activities going forward, including the AEROSURF development program, and our operations.

As of August 15, 2017, after receipt of the initial advance under the Loan Agreement, we had cash and cash equivalents of $2.9 million and believe that, assuming receipt of the two additional installments under the Lee's Loan and before any additional financings, we will have sufficient cash resources to fund our operations through November 2017.

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

Our ability to secure the needed capital through equity financings and other similar transactions is subject to regulatory and other constraints discussed in this Quarterly Report on Form 10-Q and we cannot be certain that we will be able to raise a sufficient amount when needed, if at all, on favorable terms or otherwise. In the event that we cannot raise sufficient capital, we may be forced to consider transactions on less-than-favorable terms, or limit or cease our development activities. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

In addition, our ability to secure additional capital at a time when we would like or require may be affected by the following factors: (i) our common stock is currently trading on the OTCQB, which is operated by OTC Markets Group Inc., under the symbol "WINT" and may experience periods of illiquidity; (ii) our common stock is currently considered a "penny stock," such that brokers are required to adhere to more stringent market rules, which could result in reduced trading activity and trading levels in our common stock and limited or no analyst coverage; (iii) we are no longer eligible to use a Form S-3 registration statement; (iv) we are no longer able to use our ATM Program; (v) our stockholders may not approve proposals to increase the number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, which could impair our ability to conduct equity financings or enter into certain strategic transactions; (vi) our stockholders may not approve, to the extent required under Delaware law, strategic transactions (mergers and acquisitions) recommended by our Board; (vii) our capital structure, which currently consists of common stock, convertible preferred stock, pre-funded warrants and warrants to purchase common stock, and $25 million of debt, may make it difficult to conduct equity-based financings; and (viii) negative conditions in the broader financial and geopolitical markets. In light of the foregoing restrictions, we will be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time-consuming and costly, and private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests.

We have from time to time collaborated with research organizations and universities to assess the potential utility of our KL_4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical development program. In late May 2017, we announced that we have been awarded $0.9 million under a previously announced Phase II SBIR valued at up to $2.6 million from the NHLBI of the NIH to support the AEROSURF phase 2b clinical trial. We also have received from time to time grants that support medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we expect to pursue potential additional funding opportunities as they arise and expect that we may qualify for similar programs in the future.

As of June 30, 2017, we had outstanding 2.9 million pre-funded warrants issued in a July 2015 public offering, of which the entire exercise price was prepaid upon issuance, 6,213 convertible preferred shares issued in the February 2017 private placement offering. Each preferred share is convertible into 1,000 shares of common stock. Upon exercise of the pre-funded warrants and conversion of the convertible preferred shares, we would issue common shares to the holders and receive no additional proceeds.

As of August 15, 2017, 2.5 million pre-funded warrants and 3,203 convertible preferred shares, convertible into 3.2 million shares of common stock, remained outstanding.

In addition, as of June 30, 2017, there were 120 million shares of common stock and 5 million shares of preferred stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 85.7 million shares of common stock and approximately 5 million shares of preferred stock available for issuance and not otherwise reserved.

Cash Flows

As of June 30, 2017, we had cash and cash equivalents of $2.5 million compared to $5.6 million as of December 31, 2016. Cash outflows for the six months ended June 30, 2017 consist of $12.9 million used for ongoing operating and investing activities offset by cash inflows for the six months ended June 30, 2017 of $9.8 million for financing activities.

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2017 and 2016 was $12.9 million and $18.3 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2017 and 2016 represents capital expenditures of $24,000 and $149,000, respectively.

Financing Activities

Net cash provided by financing activities for six months ended June 30, 2017 was $9.8 million and represents net cash proceeds from both the February 2017 private placement of $8.8 and the use of the ATM Program of $1.0 million.

Net cash provided by financing activities for the six months ended June 30, 2016 was $0.1 million and represents proceeds from the use of the ATM Program.

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

Private Placement Offering

On February 15, 2017, we completed a private placement offering of 7,049 Series A Convertible Preferred Stock units at a price per unit of $1,495, for an aggregate purchase price of approximately $10.5 million, including $1.6 million of non-cash consideration representing a reduction in amounts due and accrued as of December 31, 2016 for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. Each unit consists of: (i) one share of Series A Convertible Preferred Stock, par value $0.001 per share (Preferred Shares); and (ii) 1,000 Series A-1 Warrants (Warrants) to purchase one share of common stock at an exercise price equal to $1.37 per share. Each Preferred Share may be converted at the holder's option at any time into 1,000 shares of common stock at a conversion price of $1.37 per share. The Warrants may be exercised beginning August 15, 2017 and through February 15, 2024. The Preferred Shares and the Warrants may not be converted or exercised to the extent that the holder would, following such exercise or conversion, beneficially own more than 9.99% (or other lesser percent as designated by each holder) of our outstanding shares of common stock. In addition to the offering, the securities purchase agreement also provides that, until February 13, 2018, the investors are entitled to participate in subsequent bona fide capital raising transactions that we may conduct.

As of August 15, 2017, 3,846 Preferred Shares have been converted into 3,846,000 shares of common stock and 3,203 Preferred Shares remain outstanding.

At-the-Market Program (ATM Program)

ATM Program

During the three and six months ended June 30, 2017, we completed offerings of our common stock under our ATM Program of 41,231 shares and 847,147 shares, respectively. This resulted in an aggregate purchase price of approximately $48,000 ($46,000 net) and $1,082,000 ($1,036,000 net), respectively, for the three and six month periods ended June 30, 2017. During the three months ended June 30, 2016, there were no offerings under our ATM Program. During the six months ended June 30, 2016, we completed offerings of our common stock under our ATM Program of 27,971 shares for an aggregate purchase price of approximately $71,000 ($69,000 net).

Effective May 5, 2017, we were no longer able to make use of our ATM Program (*see*, "– Liquidity Risks and Management's Plans").

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended June 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

ITEM 1A. RISK FACTORS

Investing in our securities involves risks. In addition to the other information in this Quarterly Report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in the section "Item 1A. Risk Factors" in our 2016 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. The risks and uncertainties set forth below and discussed elsewhere in this Quarterly Report on Form 10-Q and described in our 2016 Form 10-K are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. If any of the risks and uncertainties set forth below or in our 2016 Form 10-K actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in "Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Overview." In addition, risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations.

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

Our business and our ability to secure the significant additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt is highly dependent upon our ability to successfully develop our AEROSURF® combination drug/device product candidate for the treatment of respiratory distress syndrome (RDS) in premature infants. We recently announced in late June 2017 that the top-line results of our AEROSURF phase 2b clinical trial did not meet the primary endpoint of reduction in nasal continuous positive airway pressure (nCPAP) failure at 72 hours due in part, we believe, to device-related dose interruptions. Although, when the data from patients with dose interruptions is removed, the results appear to show a potential meaningful effect, our failure to demonstrate a meaningful effect in the top-line results, has and is expected to make it more difficult to secure the additional capital that we require. In addition, because the market value of our common stock dropped significantly when we announced our phase 2b results, to raise the additional capital we require, we may have to issue a significantly greater number of shares of capital stock than we originally planned, which could have a dilutive impact on our stockholders. We are assessing the results of our trial in the context of our development and regulatory plans and expect that the regulatory requirements to secure approval for AEROSURF may have changed. To the extent any such change involves unforeseen additional, potentially time-consuming and expensive development work, we may be unable to secure the additional required capital that may be required or, even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may further decline.

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

We have developed a clinic-ready ADS that is suitable for use in our ongoing phase 2 clinical development program and currently are working with Battelle Memorial Institute (Battelle) to further develop a version of the ADS (NextGen) potentially for use in our remaining AEROSURF development activities and, if approved, initial commercial activities. Our device development activities are generally directed to controlling risks of mechanical and other failures, assuring consistency of performance and low variability machine to machine, and rigorous testing and verification processes to avoid design defects. In particular, we are currently assessing the dose interruptions that occurred with the phase 2 ADS and taking steps to assure that we have mitigated the chances of such failures occurring in the NextGen ADS.

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

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

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

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

During and since the period in which we completed enrollment of our AEROSURF phase 2b clinical trial and analyzed and announced the results, our cash resources have been constrained. To manage our cash, we have and plan to operate under processes to tightly control purchasing and retention of consultants, monitor the release of funds and defer payment on invoices to conserve cash availability. While proceeds from the Lee's Loan and potential Share Purchase may provide capital in the short-term to support research and development activities and operations and pay our vendors and service providers, we will still require significant additional capital. As a consequence, our aged accounts payables are expected to increase and our relationships with key vendors and service providers may be strained. While we seek the additional capital that we require, we are working closely with our vendors and service providers to preserve our key relationships. Failure to retain such key relationships could have a material adverse effect on our development activities and our business and operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

As of June 30, 2017, we issued 10,000 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during the period from January 13, 2017 through May 30, 2017. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Windtree Therapeutics, Inc.
(Registrant)

Date: August 21, 2017

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

Date: August 21, 2017

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
10.1+	License Development and Commercialization Agreement by and between the Company and Lee's Pharmaceutical (HK) Ltd. dated as of June 12, 2017	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.1	The following condensed consolidated financial statements from the Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of June 30, 2017 (unaudited) and December 31, 2016, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2017 and June 30, 2016 (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2017 and June 30, 2016, and (v) Notes to Condensed consolidated financial statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

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

Exhibit 10.1

CONFIDENTIAL TREATMENT REQUESTED
EXECUTION COPY

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

BY AND BETWEEN

WINDTREE THERAPEUTICS, INC.

AND

LEE'S PHARMACEUTICAL (HK) LTD.

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Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 under the Exchange Act of 1934, as amended. Confidential Portions are marked: [***]

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement (this "***Agreement***") is entered into as of June 12, 2017 (the "***Effective Date***"), by and between Windtree Therapeutics, Inc., a Delaware corporation with its principal offices at 2600 Kelly Rd., Suite 100, Warrington, PA 18976 ("***Licensor***"), and Lee's Pharmaceutical (HK) Ltd., a Hong Kong company organized and existing under the laws of Hong Kong with its principal offices at Unit 110-111, Bio-Informatics Centre, No. 2 Science Park West Avenue, Hong Kong Science Park, Shatin, Hong Kong ("***Licensee***"). Licensor and Licensee are sometimes referred to in this Agreement individually as a "***Party***" and together as the "***Parties***."

RECITALS

Whereas, Licensor Controls rights in and to the Surfaxin Product and Surfaxin LS and certain Licensor Technology related to the Surfaxin Product and Surfaxin LS, and desires to have Licensee Develop, manufacture and Commercialize the Surfaxin Product and Surfaxin LS in the Licensed Territory;

Whereas, Licensor Controls rights in and to Aerosurf and certain Licensor Technology related to Aerosurf, and desires to have Licensee Develop and Commercialize Aerosurf in the Licensed Territory;

Whereas, Licensor is currently conducting a Phase 2 Study in respect of Aerosurf for the treatment of respiratory distress syndrome (RDS) in up to fifty (50) clinical sites in North America, Latin America and Europe under an investigational new drug application filed with the FDA and is planning for a global Phase 3 Study in respect of Aerosurf for the treatment of RDS to support the potential registration of Aerosurf for the treatment of RDS in the U.S. and other international markets;

Whereas, Licensee possesses resources and expertise in the development, manufacture, marketing and commercialization of pharmaceutical products and medical devices in the Licensed Territory; and

Whereas, Licensor and Licensee desire to collaborate with the aim of advancing the Development, registration and Commercialization of the Surfaxin Product, Surfaxin LS, Aerosurf, and any other pharmaceutical composition containing synthetic KL4 Surfactant in the Licensed Territory, and Licensor wishes to grant Licensee certain rights in respect of the Licensor Technology, the Surfaxin Product, Surfaxin LS, Aerosurf and any other pharmaceutical composition containing synthetic KL4 Surfactant in the Licensed Territory for this purpose.

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

"***Accounting Standards***" means, with respect to a Party, as applicable, (a) United States generally accepted accounting principles as promulgated by the Financial Accounting Standards Board, (b) Hong Kong Accounting Standard and Hong Kong Financial Reporting Standards as promulgated by the Hong Kong Institute of Certified Public Accountants, or (c) international financial reporting standards as promulgated by the International Accounting Standards Board, in each case consistently applied.

"***Acquiror***" has the meaning set forth in Section 14.5.

"***Aerosolized Product(s)***" means any combination drug/device product that utilizes a pharmaceutical composition containing synthetic KL4 Surfactant and Licensor's proprietary aerosol delivery system to produce aerosolized KL4 Surfactant and includes Aerosurf.

"***Aerosurf***" means AEROSURF® (lucinactant for inhalation), a combination drug/device product that utilizes lyophilized synthetic KL4 Surfactant and Licensor's proprietary aerosol delivery system to produce aerosolized KL4 Surfactant for non-invasive aerosolized delivery.

"***Affiliate***" means, with respect to either Party, any person, firm, trust, corporation, partnership or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party; the term "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") meaning direct or indirect ownership of fifty percent (50%) or more, including ownership by one or more trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof.

"***Agreement***" has the meaning set forth in the introductory paragraph.

[***]

[***]

"***Bankruptcy Code***" means, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder, or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder, or any applicable bankruptcy laws of any other country or competent Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

"***Breaching Party***" has the meaning set forth in Section 12.5(a).

"***Business Day***" means any day other than a day on which the commercial banks in New York, New York, Hong Kong or Beijing are authorized or required to be closed.

"***Calendar Quarter***" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term commences on the Effective Date and ends on the day immediately before the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter ends on the last day of the Term.

"***Calendar Year***" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term commences on the Effective Date and ends on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term commences on January 1 of the year in which the Term ends and ends on the last day of the Term.

"***Change of Control***" means, with respect to a Party, (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (b) a merger (including a reverse triangular merger), consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party, or any Affiliate that controls such Party directly or indirectly immediately before such merger, consolidation, share exchange or other similar transaction, ceasing to hold fifty percent (50%) or more of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (c) the acquisition by a person or entity, or group of persons or entities acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of such Party; in all cases of clauses (a)-(c), where such transaction is to be entered into with any person or group of persons other than the other Party or its Affiliates.

"***Claims***" has the meaning set forth in Section 10.1.

"***Clinical Studies***" means any of Phase 1 Studies, Phase 2 Studies, Phase 3 Studies, Phase 4 Studies, or variations of such studies (*e.g.*, Phase 2/3).

"***CMC Information***" means Information related to the chemistry, manufacturing and controls of a Product as specified by the FDA and/or other applicable Regulatory Authorities.

"***Commercialization***," with a correlative meaning for "***Commercialize***" and "***Commercializing***," means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale and distribution of a Product in the Licensed Territory, including Medical Affairs Activities, strategic marketing, sales force detailing, advertising, market and product support, customer support, product distribution, logistics, order taking, invoicing and sales activities, shipping, and handling of returns and allowances; *provided*, *however*, "Commercialization" excludes any activities relating to Development or manufacture of a Product.

"***Commercialization Plan***" has the meaning set forth in Section 6.2(a).

"***Commercially Reasonable Efforts***" means, with respect to a Party's obligations or tasks under this Agreement, the performance of such obligations or tasks by such Party in an diligent, active and sustained manner, without undue interruption, pause or delay, using a level of efforts and employing resources consistent with the exercise of good faith and prudent scientific and business judgment as commonly practiced by similarly situated companies in the pharmaceutical industry for the development or commercialization of similarly situated products of similar commercial or strategic importance as a Product, and at a similar stage of development or commercialization based on conditions then prevailing, taking into account efficacy, safety, patent exclusivity, anticipated or approved labeling, competitive market conditions, the clinical setting in which such Product is expected to be used, and all other relevant factors.

"***Confidential Information***" of a Party means any and all Information of such Party or its Affiliates that is disclosed by such Party or its Affiliates to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form.

"***Control***" or "***Controlled***" means with respect to any (a) material or item of Information or (b) intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating any Third Party rights thereto or the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.

"***Default Notice***" has the meaning set forth in Section 12.5(a).

"***Develop***" or "***Development***" means all activities relating to preparing and conducting non-clinical studies, Clinical Studies and regulatory activities (*e.g.*, preparation of regulatory applications) that are necessary or useful to obtain and maintain Drug Approval of Product in the Licensed Territory.

"***Development Plan***" has the meaning set forth in Section 4.2(a).

"***Device***" means Licensor's proprietary aerosol delivery system, which produces and delivers an aerosolized form of Drug.

"***Device Manufacturing Option***" has the meaning set forth in Section 15.5.

"***Distributor***" means a Third Party that sells Product to the trade but to which a sublicense is not granted pursuant to Section 2.1(c).

"***Dollars***" or "***$***" means U.S. dollars.

"***Drug***" means KL4 Surfactant.

"***Drug Approval***" means an approval granted by the appropriate Regulatory Authority to market a Product in the Field in any particular country or jurisdiction in the Licensed Territory; *provided*, "Drug Approval" includes any and all Marketing Authorizations but excludes any and all Pricing Approvals and Reimbursement Approvals. The term Drug Approval also includes an approval of (a) a drug/device combination such as Aerosurf and (b) each of Drug and Device if required to be obtained separately.

"***Drug Approval Application***" means an application to the appropriate Regulatory Authority for approval to market a Product in the Field in any particular country or jurisdiction in the Licensed Territory; *provided*, "Drug Approval Application" includes any and all Marketing Authorization applications but excludes any and all applications for Pricing Approvals and Reimbursement Approvals.

"***Effective Date***" has the meaning set forth in the introductory paragraph.

"***Executive Officers***" has the meaning set forth in Section 3.1(d).

"***FD&C Act***" means the U. S. Federal Food, Drug, and Cosmetic Act, as amended.

"***FDA***" means the U.S. Food and Drug Administration or any successor entity.

"***Field***" means (a) with respect to Non-Aerosolized Products, the prevention, mitigation and/or treatment of any disease, disorder or condition in humans, and (b) with respect to Aerosolized Products, the prevention, mitigation and/or treatment of any respiratory disease, disorder or condition in humans.

"***First Commercial Sale***" means, with respect to a particular Product, the first sale by Licensee or its Affiliate or Sublicensee to a Third Party of such Product in a given country or regulatory jurisdiction after Drug Approval for such Product has been obtained in such country or regulatory jurisdiction.

"***Generic/Branded Generic***" shall mean, with respect to (a) a Non-Aerosolized Product, a drug product containing [***] other than any such drug product distributed by Licensee or its Affiliates or Sublicensees on an unbranded basis or under a private label of any Affiliate or Sublicensee; and (b) an Aerosolized Product, a drug/device combination product containing [***] For clarity, a drug/device combination product containing [***] shall not be considered a Generic/Branded Generic with respect to an Aerosolized Product, for purposes of this Agreement.

"***Good Clinical Practices***" or "***GCP***" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by other Regulatory Authorities applicable to the Licensed Territory, the Licensor Territory, or both, as such standards, practices and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"***Good Laboratory Practices***" or "***GLP***" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by other Regulatory Authorities applicable to the Licensed Territory, the Licensor Territory, or both, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"***Governmental Authority***" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

"***ICH***" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"***ICH Guidelines***" means the guidelines of the ICH.

"***Improvements***" means any and all ideas, Information, research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable or copyrightable, and all patent rights and other intellectual property rights in any of the foregoing.

"***In-License Agreements***" means [***]

"***In-License Agreements Royalty Rate***" means the sum of the applicable royalty rates payable by Licensor pursuant to, and as specified in, the In-License Agreements.

"***Indemnified Party***" has the meaning set forth in Section 10.3.

"***Indemnifying Party***" has the meaning set forth in Section 10.3.

"***Information***" means any non-public, proprietary data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including trade secrets, practices, techniques, methods, processes, protocols, inventions, discoveries, developments, specifications, formulations, formulae, materials, drawings, illustrations or other artwork, or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, experimentation or test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC Information, stability data and other study data and procedures, and other know-how, whether or not patentable or copyrightable.

"***JAMS Rules***" has the meaning set forth in Section 13.1.

"***JCC***" has the meaning set forth in Section 3.3(a).

"***JDC***" has the meaning set forth in Section 3.2(a).

"***JSC***" has the meaning set forth in Section 3.1(a).

"***Joint Improvements"*** has the meaning set forth in Section 8.1(c).

"***Joint Patents***" has the meaning set forth in Section 8.1(c).

"***KL4 Surfactant***" means a pharmaceutical composition containing the peptide known as KL4 with the following amino acid sequence KLLLLKLLLLKLLLLKLLLLK.

"***Knowledge***" means, with respect to a Party or its Affiliates, the actual knowledge of the executive officers of such Party or its Affiliates (without any inquiry).

"***Laws***" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

"***Licensed Marks***" has the meaning set forth in Section 8.6(b).

"***Licensed Territory***" means PRC, Hong Kong, [***]Taiwan, [***] South Korea, Thailand, [***] and subject to Licensee timely exercise of the Option, Japan.

"***Licensed Territory Development Costs***" means all costs and expenses incurred by or on behalf of Licensor or Licensee after the Effective Date in accordance with this Agreement and in accordance with the Development Plan attributable to the Development of Product in and for the Licensed Territory, including all out-of-pocket costs actually incurred by Licensor or Licensee, filing fees payable to Regulatory Authorities in the Licensed Territory, costs of Product or comparator drugs used in Clinical Studies and non-clinical studies, ethics committee fees, investigators fees, investigators meetings costs, hospital fees, and clinical research organization fees and any other development and regulatory costs in and for the Licensed Territory.

"***Licensed Territory Infringement***" has the meaning set forth in Section 8.3(a).

"***Licensee***" has the meaning set forth in the introductory paragraph.

"***Licensee Improvements"*** has the meaning set forth in Section 8.1(d).

"***Licensee Indemnitees***" has the meaning set forth in Section 10.1.

"***Licensee Know-How***" means all Information, subject to Section 8.1, that is necessary or useful for the Development, manufacture or Commercialization of a Product in the Field, and (b) is Controlled by Licensee or its Affiliates during the Term; *provided*, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee.

"***Licensee Marks***" means the trademarks to be used by Licensee in connection with its Commercialization of Product in the Licensed Territory.

"***Licensee Patent***" means any Patents, subject to Section 8.1, that (a) claim a Product, the Drug or the Device, or the manufacture or use of a Product, the Drug or the Device, in the Field, and (b) are Controlled by Licensee or its Affiliates during the Term; *provided*, that the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee.

"***Licensee Technology***" means, subject to Section 8.1, the Licensee Know-How and Licensee Patents.

"***Licensor***" has the meaning set forth in the introductory paragraph.

"***Licensor Improvements"*** has the meaning set forth in Section 8.1(b)(ii).

"***Licensor Indemnitees***" has the meaning set forth in Section 10.2.

"***Licensor Know-How***" means all Information, subject to Section 8.1, that (a) is necessary or useful for the Development or Commercialization of an Aerosolized Product in the Field but is not directed to the manufacture of Aerosolized Product, or (b) is necessary or useful for the Development, manufacture and Commercialization of Non-Aerosolized Product in the Field, and (c) in the case of either clause (a) or (b), is (i) Controlled by Licensor or its Affiliates as of the Effective Date or (ii) subject to Section 2.7, Controlled by Licensor or its Affiliates during the Term; *provided*, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensor after the Effective Date due to a Change of Control of Licensor.

"***Licensor Patent***" means any Patents, subject to Section 8.1, that (a) claim a Product, the Drug or the Device, or the manufacture or use of a Product, the Drug or the Device, in the Field, and (b) (i) are Controlled by Licensor or its Affiliates as of the Effective Date, which Patents are set forth in **Schedule 1** hereto, (ii) subject to Section 2.8, are Controlled by Licensor or its Affiliates during the Term and claims priority to a Patent Controlled by Licensor or its Affiliates as of the Effective Date, or (iii) subject to Section 2.8, are Controlled by Licensor or its Affiliates during the Term; *provided*, that the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensor after the Effective Date due to a Change of Control of Licensor.

"***Licensor Prosecuted Patents***" has the meaning set forth in Section 8.2(a).

"***Licensor Technology***" means, subject to Section 8.1, the Licensor Know-How and Licensor Patents.

"***Licensor Territory***" means the entire world, excluding the Licensed Territory.

"***Manufacturing Effective Date***" means the date the technology transfer contemplated in Section 15.3 is completed.

"***Marketed***" has the meaning set forth in Section 7.4(d).

"***Marketing Authorization***" means an official document issued by a competent Regulatory Authority for the purpose of importation, manufacturing, marketing, sale or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, subject to the prevailing Laws, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose, the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based and contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

"***Material Impact***" means with respect to a Product, a material adverse impact on the development, regulatory status or commercial sale of the Product.

"***Medical Affairs Activities***" means, with respect to a Product, activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, such Product, including, with respect to such Product: (a) conducting service based medical activities, including providing input and assistance with consultancy meetings, recommending investigators for Clinical Studies and providing input in the design of such Clinical Studies and other research related activities, and delivering non-promotional communications and conducting non-promotional activities, including presenting new clinical trial data and other scientific information; (b) grants to support continuing medical education, symposia, or Third Party research specifically related to such Product; (c) development, publication and dissemination of publications relating to such Product and relevant disease states; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call or email; (e) conducting advisory board meetings or other consultant programs; (f) support of investigator-initiated clinical trials; (g) managing relationships with cooperative groups, physician/hospital networks and advocacy groups; and (h) establishing and implementing risk, evaluation and mitigation strategies.

"***Net Sales***" means, with respect to a particular Product, the total amount invoiced by Licensee or its Affiliates or Sublicensees to each Third Party receiving such Product in arm's length transactions, less the following deductions from such total amounts that are actually incurred, allowed, accrued or specifically allocated in accordance with the Accounting Standards:

[***]

Upon the sale or other disposal of such Product, other than in a transaction generating revenues from or based on a sales price for such Product (which sales price is either customary or would be reasonably expected), such sale or disposal will constitute a sale with the consideration for the sale being the consideration for the relevant transaction and will constitute Net Sales hereunder or if the consideration is not a monetary amount, such sale or disposal will have the value of whatever consideration has been provided in exchange for the supply.

For this definition:

(i) the transfer of Product by Licensee or one of its Affiliates to another Affiliate or a Sublicensee shall not be considered a sale; and

(ii) any disposal of Product for, or use of Product in, Clinical Studies is not a sale under this definition.

The amount of Product transferred pursuant to subsections (i) and (ii) of this definition shall be determined from the books and records of Licensee or its Affiliates or Sublicensees, maintained in accordance with international financial reporting standards, consistently applied, but excluding any notes thereto.

"***Non-Aerosolized Product***" means Surfaxin Product, Surfaxin LS and any other pharmaceutical composition containing the synthetic KL4 Surfactant, in each case to be administered in any form other than as aerosol.

"***Non-Breaching Party***" has the meaning set forth in Section 12.5(a).

"***Non-Governmental Authority***" means any public body or non-Governmental Authority with the authority to control, approve, recommend or otherwise determine pricing and reimbursement of pharmaceutical products and/or medical devices, including those with authority to enter into risk sharing schemes or to impose retroactive price reductions, discounts, or rebates.

"***Option***" has the meaning set forth in Section 2.3.

"***Other Committees***" has the meaning set forth in Section 3.1(a)(ix).

"***Party***" or "***Parties***" has the meaning set forth in the introductory paragraph.

"***Patents***" means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) any other patent application claiming priority to any of the foregoing anywhere in the world; and (d) extension, renewal or restoration of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

"***Payee***" has the meaning set forth in Section 7.7.

"***PDF***" has the meaning set forth in Section 14.13.

"***Pharmacovigilance Agreement***" has the meaning set forth in Section 5.7.

"***Phase 1 Study***" means a human clinical trial of a Product with the endpoint of determining initial tolerance, safety or pharmacokinetic information in single dose, single ascending dose, multiple dose or multiple ascending dose regimens, as described in 21 C.F.R. § 312.21(a) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"***Phase 2 Study***" means a human clinical trial of a Product, the principal purpose of which is a preliminary determination of safety and efficacy in the target patient population over a range of doses and dose regimens, as described in 21 C.F.R. § 312.21(b) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"***Phase 3 Study***" means a human clinical trial of a compound or product (including a Product) in a sufficient number of subjects that is designed to establish that such compound or product is safe and efficacious for its intended use, and to determine warnings, precautions and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support Regulatory Approval of such compound or product or label expansion of such compound or product.

"***Phase 4 Study***" means a human clinical trial of a compound or product in patients commenced after receipt of Regulatory Approval for such compound or product, which clinical trial is conducted within the parameters of such Regulatory Approval, including clinical trials required or requested by any Regulatory Authority as a condition of, or in connection with, obtaining such Regulatory Approval of such compound or product, *provided*, a "Phase 4 Study" may also include clinical trials to gather additional information regarding such compound's or product's potential risks, medical or pharmacoeconomic benefits, justification and descriptions for other indications of such compound or product, data to be included in compendial listings, optimal use, dose, route and schedule of administration, epidemiological studies, modeling and pharmacoeconomic studies.

"***PRC***" means the People's Republic of China.

"***Pricing Approval***" means the governmental approval, agreement, determination or decision establishing prices for a Product that can be charged in a particular country or regulatory jurisdiction where the applicable Governmental Authorities approve or determine the price of pharmaceutical products.

"***Product License Holder***" means the holder of a Marketing Authorization.

"***Product***" means an Aerosolized Product and/or a Non-Aerosolized Product, as the context requires.

"***Publication***" has the meaning set forth in Section 11.3.

"***RDS***" means respiratory distress syndrome.

"***Regulatory Approval***" means (a) Drug Approval and all other approvals necessary for the commercial sale of a Product in a given country or regulatory jurisdiction; (b) Pricing Approval, but only in those countries or regulatory jurisdictions where Pricing Approval is required by Law for commercial sale; and (c) Reimbursement Approval, but only in those countries or regulatory jurisdictions where Reimbursement Approval is required for the price paid for a Product to be reimbursed by a Governmental Authority or a Non-Governmental Authority with the authority to approve reimbursement.

"***Regulatory Authority***" means, in a particular country or jurisdiction, any applicable Governmental Authority or Non-Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

"***Regulatory Exclusivity***" means, with respect to a Product, that Third Parties are prevented from legally developing, manufacturing or commercializing a product that could compete with such Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent rights.

"***Regulatory Materials***" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Drug Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction.

"***Regulatory Plan***" means a plan regarding the timing and approach to preparing, submitting or reviewing Regulatory Materials and obtaining and maintaining Drug Approval.

"***Reimbursement Approval***" means the approval, agreement, determination or decision recommending or approving a Product for use or establishing the prices for a Product that can be reimbursed in regulatory jurisdictions where the applicable Governmental Authority or Non-Governmental Authority approves, determines or recommends the reimbursement or use of pharmaceutical products.

"***Remedial Action***" has the meaning set forth in Section 5.8.

"***Safety Reason***" has the meaning set forth in Section 13.2(a).

"***SEC***" has the meaning set forth in Section 11.4(c).

"***Sublicense Income***" means income received by Licensee or its Affiliates in consideration for a sublicense or other agreement providing the right to negotiate or obtain a sublicense pursuant to Section 2.1(c). "Sublicense Income" shall include income received from a Sublicensee in the form of [***].

"***Sublicensee***" means any entity to which a sublicense is validly granted pursuant to Section 2.1(c). For clarity, a Distributor shall not be considered a Sublicensee. Any intended full service Distributors may be reviewed by the JSC to ensure proper capabilities of safety and/or adverse event reporting.

"***Surfaxin Product***" means Surfaxin® (lucinactant) intratracheal suspension, a pulmonary KL4 Surfactant, based on NDA No. 21-746, as approved by the FDA on March 6, 2012.

"***Surfaxin LS***" means the lyophilized dosage form of the Surfaxin Product.

"***Term***" has the meaning set forth in Section 12.1.

"***Third Party***" means any entity other than Licensor or Licensee or an Affiliate of either of them.

"***Third Party Claim***" has the meaning set forth in Section 8.4.

"***Third Party Technology***" means any Patents, Information, inventions, or other intellectual property owned or controlled by a Third Party but not Controlled by a Party or its Affiliates.

"***U.S.***" means the United States of America, its possessions and territories.

"***Valid Claim***" means a claim of (a) an issued and unexpired Patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a patent application for a patent included within the Patents and which claim has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

ARTICLE 2

LICENSES; OTHER RIGHTS

2.1. Licenses to Licensee.

(a) Aerosolized Products. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor), milestone- and royalty-bearing license, with the right to grant sublicenses solely as permitted under Section 2.1(c), under the Licensor Technology, to Develop, use, sell, offer for sale, import, distribute and otherwise Commercialize Aerosolized Products in the Field in the Licensed Territory, *provided* that Licensor or an Affiliate of Licensor will be the Product License Holder for Aerosolized Products in each country of the Licensed Territory (i) unless the prevailing Laws or regulations in any given country of the Licensed Territory would not allow Licensor or its Affiliate to hold the Marketing Authorization, in which case the identity of the Product License Holder in such country and arrangements concerning the ownership, maintenance and transferability of such Marketing Authorization shall be subject to Licensor's approval, such approval not to be unreasonably withheld or delayed, and (ii) in case, however, no alternative solution is agreed upon between the Parties, or available to the Parties in accordance with the prevailing Laws and regulations, then the Product License Holder in such country will be the Licensee (or its Affiliate or Sublicensee, as the case may be).

(b) Non-Aerosolized Products. In addition to the rights granted under Section 2.1(a), and subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor), milestone and royalty-bearing license, with the right to grant sublicenses solely as permitted under Section 2.1(c), under the Licensor Technology, to Develop, register, manufacture, use, sell, offer for sale, import, distribute and otherwise Commercialize Non-Aerosolized Products in the Field in the Licensed Territory. Licensee's right to manufacture Non-Aerosolized Products is not sublicensable other than to its Affiliates in accordance with Section 2.1(c).

(c) Sublicense Rights. Licensee may grant sublicenses of the licenses granted in Sections 2.1(a) and 2.1(b) without the prior approval of Licensor, only to (A) its Affiliates, *provided* that such sublicense will automatically terminate if such person, corporation, partnership or entity ceases to be an Affiliate of Licensee, and (B) Third Party subcontractors for the sole purpose of performing part of Licensee's obligations under this Agreement (excluding any Third Party manufacturers), and in each case on the condition that Licensee shall at all times Develop, use, sell, offer for sale, import, distribute, register and manufacture and otherwise Commercialize Product in Licensee's or its Affiliate's name. Licensee shall not grant any sublicenses of the licenses granted in Sections 2.1(a) or 2.1(b) to any Third Party (including any Third Party manufacturer but excluding any non-manufacturing Third Party subcontractors as permitted in the preceding sentence) without the prior written approval of Licensor, which approval will not be unreasonably withheld or delayed by Licensor. A Sublicensee or a subcontractor may not be a competitor or an Affiliate of a competitor identified by Licensor to Licensee in writing. Licensee shall remain responsible for and shall guarantee the performance of each Sublicensee under this Agreement, including for all payments due hereunder, even if such Sublicensee has read and agreed in writing to be bound to all of Licensee's rights and obligations under this Agreement to the same extent as Licensee. Sublicenses granted under this Section 2.1(c) shall not include the right to sublicense. As stated in Section 2.1(b), Licensee's right to manufacture Non-Aerosolized Products is not sublicensable other than to its Affiliates in accordance with this Section 2.1(c).

(d) Retained Rights. Notwithstanding the foregoing exclusive grant of rights to Licensee under this Section 2.1, Licensor retains the right to conduct development of Product in the Licensed Territory to support the development and commercialization of Product in the Licensor Territory. Such development activities specifically conducted by Licensor in the Licensed Territory will be subject to the Development Plan and JSC review and approval.

2.2. License to Licensor.

Subject to the terms and conditions of this Agreement, including section 8.1, Licensee hereby grants to Licensor an exclusive (even as to Licensee), fully paid, royalty-free right and license (with the right to grant sublicenses), under the Licensee Know How, to (A) develop Product in the Field in order to obtain or maintain Regulatory Approval in the Licensor Territory, and (B) make, use, sell, offer for sale, import, distribute, warehouse, market, promote, apply for and submit applications for Drug Approval, Pricing Approval and Reimbursement Approval, and otherwise commercialize Product in the Field in the Licensor Territory.

2.3. Option.

Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an option, exercisable in Licensee's sole discretion, to add Japan to the Licensed Territory subject to approval of the JSC based on the JSC's review and evaluation of the business case and a business plan for Japan presented by Licensee, as well as other market conditions and strategic options and considerations then relevant to the Japan market (an "***Option***"). It is expressly agreed that the JSC's review and evaluation of the business case and business plan, and its determination as to whether or not to approve the addition of Japan to the Licensed Territory, shall not be unreasonably withheld or delayed by the JSC. The Option must be exercised no later than [***], and Licensee must also provide a written progress update to the JSC [***] on activities undertaken by Licensee with respect to its strategy in Japan.

2.4. Negative Covenants.

(a) Licensee shall not, and will not permit any of its Affiliates or Sublicensees to use or practice any Licensor Technology outside the scope of the licenses granted to it under Section 2.1. Licensor shall not, and shall not permit any of its Affiliates or its Sublicensees to use or practice any Licensee Technology outside the scope of the licenses granted to it under Section 2.2.

(b) Licensee shall not at any time seek to aerosolize a Non-Aerosolized Product or use it as a powder or in combination with any aerosol device, nebulizer or other delivery system, or any device that provides a liquid/gas mixture.

(c) Neither Party will participate in any cross-territorial selling or distribution into the other Party's territory without the other Party's written consent.

2.5. Non-Compete Covenants.

(a) During the Term, for a period of ten (10) years after the later of (x) the First Commercial Sale in the PRC of the first Aerosolized Product under this Agreement, and (y) the First Commercial Sale in the PRC of the first Non-Aerosolized Product under this Agreement, Licensee, Licensee's Affiliates, and its and their respective Sublicensees shall not develop, register, manufacture, have manufactured, import, export, market, distribute, or sell anywhere in the world any product for the prevention and/or treatment of (i) RDS in premature infants, or (ii) diseases and conditions (other than RDS) in humans, in either case that administers, utilizes or contains pulmonary surfactant, other than in accordance with this Agreement, without Licensor's prior written consent, which consent Licensor may grant or withhold in its sole discretion.

(b) During the Term, Licensee shall not reverse engineer or otherwise deconstruct any active pharmaceutical ingredients or component parts of a Product for the purpose of developing a product that would compete in any way with a Product in the Field.

(c) Neither Party nor any of their respective Affiliates will take, support or encourage any action with respect to any Product that is substantially likely to have a Material Impact in the other Party's territory.

(d) For the avoidance of doubt, the Parties intend that each of Licensor and Licensee shall have the right to enjoy the benefits of Licensor Technology in its respective territory without intrusion or interruptions by the other Party. Licensee acknowledges that the provisions of this Section 2.5 are in partial consideration of the licensed rights, including trade secrets delivered and/or all other Licensor Technology rights granted to Licensee under this Agreement.

2.6. No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party will be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

2.7. Third Party Technology. If, after the Effective Date, Licensor or any of its Affiliates (i) acquires a license with the right to sublicense under Third Party Technology for use in connection with the Development or Commercialization of a Product in or for the Licensed Territory, and (ii) would be subject to payment obligations to such Third Party on account of Licensee's exploitation of such Third Party Technology in connection with the Development or Commercialization of such Product in or for the Licensed Territory, then Licensor will promptly provide Licensee with written notice of such acquisition and the additional financial terms to which Licensor would be subject if Licensee were to exploit a license under such Third Party Technology. If Licensee desires to obtain such license it will notify Licensor in writing and this Agreement will be deemed amended to reflect such additional financial terms and to provide that the applicable Third Party Technology will be included in Licensor Technology under this Agreement.

2.8. In-Licenses. All licenses and other rights granted to Licensee by Licensor under this Article 2 are subject to the rights and obligations of the parties under the In-License Agreements. Licensee agrees to be bound by the pertinent portions of the In-License Agreements to the same extent that Licensor is bound thereby. In addition, the sublicense to Licensee of the Licensor Technology, to the extent such Licensor Technology is licensed to Licensor under each In-License Agreement, and as long as such In-License Agreement remains in force, shall automatically terminate if and to the extent such In-License Agreement terminates. In such a case, Licensor will use Commercially Reasonable Efforts to allow Licensee to negotiate the continuation of the rights and licenses granted to Licensee in Article 2 directly with Licensor's respective licensor(s) under the In-License Agreement(s) being terminated.

ARTICLE 3

GOVERNANCE

3.1. Joint Steering Committee.

(a) Formation and Role. Within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the "***JSC***") for the overall coordination and oversight of the Parties' activities under this Agreement. The role of the JSC shall be:

(i) to review, discuss and approve the overall strategy for the Development and Regulatory Approval of Product in the Field in the Licensed Territory;

(ii) to review, discuss and approve the inclusion of Japan in the Licensed Territory based on the business plan presented by Licensee to the JSC;

(iii) to review and discuss the overall performance of the Parties pursuant to this Agreement and to compare such performance to the objectives outlined in the Development Plan and to the diligence obligations set forth in Section 4.4;

(iv) to review, discuss and approve the Development Plan (including the Regulatory Plan), and any amendments to the Development Plan proposed by the JDC;

(v) to review, discuss and approve the conduct by Licensee of all country-specific or jurisdiction-specific regulatory activities in the Licensed Territory;

(vi) to review and discuss the Commercialization Plan and any amendments to the Commercialization Plan proposed by either Party;

(vii) to review and discuss the overall strategy for Pricing Approval and Reimbursement Approval of Product in the Field in the Licensed Territory, and all country-specific or jurisdiction-specific pricing and reimbursement negotiations in the Licensed Territory, *provided* global pricing of Product (including pricing floors for referencing countries) will be established collaboratively at the JSC (and in conjunction with other applicable parties, as necessary);

(viii) to discuss the Parties' activities with respect to Product in the Field in the Licensed Territory in conjunction with Licensor's and its other licensees' activities with respect to Product in the Field in the Licensed Territory or the Licensor Territory;

(ix) to direct and oversee the JDC, JCC and any other operating committee (the "***Other Committees***") established by the JSC on all significant issues that fall within the purview of such committees;

(x) to appoint Other Committees, consisting of equal numbers of appropriately qualified members appointed by each Party, from time to time as it deems fit;

(xi) to attempt to resolve, in a timely manner, issues presented to it by, and disputes within, the JDC, JCC and Other Committees; and

(xii) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing.

The JSC has only the powers expressly assigned to it in this Section 3.1 and elsewhere in this Agreement. The JSC has no power to interpret, amend, modify, or waive compliance with this Agreement.

(b) Members. Each Party shall initially appoint two (2) representatives to the JSC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual written consent of its members and each Party may replace its representatives at any time upon written notice to the other Party; *provided, however*, that the JSC will at all times consist of equal numbers of members appointed by each Party. If a JSC representative from either Party is unable to attend or participate in a meeting of the JSC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting. The JSC will have a chairperson, who will be designated, on an annual basis, alternatively by Licensor or Licensee. The Licensor shall select the initial chairperson. The role of the chairperson is to convene and preside at all meetings of the JSC and to ensure the preparation of meeting minutes, but the chairperson has no additional powers or rights beyond those held by other JSC representatives.

(c) Meetings. The JSC shall meet at least one (1) time every other Calendar Quarter during the Term until Regulatory Approval of each Product is achieved; thereafter, the JSC shall meet at least one (1) time per Calendar Year during the Term. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least [***] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party shall provide the JSC no later than [***] before the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JSC may meet in person, by videoconference or by teleconference, *provided*, *however*, [***]; all other meetings shall alternate as between Licensor's headquarters and Licensee's headquarters. Each Party shall pay for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JSC meetings as non-voting observers or presenters. The chairperson of the JSC shall prepare reasonably detailed written minutes of all JSC meetings that reflect and include all material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval within [***] after each JSC meeting. Such minutes will be approved unless one or more members of the JSC object to the accuracy of such minutes within [***] after receipt.

(d) Decision Making. Actions to be taken by the JSC will be taken only following [***] vote, with each Party having [***] representing the views of its members. If the JSC fails to reach [***] agreement on a matter before it for decision for a period in excess of [***], either Party may submit the matter in writing to the other, and the Parties shall refer such dispute to a designated executive officer of Licensor and a designated executive officer of Licensee (or their respective designees) (the "***Executive Officers***") for resolution in accordance with the decision-making procedures described in Section 13.2; *provided, however*, [***]. Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party shall delegate to or vest any such rights, powers, or discretion in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the foregoing, the JSC does not have the power to interpret, amend, modify, or waive compliance with this Agreement.

3.2. Joint Development Committee.

(a) Formation and Role. Within [***] after the Effective Date, the Parties shall establish a joint development committee (the "***JDC***") that will monitor the Development of Product in the Field in the Licensed Territory. The role of the JDC is:

(i) to monitor the Development of Product in the Field in the Licensed Territory, and to discuss the development of Product in the Field in the Licensor Territory;

(ii) to prepare the Development Plan (including the Regulatory Plan) and any amendments to the Development Plan, including the budget and anticipated timeline for performing each Development activity and the design of each Clinical Study or other study included or proposed to be included in the Development Plan, for review, discussion and approval by the JSC;

(iii) to agree on the requirements for Drug Approval in the Licensed Territory;

(iv) to review, discuss and coordinate the Parties' scientific presentation and publication strategy relating to Product in the Field, if any;

(v) to discuss Development activities in the Field as between the Licensed Territory and the Licensor Territory;

(vi) to facilitate the flow of Information between the Parties with respect to the development of, and obtaining Drug Approval for, Product in the Field; and

(vii) to perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of Product in the Field in the Licensed Territory, as directed by the JSC.

(b) Members. Each Party shall initially appoint two (2) representatives to the JDC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual written consent of its members and each Party may replace its representatives at any time upon written notice to the other Party. If a JDC representative from either Party is unable to attend or participate in a meeting of the JDC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting. The JDC will have a chairperson, who will be designated, on an annual basis, alternatively by Licensor or Licensee. The Licensee shall select the initial chairperson. The role of the chairperson is to convene and preside at all meetings of the JDC and to ensure the preparation of meeting minutes, but the chairperson has no additional powers or rights beyond those held by other JDC representatives.

(c) Meetings. The JDC shall meet at least one (1) time per Calendar Quarter during the Term. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) upon at least [***] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party shall provide the JDC no later than [***] before the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JDC may meet in person, by videoconference or by teleconference; *provided, however*, [***]; all other meetings shall alternate as between Licensor's headquarters and Licensee's headquarters. Each Party shall pay for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JDC meetings as non-voting observers or presenters. The chairperson of the JDC shall prepare reasonably detailed written minutes of all JDC meetings that reflect and include all material decisions made at such meetings. The JDC chairperson shall send draft meeting minutes to each member of the JDC for review and approval within [***] after each JDC meeting. Such minutes will be approved unless one or more members of the JDC object to the accuracy of such minutes within [***] of receipt.

(d) Decision Making. Actions to be taken by the JDC will be taken only following [***] vote, with each Party having [***] the views of its members. If the JDC fails to reach unanimous agreement on a matter before it for decision for a period in excess of [***] from the date first presented to the JDC in writing, the JDC shall refer the matter promptly to the JSC for timely resolution. Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party shall delegate to or vest any such rights, powers, or discretion in the JDC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the foregoing, the JDC does not have the power to interpret, amend, modify, or waive compliance with this Agreement.

3.3. Joint Commercialization Committee.

(a) Formation and Role. At least [***] before the anticipated launch of Product in the Field in [***], whichever shall occur first, the Parties shall establish a joint commercialization committee (the "***JCC***") that will oversee the Commercialization of Product in the Field in the Licensed Territory. The role of the JCC is:

(i) to discuss the Parties' respective Commercialization activities in and as between the Licensed Territory and the Licensor Territory;

(ii) to review and comment upon the Commercialization Plan submitted by Licensee, as well as any amendments thereto submitted by Licensee, and to submit such Commercialization Plan or amendment thereto to the JSC for review and discussion;

(iii) to monitor implementation of the Commercialization Plan;

(iv) to review and discuss overall strategy for Pricing Approval and Reimbursement Approval of Product in the Field in the Licensed Territory;

(v) to review, discuss and coordinate the Parties' attendance, Product messaging and presentations (including "poster-board" presentations and industry booths) at international seminars and conferences at which Product is being discussed, if any; and

(vi) to perform such other functions as appropriate to further the purposes of this Agreement with respect to the Commercialization of Product, as directed by the JSC.

(b) Members. Each Party shall initially appoint two (2) representatives to the JCC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JCC's responsibilities. The JCC may change its size from time to time by mutual written consent of its members and each Party may replace its representatives at any time upon written notice to the other Party. If a JCC representative from either Party is unable to attend or participate in a meeting of the JCC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting. The JCC will have a chairperson, who will be designated, on an annual basis, alternatively by Licensor or Licensee. Licensee shall select the initial chairperson. The role of the chairperson is to convene and preside at all meetings of the JCC and to ensure the preparation of meeting minutes, but the chairperson has no additional powers or rights beyond those held by other JCC representatives.

(c) Meetings. The JCC shall meet at least one (1) time per Calendar Year after its formation during the Term. Either Party may also call a special meeting of the JCC (by videoconference or teleconference) upon at least five (5) Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party shall provide the JCC no later than five (5) Business Days before the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JCC may meet in person, by videoconference or by teleconference; *provided*, *however*, at least one (1) meeting every other Calendar Year occur in person at a mutually agreeable location; all other meetings shall alternate as between Licensor's headquarters and Licensee's headquarters. Each Party shall pay for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JCC meetings as non-voting observers or presenters. The chairperson of the JCC shall prepare reasonably detailed written minutes of all JCC meetings that reflect and include all material decisions made at such meetings. The JCC chairperson shall send draft meeting minutes to each member of the JCC for review and approval within [***] after each JCC meeting. Such minutes will be approved unless one or more members of the JCC object to the accuracy of such minutes within [***] of receipt.

(d) Decision Making. Actions to be taken by the JCC will be taken only following [***] vote, with each Party having [***] representing the views of its members. If the JCC fails to reach [***] agreement on a matter before it for decision for a period in excess of [***] from the date first presented to the JCC in writing, the JCC shall refer the matter promptly to the JSC for timely resolution. Each Party retains the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JCC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the foregoing, the JCC does not have the power to interpret, amend, modify, or waive compliance with this Agreement.

3.4. Good Faith. In conducting themselves on any committees, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use Commercially Reasonable Efforts to reach consensus on all matters before them. In exercising any decision-making authority granted to it under this Article 3, each Party shall conduct its discussions in good faith with a view toward operating for the mutual benefit of the Parties and in furtherance of the successful Development and Commercialization of Product in the Licensed Territory. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of their respective Affiliates will be required to take, or will be penalized for not taking, any action that is not in compliance with such Party's ethical business practices and policies or that such Party reasonably believes is not in compliance with Laws.

ARTICLE 4

PRODUCT DEVELOPMENT

4.1. Overview. The Parties desire and intend to collaborate with respect to the development of Product in the Field, as and to the extent set forth in this Agreement. As between the Parties, except as set forth in this Article 4 or in the Development Plan, Licensor shall be responsible for development of Product in the Licensor Territory and Licensee shall be responsible for Development of Product in the Licensed Territory. In particular, Licensee will take primary responsibility for Development of Non-Aerosolized Products in the Licensed Territory. Furthermore, Licensor will designate Licensee its exclusive agent and exclusive representative to Develop Aerosolized Products in the name of and on behalf of Licensor (as the Product License Holder), consistent with and subject to the license grant provided to Licensee under Section 2.1(a), in the Licensed Territory. Licensor will use Commercially Reasonable Efforts to provide Licensee access to all relevant supplies, licenses, regulatory correspondence and all other information required to enable Licensee to fulfill its responsibilities.

4.2. Development Plan.

(a) General. The Licensee shall develop Product with respect to the Field pursuant to a comprehensive written development plan (the "***Development Plan***") that specifies all Development activities for Product in the Field in the Licensed Territory, and that includes an anticipated timeline for performing those activities necessary to obtain Regulatory Approval in the Field in the PRC and other countries of the Licensed Territory (such timeline, the "***Regulatory Plan***").

(b) Preparation and Approval. Within [***] after the Effective Date, the JDC will prepare and submit to the JSC for its review, discussion and approval the initial Development Plan (which initial Development Plan, for clarity, shall also include the initial Regulatory Plan).

(c) Amendments.

(i) The JDC shall periodically (including at the specific times specified in this Section 4.2(c)) review, and, as required, prepare an amendment to the then-current Development Plan, for review, discussion and approval by the JSC. Such amended Development Plan will reflect any changes (including additions) to the Development of Product in the Field in the Licensed Territory. Once approved by the JSC, the amended Development Plan will become effective and supersede the previous Development Plan as of the date of such approval.

(ii) In addition to the foregoing, [***], and more frequently at the discretion of the JDC, the JDC shall determine if an amendment is needed to the then-current Development Plan and, if appropriate, shall prepare and submit to the JSC for its review, comment and approval, such amendment to the Development Plan.

(d) Performance. The Parties shall collaborate in good faith and each Party shall use Commercially Reasonable Efforts so that the Development activities for the Licensed Territory as set forth in the Development Plan are conducted as efficiently and as timely as possible. Each Party shall conduct its activities under the Development Plan in a good scientific manner and in compliance in all material respects with all Laws and practice standards. The Parties shall only engage in Development activities that are included in the Development Plan approved by the JSC and shall not undertake or otherwise conduct any Development that is outside the scope of the Development Plan.

4.3. Development Costs. Licensee shall pay [***] of all Licensed Territory Development Costs.

4.4. Diligence. Licensee shall use Commercially Reasonable Efforts to Develop each Product in the Field in the PRC as the primary target country and subsequently in the other countries or jurisdictions in the Licensed Territory, in accordance with the activities and responsibilities under the Development Plan. Licensee shall initiate the necessary Development activities in respect of the Surfaxin Product and Surfaxin LS set forth in the Development Plan (a) within [***], or (b) [***], whichever shall occur later.

4.5. Data Exchange and Use. Subject to the terms and conditions of this Agreement, each Party shall promptly provide to the other Party, free of charge, all Information and all clinical and non-clinical data obtained by such Party or any of its Affiliates or sublicensees related to Product. The Party that provides such Information shall be responsible for obtaining all governmental approvals or filings required by Laws for the purpose of providing such Information to the other Party. Each Party shall cooperate in good faith to provide the other Party access to and reasonable assistance with all Licensor Technology or Licensee Technology, as applicable, and other Confidential Information as may be required for such Party to exercise the rights and licenses explicitly granted to it and to perform its obligations under this Agreement.

4.6. Development Reports. Licensee shall provide the JDC with written reports detailing its Development activities under this Agreement and the results of such activities at least [***] in advance of each regularly scheduled JDC meeting. The Parties shall discuss the status, progress and results of Licensee's Development activities under this Agreement at such regularly scheduled JDC meetings.

4.7. Development Records. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all data and other Information resulting from such activities. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Licensee shall document all non-clinical studies and Clinical Studies in formal written study records according to Laws, including applicable national and international guidelines such as ICH, GCP and GLP. Licensor may review and copy all such records maintained by Licensee at reasonable times, and upon reasonable notice, may also obtain access to the original records to the extent Licensor has a right to use the data and other Information contained in such records.

4.8. Compliance with Laws. Each Party shall conduct its activities under this Agreement in a good scientific manner and comply in all material respects with all Laws, including applicable national and international guidelines such as ICH, GCP and GLP, and all applicable Laws related to data exchange.

ARTICLE 5

REGULATORY MATTERS

5.1. Regulatory Responsibilities in the Licensed Territory.

(a) Subject to the oversight of the JDC, Licensee shall lead and be responsible to conduct all country-specific or jurisdiction-specific regulatory activities and pricing and reimbursement negotiations in the Licensed Territory with respect to Product in the Field. Licensee shall use Commercially Reasonable Efforts in respect of Product as the primary interface with and shall otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning regulatory activities related to Product in the Field in the Licensed Territory, and Licensee shall prepare and file any and all Regulatory Materials for Product in the Field in the Licensed Territory at its sole expense in accordance with the Development Plan. Licensor shall assist and cooperate with Licensee in connection with the preparation and filing of such Regulatory Materials, as reasonably requested by Licensee, including preparation of ongoing Clinical Studies, study reports, Periodic Safety Update Reports, and any required Drug and Device reports. Licensor shall have the right to approve all regulatory filings and communications in the Licensed Territory for Product for which Licensor is or will be the Product License Holder. Upon the issuance of the Drug Approval for any Aerosolized Product for which Licensor is the Product License Holder, one original of the Drug Approval shall be provided to Licensor, who shall take and retain physical possession thereof.

(b) Licensee shall keep Licensor informed at JDC meetings of regulatory developments relating to Product in the Field in the Licensed Territory and shall promptly notify Licensor in writing of any action or decision by any Regulatory Authority in the Licensed Territory regarding Product in the Field. Licensee shall provide Licensor with reasonable advance notice of all non-routine meetings, conferences and discussions scheduled with any Regulatory Authority in the Licensed Territory concerning Product, and shall consider in good faith any input from Licensor in preparing for such meetings, conferences or discussions. To the extent permitted by Laws, Licensor may participate in any such meetings, conferences or discussions and Licensee shall facilitate such participation. Upon Licensor's request, Licensee shall provide Licensor with written summaries of such meetings, conferences or discussions in English as soon as practicable after the conclusion thereof.

(c) Licensor shall compile and provide to Licensee the CMC Information that is required for Licensee to obtain and maintain Regulatory Approval of Product in the Field in the Licensed Territory. Licensee shall use the CMC Information provided to it by Licensor for obtaining and maintaining Regulatory Approval of Product in the Field in the Licensed Territory. At Licensee's request, Licensor shall provide reasonable assistance to Licensee with respect to communications with Regulatory Authorities in the Licensed Territory regarding the manufacture of Product or the CMC Information. Furthermore, as expressly contemplated in Article 15, Licensor shall promptly provide to Licensee the CMC information, technology transfer information and relevant know-how that is necessary or useful for Licensee to be able to manufacture the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products in the Licensed Territory.

(d) Further to its obligations as exclusive agent and exclusive representative to Develop Aerosolized Products in the name of and on behalf of Licensor in the Licensed Territory, consistent with and subject to the license grant provided to Licensee under Section 2.1(a) and except as otherwise determined by the JSC, Licensee shall seek Regulatory Approval of Aerosurf for the prevention and/or treatment of RDS in premature infants (or the regulatory equivalent thereof in the Licensed Territory) (i) in each of [***] after Licensor's completion of a final, successful Phase 3 Study in respect of Aerosurf for the prevention and/or treatment of RDS in premature infants and Licensee's completion of such other Development obligations of each of said countries' Regulatory Authorities in respect of Aerosurf for such indication(s), or such longer period as may be required and set forth in the Development Plan, and (ii) everywhere else in the Licensed Territory, as soon as practicable following Licensor's completion of a final, successful Phase 3 Study in respect of Aerosurf for the prevention and/or treatment of RDS in premature infants and Licensee's completion of such other Development obligations of each of said countries' Regulatory Authorities in respect of Aerosurf for such indication(s). In the event that the applicable Laws or Regulatory Authorities in the Licensed Territory enforce any obligations on the Licensor as the Product License Holder, to the extent permissible by Laws, Licensor hereby authorizes and delegates Licensee to perform and complete such required obligations on behalf of Licensor.

(e) Licensee shall file a Drug Approval Application in respect of the Surfaxin Product and/or Surfaxin LS, as the case may be, with the appropriate Regulatory Authority in [***] after Licensee's completion of any Development obligations [***] in respect of Surfaxin Product and/or Surfaxin LS, as the case may be, or such longer period as may be required and set forth in the Development Plan.

5.2. Regulatory Responsibilities in the Licensor Territory.

(a) Licensor shall lead and be responsible to conduct all regulatory activities in the Licensor Territory with respect to Product.

(b) Licensor owns all Regulatory Materials (including Regulatory Approvals) for Product in the Licensor Territory and shall prepare and file any and all Regulatory Materials for Product in the Licensor Territory at its sole expense.

(c) Licensor shall keep Licensee informed of regulatory developments relating to Product in the Field in the Licensor Territory through regular reports at the JDC meetings and shall promptly notify Licensee in writing of any action or decision by any Regulatory Authority in the Licensor Territory relating to Product in the Field.

(d) Unless the Parties otherwise agree in writing: (i) Licensee shall not communicate with respect to Product with any Regulatory Authority having jurisdiction in the Licensor Territory, unless so ordered by such Regulatory Authority, in which case Licensee shall provide immediate notice to Licensor of such order; and (ii) Licensee shall not submit any Regulatory Materials or seek Regulatory Approvals for Product in the Licensor Territory.

5.3. Regulatory Costs. Licensee shall pay all costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for Product in the Field in the Licensed Territory, subject to Section 7.2. Licensor shall pay all costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for Product in the Licensor Territory.

5.4. Rights of Reference to Regulatory Materials. Licensor hereby grants to Licensee a right of reference to all Regulatory Materials filed by or on behalf of Licensor, which right of reference Licensee may use for the sole purpose of seeking, obtaining and maintaining Regulatory Approvals and Developing and Commercializing the Aerosolized Products in the Field in the Licensed Territory and Developing, manufacturing and Commercializing the Non-Aerosolized Products in the Field in the Licensed Territory. Licensee hereby grants to Licensor and Licensor's licensees in the Licensor Territory a right of reference to all Regulatory Materials filed by or on behalf of Licensee, which right of reference Licensor may use for the sole purpose of seeking, obtaining and maintaining Regulatory Approvals and developing, manufacturing (for Non-Aerosolized Products) and commercializing Product in the Licensor Territory. Each Party shall support the other Party, as reasonably requested by such other Party, in obtaining Regulatory Approvals in such other Party's territory, including providing necessary documents or other materials required by Laws to obtain Regulatory Approval in such territory, all in accordance with the terms and conditions of this Agreement.

5.5. No Harmful Actions.

(a) If Licensor reasonably believes that Licensee is taking or intends to take any action with respect to a Product that is substantially likely to have a Material Impact in the Licensor Territory, Licensor may bring the matter to the attention of the JSC. Licensee shall not proceed with any such action or alternative course of action until it is approved by the JSC in accordance with Section 3.1(d).

(b) If Licensee reasonably believes that Licensor is taking or intends to take any action with respect to a Product that is substantially likely to have a Material Impact in the Field in the Licensed Territory, Licensee may bring the matter to the attention of the JSC. Licensor shall not proceed with any such action or alternative course of action until it is approved by the JSC in accordance with Section 3.1(d).

5.6. Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may affect the Development, Commercialization or regulatory status of a Product. Upon receipt of such information, the Parties shall consult with each other to arrive at a mutually acceptable procedure for taking appropriate action.

5.7. Adverse Event Reporting and Safety Data Exchange. Within [***] the anticipated launch of a Product in the Licensed Territory, the Parties shall define and finalize the actions that the Parties shall employ with respect to such Product to protect patients and promote their well-being in a written pharmacovigilance agreement (the "***Pharmacovigilance Agreement***"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, and any other information concerning such Product's safety. Such guidelines and procedures will be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Laws. Furthermore, such agreed procedure will be consistent with relevant ICH Guidelines, except where said guidelines may conflict with existing local regulatory or safety reporting requirements, in which case local reporting requirements shall prevail. Licensee shall report quality complaints, adverse events and safety data related to such Product in the Field to applicable Regulatory Authorities in the Licensed Territory, and shall respond to safety issues and to all requests of Regulatory Authorities relating to such Product in the Field in the Licensed Territory. Licensor shall maintain a worldwide safety database pursuant to the terms of the Pharmacovigilance Agreement. Each Party shall comply with its respective obligations under the Pharmacovigilance Agreement and shall cause its Affiliates and Sublicensees to comply with such obligations.

5.8. Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that a Product may be subject to any recall, corrective or other regulatory action taken by virtue of Laws (a "***Remedial Action***"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Each Party shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to permit the Parties to trace the manufacture, distribution and use of such Product. If Licensee determines that any Remedial Action with respect to such Product in the Field in the Licensed Territory should be commenced or is required by Law or the applicable Regulatory Authority, Licensee may, at its expense (except to the extent that such Remedial Action is due to Licensor's default or inaction), control and coordinate all efforts necessary to conduct such Remedial Action; *provided* that, with respect to any such Remedial Action that is not required by Laws or the applicable Regulatory Authority, the JSC will review and approve such Remedial Action. If the JSC fails to approve a Remedial Action that is not imposed upon Licensee by Laws or a Regulatory Authority within [***] after such Remedial Action is presented to the JSC for review and approval, then the Parties' Executive Officers shall, within [***] thereafter, review and approve such Remedial Action or, if the Executive Officers fail to approve such Remedial Action within such time period, Licensee shall make the final decision regarding such Remedial Action notwithstanding Sections 13.1 and 13.2, provided that, so long as Licensor is the Product License Holder for a Product, Licensor shall make the final decision regarding such Remedial Action involving such Product notwithstanding Sections 13.1 and 13.2. Notwithstanding the foregoing, the terms and conditions of any agreements entered into by and between the Parties regarding manufacture and supply of a Product shall govern any Remedial Action that relates to the manufacture and supply of such Product.

ARTICLE 6

COMMERCIALIZATION

6.1. Overview of Commercialization in the Licensed Territory. Subject to the terms and conditions of this Article 6 and subject to oversight by the JSC, as between the Parties, Licensee is responsible for all aspects of the Commercialization of Product in the Field in the Licensed Territory, including: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Governmental Authorities regarding the price and achieving reimbursement status of such Product; (c) pre-launch, launch and post-launch marketing and promotion activities (including providing appropriate marketing personnel and various marketing tools as appropriate to meet the Parties' business objectives in the Licensed Territory); (d) booking sales, and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Laws relating to the marketing, detailing and promotion of such Product in the Field in the Licensed Territory. Licensee shall bear all of the costs and expenses incurred in connection with such Commercialization activities. For clarity, Licensee shall control and execute the commercial strategy for Product in the Field within the Licensed Territory.

6.2. Commercialization Plan for Licensed Territory.

(a) Commercialization. Licensee shall Commercialize Product in the Field in the Licensed Territory pursuant to a commercialization plan prepared by Licensee (the "***Commercialization Plan***"). The Commercialization Plan will include a reasonably detailed description and timeline of Licensee's Commercialization activities in the Field in each country or jurisdiction in the Licensed Territory for the next year, including Medical Affairs Activities, sales forecasts and projections, pricing, reimbursement, market research, sales training, distribution channels, customer service and sales force matters (such as size, structure of promotional resources and Product positioning and messaging) related to the launch and sale of Product in such country or jurisdiction in such year.

(b) Plan and Amendments. Licensee shall inform the JCC of the Commercialization Plan no later than [***] before the anticipated launch of the first Product to be Commercialized in the PRC, for review and comment, after which the JCC shall submit such Commercialization Plan to the JSC for review. On at least an annual basis, Licensee shall prepare an amendment, as appropriate, to the then-current Commercialization Plan. Licensee shall keep the JCC informed about any material amendment to the Commercialization Plan.

(c) Data Sharing. Licensor shall provide at all times during the Term, relevant data or information reasonably requested by Licensee in Licensor's possession or Control to support Commercialization of Product in the Field in the Licensed Territory. Licensee shall provide at all times during the Term, relevant data or information reasonably requested by Licensor in Licensee's possession or Control to support commercialization of Product in the Licensor Territory.

6.3. Pricing. Licensee shall determine all pricing of Product in the Field in the Licensed Territory. For the avoidance of doubt, Licensor does not have any right to direct, control, or approve Licensee's pricing of Product in the Field in the Licensed Territory. With respect to each Product that may be subject to global price referencing affecting markets outside the Licensed Territory, Licensee and Licensor shall develop through the JCC a global pricing strategy for submission and approval by the JSC.

6.4. Pricing Approval. On a country-by-country basis, Licensee shall use Commercially Reasonable Efforts to obtain and maintain Pricing Approval where applicable, for Product in the Field in each country in the Licensed Territory in which it has obtained Drug Approval for such Product.

6.5. Reimbursement Approval. On a country-by-country basis, Licensee shall use Commercially Reasonable Efforts to obtain and maintain Reimbursement Approval where applicable, for Product in the Field in each country in the Licensed Territory in which it has obtained Drug Approval for such Product.

6.6. Commercial Diligence.

(a) Licensee shall use Commercially Reasonable Efforts to Commercialize Product in the Field in each country or jurisdiction in the Licensed Territory in which it receives Regulatory Approval. After the launch of each Product in the Field in the Licensed Territory, Licensee shall commit at least the same number of sales representatives and the same level of resources and infrastructure in connection with the Commercialization of such Product as are expended by Licensee and similarly-sized pharmaceutical companies with similarly-sized infrastructure to support and carry out similar operations in connection with the commercialization of products with similar market potential.

(b) Licensee shall achieve First Commercial Sale of (i) the Surfaxin Product and/or Surfaxin LS, as the case may be, [***] after Drug Approval therefor has been obtained from the appropriate Regulatory Authority (or pricing and reimbursement approval where applicable) [***] to Commercialize the Surfaxin Product and Surfaxin LS, as applicable, [***]; and (ii) Aerosurf [***] after the appropriate Regulatory Authority [***] has approved Licensor's imported product registration permitting Licensee to Commercialize Aerosurf [***], provided that Aerosurf is made available [***] by Licensor within a reasonable period of time in advance of the deadlines set forth in this Section 6.6(b).

(c) Licensee's FTE and marketing spend (inclusive of costs of sales force, marketing materials, trade show attendance and medical affairs team) in respect of Commercializing the Surfaxin Product, Surfaxin LS and Aerosurf in the Licensed Territory shall be not less than [***] of the gross forecasted revenues expected to be derived from the sale of such Products as set forth in the Commercialization Plan.

6.7. Cross-Territorial Restrictions. As permitted by Law, Licensee shall not, and shall ensure that its Affiliates and Sublicensees will not, either directly or indirectly, knowingly promote, market, distribute, import, sell or have sold Product, including via internet or mail order, into countries in the Licensor Territory. As to such countries in the Licensor Territory, Licensee shall not, and shall ensure that its Affiliates and Sublicensees will not: (i) establish or maintain any branch, warehouse or distribution facility for Product in such countries, (ii) engage in any advertising or promotional activities relating to Product that are directed primarily to customers or other purchasers or users of Product located in such countries, (iii) solicit or accept orders from any prospective purchaser located in such countries, or (iv) sell or distribute Product to any person in the Licensed Territory who it knows intends to sell Product in such countries. If Licensee receives any order from a prospective purchaser located in a country in the Licensor Territory, Licensee shall refer that order to Licensor, and Licensee shall not accept any such orders. Licensee shall not deliver or tender (or cause to be delivered or tendered) Product into a country in the Licensor Territory.

6.8. Territorial Coordination. The Parties shall, where appropriate, coordinate their Commercialization activities between the Licensor Territory and the Licensed Territory through the JCC, which coordination may include implementation of a global branding strategy for each Product in the Field.

6.9. Reports. Each Party shall update the JCC at each regularly scheduled JCC meeting regarding its commercialization activities and results metrics with respect to Product in the Field in its applicable territory. Each such update will be in a form to be agreed by the JCC and will summarize such Party's significant commercialization activities with respect to Product in the Field in its applicable territory pursuant to this Agreement, covering subject matter at a level of detail reasonably requested by the Parties and sufficient to enable each Party to assess the other Party's compliance with its obligations pursuant to Section 6.6.

ARTICLE 7

COMPENSATION

7.1. Upfront Payment. In partial consideration of Licensor's investment in development of Product in the Field before the Effective Date and Licensor's grant of exclusive licenses to Licensee under the Licensor Technology, on or before July 5, 2017, Licensee shall pay to Licensor a one-time upfront fee of One Million Dollars ($1,000,000). Such fee shall be non-creditable and non-refundable.

7.2. Licensed Territory Development Costs. Pursuant to Section 4.3, Licensee shall solely bear [***] Licensed Territory Development Costs and shall reimburse Licensor for any expenses paid by Licensor with respect to Development costs directly incurred in or for the Licensed Territory. Such costs will be discussed with Licensee and approved by Licensee in advance. Notwithstanding the above, so long as Licensor is the Product License Holder of a Product in the Licensed Territory, Licensor shall solely bear all Licensed Territory Development costs in connection with any filing fees payable to Regulatory Authorities in the Licensed Territory relative to such Product.

7.3. Milestone Payments.

(a) Regulatory/Commercial Milestones. In addition to the payment set forth in Section 7.1, Licensee shall pay the following one-time non-refundable regulatory/commercial milestone payments to Licensor, each within [***] after the first achievement of each regulatory/commercial milestone event indicated below:

Regulatory/Commercial Milestone Event	Milestone Payment, US$
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Net Sales Milestone Payments in the Licensed Territory. Licensee shall make the following one-time, non-refundable, non-creditable milestone payments to Licensor when the aggregate Net Sales of a given Product or Products, as applicable, in the Field in the Licensed Territory first reaches the specified amount listed in the "Milestone Event" column below in any Calendar Year. Licensee shall pay to Licensor such amount within [***] in which such Milestone Event is achieved.

Milestone Event	Milestone Payment, US$
[***]	[***]
[***]	[***]
[***]	[***]

(c) Milestones for [***]

7.4. Royalties.

(a) Royalty Rates. Licensee shall pay to Licensor non-refundable, non-creditable royalties on Net Sales of each Product in the Field in the Licensed Territory during the Term, as calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of incremental, aggregated Net Sales of each Product or Products, as applicable, in the Field in the Licensed Territory each Calendar Year.

(i) Royalty Rates for [***]

Annual Net Sales of [***] in the Licensed Territory	Royalty Rate, %
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(ii) Royalty Rates for Products other than [***]

Annual Net Sales of [***]Products (other than [***]) in the Licensed Territory	Royalty Rate,%
[***]	[***]
[***]	[***]
[***]	[***]

(b) Duration. Licensee shall pay to Licensor royalties under this Section 7.4 on a country-by-country and Product-by-Product basis as follows:

(i) **[***]** In consideration of licensed rights to Regulatory Materials, the technology transfer contemplated under Section 15.3 and trade secrets delivered and/or any other Licensor Technology rights granted to Licensee under this Agreement, with respect to [***] as applicable, from the time of First Commercial Sale of such Product in such country until the latest of (A) the expiration of the last Valid Claim of all Licensor Patents claiming or covering such Product, as applicable, 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 from the date of First Commercial Sale of such Product in such country, at the rates set forth in Section 7.4(a)(i). Thereafter, for the remainder of the Term, Licensee shall pay to Licensor royalties on a country-by-country basis equal to (x) [***] of the royalty rates set forth in Section 7.4(a)(i) for a period of [***], and (y) [***] of the royalty rates set forth in Section 7.4(a)(i) thereafter.

(ii) **Product other than [***]**, from the date of First Commercial Sale of such Product in such country until the latest of (A) the expiration of the last Valid Claim of all Licensor Patents claiming or covering such Product, the Drug or the Device, as applicable, or a component thereof, 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 from the date of First Commercial Sale of such Product in such country, at the rates set forth in Section 7.4(a)(ii); *provided*, thereafter, in consideration of trade secrets delivered and/or any other Licensor Technology rights granted to Licensee under this Agreement, for the remainder of the Term, Licensee shall pay to Licensor royalties on a country-by-country basis of [***] the rates set forth in Section 7.4(a)(ii) for a period of (x) [***] and, thereafter, of [***] of the royalty rates set forth in Section 7.4(a)(ii) or (y) [***], if any, whichever is the higher.

(c) Reports and Payments. Within [***] following the end of each Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of a Product is made anywhere in the Licensed Territory, Licensee shall provide Licensor with a report containing the following information for such Calendar Quarter, on a country-by-country basis: (i) the amount of gross sales of each Product in the Licensed Territory, (ii) an itemized calculation of Net Sales of each Product in the Licensed Territory showing deductions provided for in the definition of "Net Sales" and any rebates that are known to be required in respect of the Calendar Quarter in question, (iii) the conversion of such Net Sales from the currency of sale into Dollars, and (iv) the calculation of the royalty payment due on such sales, showing the application of the reduction, if any, made in accordance with the terms of Sections 7.4(a) or 7.4(b). Concurrent with the delivery of the applicable quarterly report, Licensee shall pay in Dollars all amounts due to Licensor pursuant to this Section 7.4 with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such Calendar Quarter.

(d) Royalty Adjustment. In the event that, at any time during the Term, a Generic/Branded Generic of a Product is Marketed by a Third Party in any country in the Licensed Territory, the royalty rate applicable to such Product in such country shall be reduced by (i) [***] for as long as there is only one Generic/Branded Generic of such Product being Marketed in such country; and (ii) [***] for as long as there is more than one Generic/Branded Generic of such Product being Marketed in such country. Notwithstanding the foregoing: [***]. Prior to any royalty reduction pursuant to this Section 7.4(d), Licensee shall provide evidence of such Generic/Branded Generic of Product in such country. Solely for purposes of this Section 7.4(d), "***Marketed***" means the Third Party is active in its marketing and promotional efforts with respect to such Generic/Branded Generic of Product. Examples of "active" include: (x) pursuing inclusion in a tender process, and (y) marketing and promotional activities that are similar to those undertaken by Licensee with respect to such Product.

7.5. Sublicense Income. In partial consideration of Licensor's investment in development of Products in the Field before the Effective Date and Licensor's grant of exclusive licenses to Licensee under the Licensor Technology, Licensee shall pay to Licensor [***] of any Sublicense Income it receives during the Term. Licensee will make such payment to Licensor on or before the following dates:

(a) February 28 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending December 31 of the prior Calendar Year;

(b) May 31 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending March 31 of such Calendar Year;

(c) August 31 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending June 30 of such Calendar Year; and

(d) November 30 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending September 30 of such Calendar Year.

Within [***] after the end of each Calendar Quarter (i.e. Feb. 28, May 31, August 31 and Nov. 30), Licensee shall deliver to Licensor a report setting out all details necessary to calculate Sublicense Income due under this Section 7.5 for such Calendar Quarter, including the method and currency exchange rates (if any) used to calculate Sublicense Income.

7.6. Foreign Exchange. Conversion of sales recorded in local currencies to Dollars will be calculated, on a quarterly basis, using the mid-point rate of exchange for the last Business Day of the Calendar Quarter as reported in the Financial Times (London edition) on the last Business Day of each Calendar Quarter in the quarter before the date of payment.

7.7. Payment Method; Late Payments. Each Party shall make all payments due hereunder in Dollars by wire transfer of immediately available funds into an account designated by the Party that is owed such payment (such Party, the "***Payee***"). For the avoidance of doubt, to the extent permissible by Laws, the Payee for Licensee shall be a non-PRC entity. If the Payee does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to the Payee until the date of payment at the per annum rate of two percent (2%) over the then-current prime rate as reported in The Wall Street Journal or the maximum rate allowable by Laws, whichever is lower.

7.8. Records. Each Party shall keep (and shall ensure that its Affiliates and Sublicensees keep) such records as are required to determine, in accordance with the Accounting Standards, and this Agreement, the sums or credits due under this Agreement, including Licensed Territory Development Costs, Net Sales and Sublicense Income. Such Party shall retain all such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Laws. Licensee shall require its Sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such Sublicensee, which report will be made available to Licensor in connection with any audit conducted by Licensor pursuant to Section 7.9.

7.9. Audits. Each Party may have an independent certified public accountant, reasonably acceptable to the audited Party, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the audited Party (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than three (3) years before such Party's request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Reports of the results of any such examination will be (a) limited to details of any discrepancies in the audited Party's records relating to Product together with an explanation of the discrepancy and the circumstances giving rise to the discrepancy (b) made available to both Parties and (c) subject to Article 11. If the audit report concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 7.7 or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, with interest from the date when the original payment was made, in either case ((i) or (ii)), within thirty (30) days after the date on which such audit report is delivered to both Parties. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit, which covers the entire Calendar Year, discloses a variance to the detriment of the auditing Party of more than five percent (5%) from the amount of the original report, royalty or payment calculation, in which case the audited Party shall bear the full cost of the performance of such audit. The results of such audit will be final, absent manifest error.

7.10. Taxes.

(a) Taxes on Income. Each Party shall pay all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by one Party to the other Party under this Agreement. To the extent a Party is required to deduct and withhold taxes on any payment to the other Party, it shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable the other Party to claim such payment of taxes. The other Party shall provide the deducting Party any tax forms that may be reasonably necessary in order for it to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

ARTICLE 8

INTELLECTUAL PROPERTY MATTERS

8.1. Ownership of and Rights to Intellectual Property.

(a) As between the Parties, (i) Licensor is and shall remain the sole owner of the Licensor Technology, and (ii) Licensee is and shall remain the sole owner of the Licensee Technology existing as of the Effective Date.

(b) Licensor shall own:

(i) all Improvements to the Licensor Technology and all Improvements to the Licensee Technology that are conceived, created and reduced to practice solely by Licensor or Licensee or jointly by the Parties during the Term, which Improvements relate to (A) Device, its manufacture and use; and (B) Aerosolized Product, its manufacture and use. Licensee hereby assigns to Licensor all Improvements to the Licensor Technology and all Improvements to the Licensee Technology that are identified or developed by Licensee during the Term; and

(ii) all Improvements to the Licensor Technology and all Improvements to the Licensee Technology that are conceived, created and reduced to practice solely by Licensor during the Term, which Improvements relate to Drug, its manufacture and use (collectively (i) and (ii) are "***Licensor Improvements***");

(c) Licensor and Licensee shall jointly own all Improvements to the Licensor Technology and all Improvements to the Licensee Technology that are jointly conceived, created and reduced to practice by Licensor and Licensee during the Term, which Improvements relate to Drug, its manufacture and use ("***Joint Improvements***") and all Patents arising under this Section 8.1(c) are referred to as "***Joint Patents***".

(d) Licensee shall own all Improvements to the Licensor Technology and all Improvements to the Licensee Technology that are conceived, created and reduced to practice solely by Licensee during the Term, which Improvements relate to Drug, its manufacture and use ("***Licensee Improvements***");

(e) Subject to the terms and conditions of this Agreement, Licensee, to the extent not already granted in Section 2.2, hereby grants to Licensor during the Term, an exclusive (even as to Licensee), sublicensable license under the Licensee Technology and Licensee Improvements, including any Joint Improvements and Joint Patents, to (i) Develop Product in the Field to obtain or maintain Regulatory Approval in the Licensor Territory, and (ii) use, sell, offer for sale, import, export, make, have made, distribute, warehouse, market, promote, apply for and submit applications for Drug Approval and Reimbursement Approval and otherwise commercialize Product in the Field in the Licensor Territory. If Licensor desires to use any of the Licensee Technology, Licensee Improvements or any Joint Improvements in the Licensor Territory during the Term pursuant to the foregoing license grant, Licensor shall notify Licensee in writing and such license shall be royalty-free except as set forth below with respect to Licensee Patents and/or Joint Patents. If Licensor desires to exclusively license any of the Licensee Technology, Licensee Improvements or any Joint Improvements in the Licensor Territory after the termination or expiration of this Agreement, Licensor shall notify Licensee in writing. Following Licensee's receipt of such notice, the Parties shall negotiate in good faith and on a case-by-case basis the terms and conditions of such license, including commercially reasonable royalty rates, *provided* that such royalty shall, in no event, exceed [***] and provided further that such terms and conditions relating to quarterly reporting and payment, currency exchange, audit rights, prosecution, maintenance and enforcement of intellectual property, and indemnification for Licensor's use of such intellectual property, will otherwise be substantially similar to the comparable terms contained in this Agreement. Notwithstanding the first sentence of this Section 8.1(e), if Licensor desires to exclusively license any of the Licensee Patents and/or Joint Patents in the Licensor Territory during the Term and/or after the termination or expiration of this Agreement, Licensor shall notify Licensee in writing. Following Licensee's receipt of such notice, the Parties shall negotiate in good faith and on a case-by-case basis, the terms and conditions of such license, including commercially reasonable royalty rates, *provided* that such royalty shall, in no event, exceed [***], and provided further that such terms and conditions relating to quarterly reporting and payment, currency exchange, audit rights, prosecution, maintenance and enforcement of intellectual property, and indemnification for Licensor's use of such intellectual property, will otherwise be substantially similar to the comparable terms contained in this Agreement.

(f) Licensor hereby provides a license to Licensee to use Licensor Improvements under the same conditions as described in Section 2.1.

(g) For purposes of this Article 8, the term "Party" includes Affiliates, Sublicensees and designees in the performance of this Agreement.

8.2. Filing, Prosecution and Maintenance of Patents.

(a) Subject to Section 8.2(b), as between the Parties, Licensor may prepare, file, prosecute and maintain Licensor Patents and any Patents arising under Section 8.1(b) (the "***Licensor Prosecuted Patents***"). As between the Parties, Licensor shall bear all costs incurred by Licensor in connection with the preparation, filing, prosecution and maintenance of any Licensor Prosecuted Patent.

(b) If Licensor decides anywhere in the Licensed Territory to abandon any Licensor Prosecuted Patent or not to apply for an extension of any Licensor Prosecuted Patent, including a supplementary protection certificate or equivalent thereof, Licensee may assume Licensor's rights and responsibilities under this Section 8.2 with respect to such Licensor Prosecuted Patent in the Licensed Territory, and in connection with assuming such rights and responsibilities, Licensee may apply for any such extension (including a supplementary protection certificate or equivalent thereof) and Licensee will thereafter be responsible at Licensee's cost and expense for the prosecution and maintenance of such Licensor Prosecuted Patent in the Licensed Territory.

(c) Subject to Section 8.2(d), as between the Parties, Licensee may prepare, file, prosecute and maintain all Licensee Patents that are not assigned to Licensor pursuant to Sections 8.1(b). As between the Parties, Licensee shall bear all costs incurred by Licensee in connection with the preparation, filing, prosecution and maintenance of any Licensee Patent.

(d) If Licensee decides anywhere in the Licensor Territory to abandon any Licensee Patent or to not apply for an extension of any Licensee Patent, including a supplementary protection certificate or equivalent thereof, Licensor may assume Licensee's rights and responsibilities under this Section 8.2 with respect to such Licensee Patent, and in connection with assuming such rights and responsibilities, Licensor may apply for any such extension (including a supplementary protection certificate or equivalent thereof) and Licensor will thereafter become responsible for the prosecution and maintenance of such Licensee Patent in the Licensor Territory.

(e) The Parties shall agree on a case-by-case basis the appropriate allocation of costs and control concerning matters regarding the prosecution, maintenance, defense and infringement of any Joint Patent.

8.3. Patent Enforcement in the Licensed Territory.

(a) **Notification**. If either Party become aware of any existing or threatened infringement of any of the Licensor Patents, Joint Patents, or Licensee Patents in the Field in the Licensed Territory by a Third Party ("***Licensed Territory Infringement***"), such Party shall promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Licensed Territory Infringement.

(b) **Enforcement Rights**. For any Licensed Territory Infringement, each Party shall share with the other Party all Information available to it regarding such actual or alleged infringement. As between the Parties, Licensor may bring an appropriate suit or other action against any person or entity engaged in such Licensed Territory Infringement, at Licensor's cost and expense. Licensor shall have a period of [***] after its receipt or delivery of notice under Section 8.3(a) to elect to so enforce the Joint Patents, Licensor Patents or Licensee Patents against such Licensed Territory Infringement (or to settle or otherwise secure the abatement of such Licensed Territory Infringement). If Licensor fails or declines to commence a suit to enforce the applicable Joint Patents, Licensor Patents or Licensee Patents against such Licensed Territory Infringement or to settle or otherwise secure the abatement of such Licensed Territory Infringement within such period, then Licensee may commence a suit or take action to enforce such Joint Patents, Licensor Patents or Licensee Patents against such Licensed Territory Infringement at its own cost and expense. In this case, Licensor shall take appropriate actions to enable Licensee to commence a suit or take the actions set forth in the preceding sentence, at Licensee's expense.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which consent will not be unreasonably withheld, conditioned or delayed. The non-enforcing Party may obtain separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Settlement.

(i) Licensee shall not settle any claim, suit or action that it brought under Section 8.3(b) in any manner that would negatively impact the applicable Licensor Patents, Joint Patents or Licensee Patents or that would limit or restrict the ability of Licensor to develop, make, use, import, offer for sale, sell or otherwise Commercialize a Product anywhere in the Licensor Territory, or to make or have made such Product anywhere in the world, without the prior written consent of Licensor, which consent will not be unreasonably withheld or delayed. Nothing in this Article 8 requires Licensor to consent to any settlement that is reasonably anticipated by Licensor to have a substantially adverse impact upon any Licensor Patent, Joint Patent or Licensee Patent in the Licensor Territory, or on the development, commercialization, use, importation, offer for sale or sale of a Product in the Licensor Territory, or to the manufacture of such Product anywhere in the world.

(ii) Licensor shall not settle any claim, suit or action that it brought under Section 8.3(b) in any manner that would negatively impact the applicable Licensor Patents, Joint Patents or Licensee Patents or that would limit or restrict the ability of Licensee to Develop, make, use, import, offer for sale, sell or otherwise Commercialize a Product in the Field anywhere in the Licensed Territory, without the prior written consent of Licensee, which consent will not be unreasonably withheld, conditioned or delayed. Nothing in this Article 8 requires Licensee to consent to any settlement that is reasonably anticipated by Licensee to have a substantially adverse impact upon any Licensor Patent, Joint Patent or Licensee Patent in the Licensed Territory, or to the Development, manufacture, Commercialization, use, importation, offer for sale or sale of a Product in the Field in the Licensed Territory.

(e) Expenses and Recoveries. The enforcing Party bringing a claim, suit or action under Section 8.3(b) shall pay for any expenses incurred by such Party as a result of such claim, suit, or action. If such Party recovers monetary damages in such claim, suit or action, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts will be retained by the Party bringing suit; *provided* that, if Licensee is the Party bringing suit, such remaining amounts (after deduction of expenses (including legal fees)) will be deemed Net Sales and Licensee shall make a royalty payment to Licensor with respect thereto in accordance with Section 7.4.

8.4. Infringement of Third Party Rights in the Licensed Territory. Subject to Article 10, if a Product used or sold by Licensee, its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Licensed Territory (each such claim or assertion a "***Third Party Claim***"), Licensee shall promptly notify Licensor and the Parties shall agree on and enter into a common interest agreement, pursuant to which the Parties will agree to work toward their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the Third Party Claim and the appropriate course of action. Licensee shall defend any such Third Party Claim, at Licensee's cost and expense; *provided* that the provisions of Section 8.3 govern the right of Licensee to assert a counterclaim of infringement of any Licensor Patents, Joint Patents or Licensee Patents.

8.5. Patent Marking. Licensee and its Affiliates and Sublicensees shall mark any Product marketed and sold by Licensee or its Affiliates or Sublicensees hereunder with appropriate patent numbers or indicia; *provided, however*, that Licensee will only be required to so mark such Product to the extent such markings or such notices would affect recoveries of damages or equitable remedies available under Laws with respect to infringement of Patents in the Licensed Territory.

8.6. Packaging; Trademarks.

(a) Packaging. Licensee shall design all final commercial packaging and labeling of each Product for use in the Licensed Territory, and may select the trademark (s) of each Product in the Licensed Territory and register any Licensee Mark(s) resulting therefrom at Licensee's sole cost and expense and in consultation with Licensor to explore the benefit of a global brand. Licensee shall provide the design of the packaging and labeling for Aerosolized Products to Licensor for manufacturing purposes and be responsible for insuring such design complies with applicable Laws in the Licensed Territory. To the extent practicable and allowed by Laws as to size, location, and prominence, all Product packaging and package inserts and any promotional materials associated with each Product, as applicable, in the Licensed Territory will carry, in a conspicuous location, the Licensee Mark(s) and the Licensed Marks, if applicable. Licensor authorizes the use of its Licensed Marks pursuant to Section 8.6(b). Licensor shall not register or use, in either the Licensor Territory or the Licensed Territory, any Licensee Mark without Licensee's prior written consent.

(b) Trademark License. Licensor grants to Licensee the exclusive right to use, free of charge, in the Licensed Territory, the trademarks set forth on **Exhibit A** and any future Product's trademarks available to and Controlled by Licensor in the Licensor Territory (the "***Licensed Marks***"), and Licensee may elect, at its discretion, to use such Licensed Marks in the Licensed Territory. Licensee shall not use any Licensed Mark outside the scope of this Agreement, or take any action that would materially adversely affect the value of any Licensed Mark. Licensor retains the right to monitor the use of the Licensed Marks to the extent necessary to maintain its trademark rights and goodwill therein. Licensee shall not use any Licensed Mark in packaging materials, package inserts, labels, labeling and marketing, sales, or advertising and promotional materials in a manner that has not been approved by Licensor before such use. Notwithstanding the foregoing, Licensor reserves the right to use the Licensed Marks in the Licensed Territory for purposes consistent with Licensor's rights and obligations under this Agreement.

(c) Enforcement of Licensed Marks. If either Party or its Affiliate becomes aware of actual or threatened infringement in the Licensed Territory of any Licensed Mark, Licensee Mark or of a mark or name confusingly similar to any Licensed Mark or Licensee Mark, such Party shall promptly notify the other Party in writing. Licensee may bring infringement or unfair competition actions in the Licensed Territory involving a Licensed Mark or Licensee Mark. Licensor shall, at the request and expense of Licensee, cooperate and provide reasonable assistance in any action described in this Section 8.6(c) and, if required by Law, join such action. Licensee shall bear the entire cost and expense associated with such action, and any recovery resulting from such proceeding will belong entirely to Licensee. Notwithstanding the foregoing, Licensee shall not settle or accept any settlement from any Third Party in connection with the adverse use of any Licensed Mark without the prior written consent of Licensor (such consent not to be unreasonably withheld, conditioned or delayed).

ARTICLE 9

REPRESENTATIONS AND WARRANTIES; COVENANTS

9.1. Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) Corporate Existence. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed;

(b) Corporate Power, Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to enforcement of remedies under applicable bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies;

(c) No Conflict. The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Laws existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date;

(d) Other Rights. Neither Party nor any of their respective Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of such Party's rights under this Agreement;

(e) No Violation. Neither Party nor any of their respective Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of such Party's obligations hereunder; and

(f) No Debarment. As of the Effective Date, none of such Party's employees, consultants or contractors:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority;

(ii) has, to such Party's Knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or non-procurement programs.

9.2. Additional Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as of the Effective Date as follows:

(a) Licensor Controls the Licensor Patents existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The Licensor Technology existing as of the Effective Date constitutes all of the Licensor Patents and the Licensor Know-How Controlled by Licensor as of the Effective Date that are necessary or useful to Develop and Commercialize Product in the Field in the Licensed Territory. Licensor has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Licensor Technology in the Field in the Licensed Territory in a manner that conflicts with any rights granted to Licensee hereunder.

(b) To the Knowledge of Licensor and except as publicly disclosed by Licensor in its SEC filings, there is no actual or threatened infringement of the Licensor Patents in the Field in the Licensed Territory by any Third Party that would adversely affect Licensee's rights under this Agreement.

(c) To the Knowledge of Licensor and except as publicly disclosed by Licensor in its SEC filings, the Licensor Patents existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by Licensor or any of its Affiliates relating to the Licensor Patents; and no claim or litigation has been brought or threatened by any Third Party alleging same.

(d) There are no claims, judgments or settlements against or owed by Licensor or its Affiliates or, except as publicly disclosed by Licensor in its SEC filings, pending or, to the Knowledge of Licensor, threatened claims or litigation relating to the Licensor Technology in the Field in the Licensed Territory.

9.3. Additional Representations and Warranties of Licensee. Licensee represents and warrants to Licensor as of the Effective Date as follows:

(a) Each of Licensee and its relevant Affiliates has obtained all licenses, approvals, permits, registrations, qualifications and authorizations necessary to carry out and perform its obligations in the Licensed Territory.

(b) None of Licensee or, to the Knowledge of Licensee, its Affiliates have received written notice of any proceedings before or threatened by any Regulatory Authority with respect to Licensee or its Affiliates or any facility at which the Drug, any Product or the Device may be manufactured.

9.4. Covenants

(a) In the course of the Development and Commercialization of Product in the Licensed Territory, neither Party shall use any employee, consultant or contractor:

(i) who has been debarred under Section 306(a) or 306(b) of the FD&C Act or pursuant to the analogous Laws of any Regulatory Authority;

(ii) who, to such Party's Knowledge, has been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or otherwise pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority, during the employee's or consultant's employment or contract term with such Party; and

(iii) who is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or non-procurement programs. Each Party shall notify the other Party promptly, but in no event later than five (5) Business Days, upon becoming aware that any of its employees or consultants has been excluded, debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by any Regulatory Authority.

(b) Each Party and its Affiliates shall comply in all material respects with all Laws in the Development and Commercialization of Product in the Licensed Territory and the performance of its obligations under this Agreement, including where applicable the statutes, regulations and written directives of the FDA and any Regulatory Authority having jurisdiction in the Licensed Territory, the FD&C Act, and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time and each to the extent applicable;

(c) Neither Party shall practice or exploit the intellectual property licensed to such Party under this Agreement except to the extent expressly permitted under the terms and conditions of this Agreement.

(d) Neither Party shall grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to the other Party under this Agreement.

(e) Each of Licensee and its relevant Affiliates and Sublicensees shall maintain in full force and effect all licenses, approvals, permits, registrations, qualifications and authorizations necessary to carry out and perform its obligations in the Licensed Territory.

(f) Licensee will promptly notify Licensor in writing if Licensee, its Affiliates, Sublicensees or subcontractors receive written notice of any proceedings before or threatened by any Regulatory Authority with respect to Licensee, its Affiliates, Sublicensees or subcontractors or any facility at which the Drug, any Product or the Device may be manufactured.

(g) None of Licensee or any of its officers, employees or agents shall make to any Regulatory Authority or in any filing submitted to any Regulatory Authority any untrue statement of a material fact or omit to state a material fact required to be provided to such Regulatory Authority or stated in such filing, or necessary in order to make the statements thereto or therein, in the light of the circumstances under which they were made, not misleading.

9.5. No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 10

INDEMNIFICATION

10.1. Indemnification by Licensor. Licensor shall, at its sole expense, defend, indemnify and hold Licensee and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "***Licensee Indemnitees***") harmless from and against any and all Third Party claims, suits, proceedings, damages, losses, liabilities, costs, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries (collectively, "***Claims***") to the extent such Claims arise out of, are based on, or result from (a) the Development of Product by or on behalf of Licensor or its Affiliates or its or their sublicensees (other than Licensee and its Affiliates or Sublicensees), (b) the commercialization of Product by or on behalf of Licensor or its Affiliates or its or their sublicensees (other than Licensee or its Affiliates or Sublicensees), (c) Licensor's manufacturing of Aerosolized Products, (d) the breach of any of Licensor's obligations under this Agreement, including Licensor's representations and warranties, covenants and agreements, or (e) the willful misconduct or negligent acts of Licensor, its Affiliates, its or their sublicensees (other than Licensee and its Affiliates or Sublicensees) or the officers, directors, employees, or agents of Licensor or its Affiliates or its or their sublicensees (other than Licensee and its Affiliates or Sublicensees). The foregoing indemnity obligation will not apply (i) to the extent that the Licensee Indemnitees fail to comply with the indemnification procedures set forth in Section 10.3 and Licensor's defense of the relevant Claim is prejudiced by such failure; or (ii) to Claims for which Licensee has an obligation to indemnify Licensor pursuant to Section 10.2, as to which Claims each Party shall indemnify the other to the extent of its respective liability for such Claims.

10.2. Indemnification by Licensee. Licensee shall, at its sole expense, defend, indemnify and hold Licensor and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "***Licensor Indemnitees***") harmless from and against any and all Claims to the extent such Claims arise out of, are based on, or result from (a) the Development of Product by or on behalf of Licensee or its Affiliates or its or their Sublicensees, (b) Licensee's manufacturing of Non-Aerosolized Products, (c) Commercialization of Product by or on behalf of Licensee or its Affiliates or its or their Sublicensees, (d) the breach of any of Licensee's obligations under this Agreement, including Licensee's representations and warranties, covenants and agreements, or (e) the willful misconduct or negligent acts of Licensee, its Affiliates, or the officers, directors, employees, or agents of Licensee or its Affiliates. The foregoing indemnity obligation will not apply (i) to the extent that the Licensor Indemnitees fail to comply with the indemnification procedures set forth in Section 10.3 and Licensee's defense of the relevant Claim is prejudiced by such failure; or (ii) to Claims for which Licensor has an obligation to indemnify Licensee pursuant to Section 10.1, as to which Claims each Party shall indemnify the other to the extent of its respective liability for such Claims.

10.3. Indemnification Procedures. The Party claiming indemnity under this Article 10 (the "***Indemnified Party***") shall give written notice to the Party from whom indemnity is being sought (the "***Indemnifying Party***") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party may assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned or delayed, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 10.

10.4. Limitation of Liability. EXCEPT AS SET FORTH IN SECTION 12.7, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 10.1 OR 10.2, (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11, OR (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OF A PARTY.

10.5. Insurance. Each Party shall procure and maintain insurance, including product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations under this Agreement and consistent with normal business practices of prudent companies similarly situated at all times during which Product is being clinically tested or commercially distributed or sold by such Party. Each Party shall procure insurance or self-insure at its own expense. Such insurance does not create a limit of either Party's liability with respect to its indemnification obligations under this Article 10. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days before the cancellation, non-renewal or material change in such insurance.

ARTICLE 11

CONFIDENTIALITY

11.1. Confidentiality. Each Party agrees that, during the Term and for a period of [***] thereafter (except in respect of trade secrets, for which the obligations under this Section 11.1 shall expire upon such trade secret no longer being a trade secret through no fault of the receiving Party or anyone to whom the receiving Party disclosed the trade secret), it and its Affiliates shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it or its Affiliate by the other Party or its Affiliate pursuant to this Agreement, except to the extent expressly authorized by this Agreement or as otherwise agreed to in writing by the Parties. The foregoing confidentiality and non-use obligations do not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party or its Affiliate;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party or its Affiliate;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliate in breach of this Agreement;

(d) was disclosed on a non-confidential basis to the receiving Party or its Affiliate by a Third Party who had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party or its Affiliate; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

11.2. Authorized Disclosure. Notwithstanding the obligations set forth in Section 11.1, a Party or its Affiliate may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of a Product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; *provided* that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; *provided* that in each case, the disclosees are bound by written obligations of confidentiality and non-use having a minimum term of [***] (or in respect of trade secrets, for such longer period as is set forth in the initial clause of Section 11.1); or

(d) such disclosure is reasonably necessary to comply with Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or other order.

Notwithstanding the foregoing, if a Party or its Affiliate is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.2(a) or 11.2(d), such Party shall promptly notify the other Party of such required disclosure and, upon the other Party's request, such Party and its Affiliates shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

11.3. Technical Publication. Licensee shall ensure that all publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise relating to a Product (each of the foregoing, a "***Publication***") comply with the strategy established by the JDC pursuant to Section 3.2(a)(iv). Licensee shall not submit for publication, publish or present a Publication without the opportunity for prior review by Licensor, except to the extent required by Laws. If Licensee or its Affiliate seeks to submit, publish or present a Publication, it shall provide Licensor the opportunity to review and comment on the proposed Publication at least sixty (60) days before its intended submission for publication or presentation. Licensor shall provide Licensee or its Affiliate with Licensor's reasonable comments in writing, if any, within thirty (30) days after receipt of such proposed Publication. Licensee or its Affiliate shall consider in good faith such comments provided by Licensor and shall comply with Licensor's request to remove any and all of Licensor's Confidential Information from the proposed Publication. In addition, Licensee or its Affiliate shall delay the submission for a period of up to forty-five (45) days if Licensor can demonstrate reasonable need for such delay to prepare and file a patent application for which it has prosecution control pursuant to this Agreement. If Licensor fails to provide its comments to Licensee or its Affiliate within such thirty (30)-day period, Licensor will be deemed to not have any comments, and Licensee or its Affiliate may submit for publication or present in accordance with this Section 11.3 after the thirty (30)-day period has elapsed. Licensee or its Affiliate shall provide Licensor a copy of the manuscript, abstract or presentation at the time of the submission or presentation, as applicable. Licensee or its Affiliate agrees to acknowledge the contributions of Licensor and its Affiliates and their respective employees in all publications, as scientifically appropriate.

11.4. Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 11.4.

(b) The Parties shall make a joint public announcement of the execution of this Agreement in a form acceptable to both Parties, which press release will be issued on or promptly after the Effective Date.

(c) After release of such press release, if Licensee or its Affiliate desires to make a public announcement concerning this Agreement or any scientific, clinical or regulatory announcements, Licensee or its Affiliate shall give reasonable prior advance notice of the proposed text of such announcement to Licensor for its prior review and approval (except as otherwise provided), such approval not to be unreasonably withheld, conditioned or delayed. Licensor shall provide its comments, if any, within five (5) Business Days after receiving the announcement for review, or such shorter period as may be reasonably required in order for Licensee or its Affiliate to comply with any applicable deadline for making such announcement (as such deadline is communicated by Licensee or its Affiliate to Licensor). In addition, where required by Laws, including regulations promulgated by applicable security exchanges, Licensee or its Affiliate may make a press release announcing the achievement of each milestone under this Agreement as it is achieved, the achievements of Regulatory Approvals in the Licensed Territory as they occur, or any other material event with respect to this Agreement or Licensee's performance thereof, subject to the review procedure set forth in the preceding sentence; *provided* that the review period will be reduced to two (2) Business Days (or such shorter period as may be reasonably required in order for Licensee or its Affiliate to comply with any applicable deadline for making such press release, as such deadline is communicated by Licensee or its Affiliate to Licensor) if the deadline for making such disclosure is five (5) or fewer Business Days after such achievement or event. In relation to Licensor's review of such an announcement, Licensor may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold, condition, or delay its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved or material event has occurred. Neither Licensee nor its Affiliate is required to seek the permission of Licensor to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by Licensee or its Affiliate in accordance with this Section 11.4, if such information remains accurate as of such time.

(d) The Parties acknowledge that either or both Parties may be obligated to file under Laws a copy of this Agreement with the U. S. Securities and Exchange Commission ("***SEC***"), the Hong Kong Securities and Exchange Commission or other Governmental Authorities. Each Party shall make such a required filing and shall request confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

11.5. Prior Confidentiality Agreements. Any prior confidentiality agreements (including the Mutual Confidential Disclosure Agreement dated [***] between the Parties) shall remain in full force and effect. All Information disclosed by a Party or its Affiliate to the other Party or its Affiliate pursuant to any prior confidentiality agreements is such Party's Confidential Information disclosed hereunder and the other Party shall, and its Affiliates and disclosees will have, the confidentiality, non-use and non-disclosure obligations set forth in this Article 11. If any such obligations conflict with the obligations set forth in such prior confidentiality agreements, then the other Party and its Affiliates and disclosees shall comply with the obligations set forth in this Article 11.

11.6. Return of Confidential Information. Except as otherwise set forth in this Agreement, upon termination of this Agreement, the receiving Party will promptly return all of the disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the receiving Party may retain one copy for its legal files.

11.7. Unauthorized Use. If either Party becomes aware or has Knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it will promptly notify the other Party of such unauthorized use or disclosure.

11.8. Exclusive Property. All Confidential Information is the sole and exclusive property of the disclosing Party and the permitted use thereof by the receiving Party will be in accordance with the license and other rights granted by either Party to the other Party as provided for in this Agreement.

ARTICLE 12

TERM AND TERMINATION

12.1. Term. This Agreement becomes effective on the Effective Date, and, unless sooner terminated as specifically provided in this Agreement, continues in effect on a country-by-country basis for the commercial life of each Product in each country in the Licensed Territory (the "***Term***").

12.2. Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement in its entirety upon immediate written notice to the other Party in the event such other Party (i) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (ii) makes a general assignment for the benefit of its creditors, (iii) commences a voluntary case under the Bankruptcy Code of any country, (iv) files a petition seeking to take advantage of any applicable Laws relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, (v) fails to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code of any country, (vi) takes any corporate action for the purpose of effecting any of the foregoing, (vii) has a proceeding or case commenced against it in any court of competent jurisdiction, seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of all or any substantial part of its assets, or (C) similar relief under the Bankruptcy Code of any country, or an order, judgment or decree approving any of the foregoing is entered and continues unstayed for a period of sixty (60) days, or (viii) has an order for relief against it entered in an involuntary case under the Bankruptcy Code of any country.

12.3. Termination by Regulatory Authority. Should any serious and unexpected events or issues occur with respect to the safety of a Product as a result of which (i) Regulatory Approval for such Product is terminated or suspended in one or more regulatory jurisdictions or countries in the Licensed Territory, or (ii) a Regulatory Authority directs or requests discontinuance of Development, use or sale of such Product in one or more jurisdictions or countries in the Licensed Territory, then each Party's obligations under this Agreement with respect to such Product will be suspended in such regulatory jurisdictions or countries (as applicable) until such serious safety event is resolved and Regulatory Approval for such Product is no longer terminated or suspended or the Regulatory Authority has given approval again to distribute or sell such Product (as applicable) in such regulatory jurisdictions or countries. Either Party may, at its discretion and upon written notice to the other Party, terminate this Agreement with respect to such Product in such regulatory jurisdictions or countries pursuant to this Section 12.3 if such Party's obligations under this Agreement are suspended pursuant to this Section 12.3 for a period in excess of eighteen (18) months.

12.4. Termination for Breach. Each Party (the "***Non-Breaching Party***") may terminate this Agreement in its entirety or on a country-by-country basis immediately upon written notice to the other Party (the "***Breaching Party***") if the Breaching Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail (a "***Default Notice***"), fails to cure such material breach within [***] after delivery of the Default Notice (or within [***] after delivery of the Default Notice if such material breach is solely based on the Breaching Party's failure to pay any amounts due hereunder). If a Party gives notice to the Breaching Party pursuant this Section 12.4 as a result of a material breach (or alleged material breach) by the Breaching Party and, on or before the end of the cure period therefor, either Party has referred the matter to arbitration pursuant to Section 13.1, in either case where the Breaching Party is in good faith disputing such basis for termination pursuant to this Section 12.4, then (i) such cure period will be suspended, and (ii) this Agreement will not terminate, unless and until such senior executives resolve the dispute or such arbitrator issues a final ruling or award upholding such basis for termination (or unless and until the Breaching Party is no longer disputing such basis in good faith, if earlier). If such arbitrator issues a final ruling or award upholding such basis for termination, then the cure period will resume, and the Breaching Party will have the remainder of the cure period to cure the material breach. If the material breach is so cured within the remainder of the cure period, then this Agreement will remain in full force and effect, otherwise this Agreement will terminate. If such court issues a final ruling rejecting such basis for termination, then this Agreement will remain in full force and effect.

12.5. Effects of Early Termination. Upon early termination of this Agreement in its entirety, or with respect to a Product or country in the Licensed Territory by Licensor pursuant to Sections 12.2 (subject to Section 12.6), 12.3 or 12.4, or by Licensee pursuant to Sections 12.2 (subject to Section 12.6),12.3 or 12.4, the following will apply only with respect to such Product or country:

(a) Reversion of Rights. All rights and licenses granted to Licensee in Article 2 will terminate, all rights of Licensee under the Licensor Technology will revert to Licensor, and Licensee and its Affiliates will cease all use of the Licensor Technology. Except as set forth below, all rights and licenses granted to Licensor in Article 2 will terminate, all rights of Licensor under the Licensee Technology will revert to Licensee, and Licensor and its Affiliates will cease all use of the Licensee Technology.

(b) Regulatory Materials and Approvals. Licensee will assign, and hereby does assign effective as of the effective date of such early termination, to Licensor all Regulatory Materials and Regulatory Approvals and all other documents necessary to further Develop and Commercialize any terminated Product in the Licensed Territory, as they exist as of the date of such early termination (and all of Licensee's right, title and interest therein and thereto). Licensee will provide to Licensor one (1) copy of the foregoing documents, all documents and filings contained in or referenced in any such Regulatory Materials and Regulatory Approvals, together with the raw and summarized data for any preclinical and Clinical Studies of such terminated Product. For clarity, Licensor will have the right to use the foregoing material information, materials and data developed by Licensee solely in connection with Licensor's development, manufacture and commercialization of the terminated Product. Licensor will have the right to seek specific performance of Licensee's obligations referenced in this Section 12.5(b) and/or in the event of failure to obtain assignment, Licensee hereby consents and grants to Licensor the right to access and reference (without any further action required on the part of Licensee, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such Regulatory Materials and Regulatory Approvals for any regulatory or other use or purpose. Without limiting the foregoing in this paragraph, to the extent applicable, Licensee's obligations under this Section 12.5(b) will continue with respect to all countries in the Licensed Territory for which there is a failure to obtain assignment of all Regulatory Materials and Regulatory Approvals.

(c) Information Transfer. Licensee will provide to Licensor all data and Information generated during the Term necessary for the development and/or commercialization of the terminated Product and assign (or, if applicable, cause its Affiliate to assign) to Licensor all of Licensee's (and such Affiliate's) entire right, title and interest in and to all such data and Information. Licensee will provide to Licensor the tangible embodiments of all other Information Controlled by Licensee and its Affiliates in existence as of the effective date of such early termination relating to the development, manufacturing, and commercialization of the terminated Product, including without limitation Licensee's manufacturing processes, techniques and trade secrets necessary for and used in the manufacture of such terminated Product as of the effective date of such early termination and all Information specifically relating to any composition, formulation, method of use or manufacture of the terminated Product. Licensee will grant, and hereby does grant effective as of the effective date of such early termination, to Licensor a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide right and license under such Information for developing, making, using, importing, selling and offering for sale the terminated Product in the Licensed Territory. Licensee will reasonably cooperate with Licensor to assist Licensor with understanding and using the Information provided to Licensor under this Section 12.5(c).

(d) Trademarks. All rights and licenses granted to Licensee under Section 8.6(b) will terminate, all rights of Licensee to use the Licensed Marks will revert to Licensor, and Licensee and its Affiliates will cease all use of the Licensed Marks. To the extent that Licensee owns any Licensee Marks (including without limitation any Product trademarks) and/or domain names that pertain specifically to the terminated Product that Licensor believes would be necessary for the commercialization of the terminated Product (as then currently marketed, but not including any marks that include, in whole or part, any corporate name or logo of Licensee), except as provided in Section 12.6, Licensee will assign (or, if applicable, cause its Affiliate to assign), and hereby does assign effective as of the effective date of such early termination, to Licensor all of Licensee's (and such Affiliate's) right, title and interest in and to any such Licensee Marks (including any registered or unregistered trademark, trademark application, trade name or internet domain name) in such country.

(e) Continuing Obligations. Neither Party will be relieved of any obligation that accrued prior to the effective date of such early termination. All amounts due or payable to Licensor or to Licensee, as the case may be, that were accrued prior to the effective date of early termination will remain due and payable. Except as otherwise expressly provided herein, no additional amounts will be payable based on events occurring after the effective date of termination; *provided* that the foregoing will not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the effective date of such early termination that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the effective date of such early termination.

(f) Retention of Payments. Licensor will have the right to retain all amounts previously paid to Licensor by Licensee and Licensee will have the right to retain all amounts previously paid to Licensee by Licensor.

(g) No Compensation. Licensor will not owe any compensation to Licensee for the research, development, manufacture, or commercialization of the terminated Product in the event of any such early termination of this Agreement by Licensor, without prejudice to any rights that either Party may have to bring a claim for damages arising out of this Agreement and the termination thereof or any other amounts payable with respect to activities conducted prior to the effective date of such early termination.

(h) Costs. Any costs and expenses incurred by Licensee in connection with the assignments and transfers made by Licensee under this Section 12.5 will be borne by Licensee.

(i) Transition Assistance. In addition to the obligations of Licensee set forth above in this Section 12.5, upon early termination of this Agreement by Licensor in its entirety or with respect to a Product or country in the Licensed Territory pursuant to Sections 12.2, 12.3 or 12.4 or by Licensee pursuant to Section 12.3, the following will apply only with respect to such terminated Product and/or country: Licensee shall provide such assistance, as expeditiously as possible, at no cost to Licensor, and as may be, and for so long as, reasonably necessary for Licensor to continue Development and/or Commercialization of the terminated Product throughout the Licensed Territory (to the extent Licensee, its Affiliates and Sublicensees are then performing or having performed such activities), including (i) furnishing to Licensor any safety information owned or Controlled by Licensee and (ii) assigning or amending as appropriate, upon request of Licensor, any agreements or arrangements with Third Party contractors to Develop, distribute, sell or otherwise Commercialize the terminated Product in the Licensed Territory. To the extent that any such contract between Licensee and a Third Party is not assignable to Licensor, Licensee shall reasonably cooperate with Licensor to arrange to continue to provide such services for a reasonable time after such early termination.

12.6 Intellectual Property. Notwithstanding Sections 12.2 and 12.5, the Parties acknowledge and agree that the licenses granted by the Parties pursuant to Sections 2.1, 2.2 and all other rights granted under or pursuant to this Agreement are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code (or analogous provisions of the bankruptcy laws of any foreign Governmental Authority), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code (or analogous foreign provisions), and that this Agreement is an executory contract governed by Section 365(n) of the Bankruptcy Code (or analogous foreign provisions) in the event that a bankruptcy proceeding is commenced involving either Party (as licensor hereunder). Licensee, as the licensee of such rights under Sections 2.1 and 8.6 (b), and Licensor, as the licensee of such rights under Section 2.2, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code (or analogous foreign provisions). The foregoing provisions of this Section 12.6 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other applicable Laws.

12.7 Termination by Licensee; Liquidated Damages. Notwithstanding Sections 12.4 and 12.5, in the event Licensor and/or its Affiliates is in material breach of its obligation(s) under this Agreement due to a material failure to honor Licensee's exclusive rights in and for the Licensed Territory as set forth in Section 2.1 of this Agreement, and such breach is not cured in accordance with the cure provisions and modalities set forth in Section 12.4, then Licensee may either (a) terminate this Agreement in accordance with Section 12.4, in which case the effects of termination set forth in Section 12.5 shall apply, or (b) not terminate this Agreement,[***] For clarity, such [***] shall not eliminate or in any way compromise Licensee's right to also seek an injunction that orders Licensor and its Affiliates to cure its/their material breach to honor Licensee's exclusive rights in and for the Licensed Territory as set forth in Section 2.1 of this Agreement.

12.8. Survival. Early termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued before the date of early termination or expiration. Notwithstanding anything to the contrary contained herein, the following provisions will survive any expiration or early termination of this Agreement: Article 1 (Definitions) to the extent applicable, Sections 7.8, 7.9 and 7.10, Article 8 (Intellectual Property Matters) to the extent applicable, Article 10 (Indemnification), Article 11 (Confidentiality), Article 12 (Term and Termination), Article 13 (Dispute Resolution) and Article 14 (Miscellaneous).

ARTICLE 13

DISPUTE RESOLUTION

13.1. Arbitration. In the event of any disputes, controversies or differences between the Parties (except for disputes arising from the JSC, which will be handled pursuant to Section 13.2 and only handled pursuant to this Section 13.1 as provided in Section 13.2), arising out of, in relation to, or in connection with, this Agreement, including any alleged failure to perform or breach of this Agreement, or any issue relating to the validity, construction, interpretation, enforceability, performance, application or early termination of this Agreement (each, a "***Dispute***"), upon the written request of either Party, the Parties agree to meet and discuss in good faith an amicable resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party. If the Dispute is not resolved within thirty (30) days following the written request for amicable resolution, then either Party may then initiate arbitration under this Section 13.1. Any Dispute that the Parties do not resolve through amicable resolution will be settled by binding arbitration administered by JAMS, Inc., pursuant to its Comprehensive Arbitration Rules and Procedures then in effect (the "***JAMS Rules***"), except as otherwise provided. The number of arbitrators will be three (3). The first arbitrator will be selected by Licensor, the second arbitrator will be selected by Licensee, and the third arbitrator will be selected by mutual agreement of the first and second arbitrators. The arbitration will be conducted in London (United Kingdom). The language of the arbitration will be English. Judgment on the award may be entered in any court having jurisdiction. Except as may be required by Law, neither Party may disclose the existence, content or results of any arbitration hereunder without the prior written consent of the other Party.

13.2. Referred from JSC. With respect to disputes arising from matters delegated or referred to the JSC pursuant to the terms of this Agreement, either Party may, by written notice to the other Party, have such dispute referred to each Party's Executive Officers for attempted resolution by good faith negotiations within [***] after such notice is received. If the Executive Officers of the Parties are not able to resolve the dispute within the [***] period described above, then the Executive Officer of Licensor or Licensee, as the case may be, may cast the deciding vote for the JSC as provided in Section 13.2(a) or 13.2(b). If neither Party has the right to cast the deciding vote for the JSC pursuant to Section 13.2(a) or 13.2(b) (*e.g.*, where Section 13.2(a) or 13.2(b) provides for exceptions to the Executive Officer's right to make the final decision), then either Party may submit the dispute for resolution pursuant to Section 13.1.

(a) Licensor Decisions. The Executive Officer of Licensor may make the final decision with respect to: [***] Nothing in this Section 13.2(a) will be construed to limit Licensor's (A) ability to carry out day-to-day decisions related to its Development activities, if any, as set forth in the Development Plan, (B) compliance with Laws or reporting requirements to Regulatory Authorities, or (C) sole discretion with respect to pricing decisions for Product in the Licensor Territory.

(b) Licensee Decisions. The Executive Officer of Licensee may make the final decision with respect to: [***] Nothing in this Section 13.2(b) will be construed to limit Licensee's (A) ability to carry out day-to-day decisions related to its Development activities as set forth in the Development Plan, (B) compliance with Laws or reporting requirements to Regulatory Authorities, or (C) sole discretion with respect to pricing decisions for Product in the Field in the Licensed Territory.

13.3. Equitable Relief. Notwithstanding Sections 13.1 and 13.2, each Party acknowledges that its breach of Article 11 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated by damages in an action at law. By reason thereof, each Party agrees that the other Party may, in addition to any other remedies it may have under this Agreement or otherwise, seek preliminary and permanent injunctive and other equitable relief from any court of competent jurisdiction to prevent or curtail any actual or threatened breach of Article 11 that is reasonably likely to cause it irreparable harm. In addition, notwithstanding Sections 13.1 and 13.2, to the fullest extent provided by Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect a Party's rights or enforce a Party's obligations under this Agreement pending final resolution of any claims related thereto pursuant to the dispute resolution procedure set forth in Section 13.1.

13.4. No Limitation of Remedies. Each Party shall be free, pursuant to Section 13.1, to seek (without restriction as to the number of times it may seek) damages, costs and remedies that may be available under Laws or in equity and shall be entitled to offset the amount of any damages and costs obtained in a final determination under Section 13.1 of monetary damages or costs (as permitted by this Agreement) against the other Party against any amounts otherwise due to such other Party under this Agreement. It is understood and agreed that either Party shall be entitled to seek specific performance as a remedy to enforce the provisions of this Article 13, in addition to any other remedy to which such Party may be entitled by Laws. Nothing in this Article 13 shall be deemed to limit any remedy to which either Party may be entitled by Laws.

13.5. Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of England and Wales, without giving effect to any choice of law principles that would require the application of the Laws of a different state.

ARTICLE 14

MISCELLANEOUS

14.1. Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, together with the Development Plan, the Pharmacovigilance Agreement and any other documents delivered pursuant hereto or thereto sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and thereto and their Affiliates with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter of this Agreement other than as are set forth in this Agreement, the Development Plan and the Pharmacovigilance Agreement. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.2. Force Majeure. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse will continue for so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure includes conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, and storm or like catastrophe. Notwithstanding the foregoing, except in the case of a force majeure event that directly prohibits or otherwise directly prevents a Party from performing its payment obligations under this Agreement, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [***], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement to mitigate the delays caused by such force majeure.

14.3. Notices. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.3, and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Licensor:

Windtree Therapeutics, Inc.
2600 Kelly Rd., Suite 100
Warrington, PA 18976
Attn: Legal Department
Fax: 215-488-9557

With copies to (which will not constitute notice):

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312
Attn: Timothy C. Atkins
Fax: 610-640-7835

If to Licensee:

Lee's Pharmaceutical (HK) Ltd.
Unit 110-111, Bio-Informatics Centre
No. 2 Science Park West Avenue
Hong Kong Science Park
Shatin, Hong Kong
Attn: CEO
Fax: +852 2314 1708

14.4. No Strict Construction; Interpretation; Headings. The language in this Agreement is to be construed in all cases according to its fair meaning. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, and the use of any gender applies to all genders. The word "or" is used in the disjunctive sense and the word "and" is used in the conjunctive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms "including," "include," or "includes" mean including, without limiting the generality of any description preceding such term. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws will be construed as referring to such Laws as from time to time are enacted, repealed or amended, (iii) any reference to any person will be construed to include the person's successors and permitted assigns, (iv) the words "herein", "hereof," and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (v) any reference to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, (vi) all references to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits and Schedules to this Agreement, (vii) the word "days" means calendar days unless otherwise specified, and (viii) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

14.5. Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to its Affiliates or to a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates (such Third Party, an "***Acquiror***"), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights or obligations permitted hereunder will, in a writing to the other Party, expressly assume performance of such rights or obligations. The Licensor Technology, in the case of Licensor as assignor or transferor, or the Licensee Technology, in the case of Licensee as assignor or transferor, excludes any Patents and Information Controlled by any Acquiror (or any Affiliate thereof, but excluding a Party as a result of such transaction). Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.5 is null, void and of no legal effect.

14.6. Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.7. Further Assurances and Actions. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the transactions contemplated by this Agreement.

14.8. Severability. Each of the provisions contained in this Agreement will be severable, and the unenforceability of one will not affect the enforceability of any others or of the remainder of this Agreement. If any one or more of the provisions of this Agreement, or the application thereof in any circumstances, is held to be invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided*, *however*, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions of this Agreement will not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties will be enforceable to the fullest extent permitted by Law.

14.9. No Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver, delay or the failure of any Party to enforce or exercise any term, condition or part of this Agreement at any time or in any one or more instances will not be deemed to be or construed as a waiver of the same or any other term, condition or part, nor will it forfeit any rights, power or privilege to future enforcement thereof. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Laws, (a) no claim or right arising out of this Agreement or any of the documents referred to in this Agreement can be discharged by one Party, in whole or in part, by a waiver or renunciation of the claim or right unless in a writing signed by the other Party; (b) no waiver that may be given by a Party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one Party will be deemed to be a waiver of any obligation of that Party or of the right of the Party giving such notice or demand to take further action without notice or demand as provided in this Agreement or the documents referred to in this Agreement. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Laws or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

14.10. Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Licensor's legal relationship to Licensee under this Agreement will be that of independent contractor. This Agreement is not a partnership agreement. Nothing in this Agreement will be construed to establish a relationship of partners or joint venturers between the Parties. The relationship between Licensee and Licensor does not constitute a partnership, joint venture, or agency. Neither Licensee nor Licensor shall make any statements, representations, or commitments of any kind, or take any action that is binding on the other, without the prior written consent of the other Party.

14.11. Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement gives either Party the power or authority to act for, bind or commit the other Party in any way. Nothing in this Agreement creates the relationship of partners, principal and agent, or joint-venture partners as between the Parties.

14.12. English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. Any formal notices referred to in this Agreement, plans and clinical trial, safety and related summary reports of any committee, and any progress and sales reports will, in each case be written in the English language.

14.13. Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, but all of which together constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format ("***PDF***") sent by electronic mail. In addition, facsimile or PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any Party will constitute due execution and delivery of this Agreement.

14.14. Schedules. The disclosure of any matter in any Section of or on any Schedule to this Agreement will only be deemed to be a disclosure for the Section or subsection of this Agreement to which it corresponds in number, unless the applicability of such Schedule to any other Section is readily apparent. The disclosure of any matter in any Schedule to this Agreement will expressly not be deemed to (a) constitute an admission by either Party hereto, or (b) imply that any such matter is material for purposes of this Agreement.

14.15. Non-Solicitation of Employees. During the Term, neither Party may, directly or indirectly, recruit or solicit any employee of the other Party who became known to the other Party through contact or interactions for negotiating or performing this Agreement, without the prior written consent of the other Party. For purposes of the foregoing, "recruit" or "solicit" shall exclude: (a) circumstances where an employee of a Party initiates contact with the other Party solely on its own with regard to possible employment without being encouraged, suggested or otherwise induced to make such contact by the other Party; or (b) general solicitations of employment not specifically targeted at employees of a Party, including responses to general advertisements.

14.16. Expenses. Each Party will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby.

14.17. Registration of Agreement. Licensee shall take all reasonable and necessary steps to register this Agreement in any country where such registration is required to permit the transfer of funds and/or payment of royalties to Licensor hereunder or is otherwise required by a Governmental Authority or Laws of such country to effectuate or carry out this Agreement. Notwithstanding anything contained in this Agreement to the contrary, Licensee shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, Licensee shall not be relieved of its obligation to make any payment due to Licensor hereunder where such payment is blocked due to any failure to register this Agreement.

ARTICLE 15

MANUFACTURING

15.1. Non-Aerosolized Products. Pursuant to the rights granted under Section 2.1(b), Licensee shall manufacture the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products in the Licensed Territory. Licensor shall provide sourcing for active pharmaceutical ingredients, including the Drug, to be used in the manufacture of the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products in the Licensed Territory pursuant to the terms of a written supply agreement (if Licensee desires to obtain such active pharmaceutical ingredients from Licensor). In such a case, the transfer price for such active pharmaceutical ingredients, including the Drug, shall correspond to Licensor [***] Licensee shall maintain standards no less rigorous than those required by FDA in connection with its manufacture of the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products. Licensor will provide the necessary support to Licensee in the selection, contracting and certification of approved (pursuant to Section 2.1(c)) third party manufacturers, if any, for the manufacture of the Drug, the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products, as the case may be, in the Licensed Territory.

15.2. Aerosolized Products. Licensor shall manufacture or cause to be manufactured Drug and Device components of Aerosurf and other Aerosolized Products in the Licensor Territory and supply Aerosurf and such components and other Aerosolized Products to Licensee during the Term pursuant to the terms of a written supply agreement at a transfer price equal to Licensor's [***]

15.3. Technology Transfer and Supply. Promptly after the Effective Date, Licensor shall commence a technology transfer to Licensee of the manufacturing process for the Surfaxin Product, Surfaxin LS and other Non-Aerosolized Products, such technology transfer to be completed no later than [***] after the Effective Date. The Parties shall negotiate the terms of an appropriate technology transfer agreement within [***] after the Effective Date which, among other things, identifies the roles and responsibilities of the Parties necessary to accomplish such technology transfer. Upon the successful completion of such technology transfer and upon Licensor's written request, the Parties shall enter into a supply agreement providing for the supply of Surfaxin Product and Surfaxin LS and other Non-Aerosolized Products by Licensee to Licensor, for use by or on behalf of Licensor of such Surfaxin Product and Surfaxin LS and other Non-Aerosolized Products outside the Licensed Territory.

15.4. Timing. The supply agreements described in Sections 15.1 and 15.2 shall be entered into between the Parties, subject to the terms and conditions set forth in this Article 15 and elsewhere in this Agreement, within [***] after the Effective Date. The technology transfer agreement described in Section 15.3 shall be entered into between the Parties, subject to the terms and conditions set forth in this Article 15 and elsewhere in this Agreement, within [***] from the Effective Date. Additionally, the supply agreement described in the last paragraph of Section 15.3 shall be entered into between the Parties, subject to the terms and conditions set forth in this Article 15 and elsewhere in this Agreement, within [***] after Licensor's written request under Section 15.3.

15.5. Manufacturing Option for Device. Notwithstanding any other provision of this Agreement to the contrary, Licensor hereby grants to Licensee an option, exercisable in Licensee's sole discretion, to manufacture and assemble the Device in and for the Licensed Territory (the "***Device Manufacturing Option***"). The Device Manufacturing Option shall be exercisable by Licensee for a period of [***] beginning upon Licensor's completion of a final, successful Phase 3 Study in respect of Aerosurf for the prevention and/or treatment of RDS and Licensee's completion of such other Development obligations as may be required by the Regulatory Authority in the PRC in respect of Aerosurf. [***] Licensee may exercise the Device Manufacturing Option by notifying Licensor in writing of Licensee's intent to exercise the Device Manufacturing Option. Within thirty (30) days of Licensor's receipt of such notice, the Parties will enter into good faith discussions to reach definitive agreements as to a manufacturing plan and any amendments to this Agreement as may be required to enable the provision by Licensor to Licensee of such rights and information, including technology transfer, as are necessary for Licensee to manufacture the Device in and for the Licensed Territory with all related costs to be borne by Licensee. Such manufacturing plan shall be submitted to the JSC for its review and approval.

[*remainder of this page intentionally left blank*]

In Witness Whereof, the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

WINDTREE THERAPEUTICS, INC.

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

LEE'S PHARMACEUTICAL (HK) LTD.

By: /s/Benjamin Li, Ph.D
Name: Benjamin Li, Ph.D
Title: Chief Executive Officer

EXHIBIT A

LICENSED MARKS

Trademark	Registration No.	Class /Goods	Country
[***]	[***]	[***]	[***]

SCHEDULE 1

LICENSOR PATENTS

1.1 AEROSURF® Aerosol Delivery System Portfolio (licensed from PHILIP MORRIS PRODUCTS S.A. (PMPSA))

Ref #	**Application No**	**Patent No.**	**Filing Date**	**Issue Date**	***Expiration Date***	**Title**	**Status**	**Country**
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

1.2 KL4 Pulmonary Surfactant Portfolio (AEROSURF and SURFAXIN LS)

Ref. #	**Program**	**Application Serial No./ Patent No.**	**Filing Date/ *Expiration Date***	**Title**	**Status**	**Country**
[***]	[***]	[***]	*[***]*	[***]	[***]	[***]

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 21, 2017

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

Exhibit 31.2

CERTIFICATIONS

I, John A. Tattory, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 21, 2017

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

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Windtree Therapeutics, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 21, 2017

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

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

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to us and will be retained by us and furnished to the SEC or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.