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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 **September 30, 2022**

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 (State or other jurisdiction of incorporation or organization)	**94-3171943** (I.R.S. Employer Identification No.)
2600 Kelly Road, Suite 100 **Warrington, Pennsylvania** (Address of principal executive offices)	**18976-3622** (Zip Code)

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**WINT**	**The Nasdaq Capital Market**

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	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 November 14, 2022, there were 38,610,119 shares of the registrant's common stock outstanding, 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 consolidated subsidiaries.

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, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These 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," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking.

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

- our estimates regarding future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- how long we can continue to fund our operations with our existing cash and cash equivalents;
- we received written notice from The Nasdaq Stock Market LLC, or Nasdaq, that we have failed to comply with Nasdaq's continued listing standards; if we fail to regain compliance within the allowed grace periods or other processes provided under the Nasdaq listing requirements, our common stock may be delisted and the value of our common stock may decrease;
- the potential impairment of our intangible assets and goodwill on our condensed consolidated balance sheet, which could lead to material impairment charges in the future;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the novel coronavirus, or COVID-19, pandemic on our clinical trial operations;
- the costs, timing, and results, of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States, or U.S., and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- risks related to manufacturing active pharmaceutical ingredients, drug product, and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the plans of our AEROSURF and KL4 licensee, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), and its ability to successfully execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialize the licensed product candidates;
- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contract laboratories, and independent contractors;
- the size and growth of the potential markets for our product candidates, the regulatory requirements in such markets, the rate and degree of market acceptance of our product candidates, and our ability to serve those markets;
- the success of competing therapies and products that are or may become available;
- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;

- recently enacted and future legislation, including but not limited to, the Inflation Reduction Act of 2022, regarding the healthcare system in the U.S. or the healthcare systems in foreign jurisdictions;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to secure electronically stored work product, including clinical data, analyses, research, communications, and other materials necessary to gain regulatory approval of our product candidates, including those acquired from third parties, and assure the integrity, proper functionality, and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption; and
- economic uncertainty resulting from inflation or geopolitical instability, including the ongoing military conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan).

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

The forward-looking statements contained in this Quarterly Report on Form 10-Q 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.

You should also read carefully the factors described in the "Risk Factors" included in Part II, Item 1A of this Quarterly Report on Form 10-Q in conjunction with Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as supplemented by our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements.

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,436	$ 22,348
Prepaid expenses and other current assets	1,596	1,143
Total current assets	10,032	23,491
Property and equipment, net	286	1,011
Restricted cash	154	154
Operating lease right-of-use assets	1,964	2,381
Intangible assets	32,070	32,070
Goodwill	3,592	15,682
Total assets	$ 48,098	$ 74,789
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 410	$ 693
Accrued expenses	2,496	3,408
Operating lease liabilities - current portion	416	528
Loans payable - current portion	629	294
Total current liabilities	3,951	4,923
Operating lease liabilities - non-current portion	1,732	2,071
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	6,195	7,114
Total liabilities	30,678	32,908
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at September 30, 2022 and December 31, 2021; 32,646,735 and 28,268,950 shares issued at September 30, 2022 and December 31, 2021, respectively; 32,646,711 and 28,268,926 shares outstanding at September 30, 2022 and December 31, 2021, respectively	33	28
Additional paid-in capital	835,281	830,231
Accumulated deficit	(814,840)	(785,324)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	17,420	41,881
Total liabilities & stockholders' equity	$ 48,098	$ 74,789

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Expenses:				
Research and development	$ 1,543	$ 4,680	$ 9,883	$ 13,311
General and administrative	2,653	3,467	8,548	11,507
Loss on impairment of goodwill	454	-	12,090	-
Loss on impairment of intangible assets	-	-	-	37,770
Total operating expenses	4,650	8,147	30,521	62,588
Operating loss	(4,650)	(8,147)	(30,521)	(62,588)
Other income (expense):				
Interest income	39	1	57	90
Interest expense	(14)	(14)	(40)	(101)
Other income (expense), net	569	(53)	988	(296)
Total other income (expense), net	594	(66)	1,005	(307)
Loss before income taxes	(4,056)	(8,213)	(29,516)	(62,895)
Deferred income tax benefit	-	-	-	8,332
Net loss	$ (4,056)	$ (8,213)	$ (29,516)	$ (54,563)
Net loss per common share				
Basic and diluted	$ (0.13)	$ (0.31)	$ (1.00)	$ (2.31)
Weighted average number of common shares outstanding				
Basic and diluted	31,135	26,704	29,554	23,616

See notes to condensed consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance - December 31, 2020	**16,922**	**$ 17**	**$ 790,277**	**$ (717,688)**	**-**	**$ (3,054)**	**$ 69,552**
Net loss	-	-	-	(8,961)	-	-	(8,961)
Issuance of common stock and common stock warrants, net of issuance costs	9,230	9	27,381	-	-	-	27,390
Stock-based compensation expense	-	-	2,443	-	-	-	2,443
Issuance of common stock, ATM Program, net of issuance costs	105	-	570	-	-	-	570
Issuance of common stock warrants, equity consideration for service agreement	-	-	494	-	-	-	494
Balance - March 31, 2021	**26,257**	**$ 26**	**$ 821,165**	**$ (726,649)**	**-**	**$ (3,054)**	**$ 91,488**
Net loss	-	-	-	(37,389)	-	-	(37,389)
Stock-based compensation expense	-	-	1,544	-	-	-	1,544
Issuance of common stock, ATM Program, net of issuance costs	447	1	1,119	-	-	-	1,120
Balance - June 30, 2021	**26,704**	**$ 27**	**$ 823,828**	**$ (764,038)**	**-**	**$ (3,054)**	**$ 56,763**
Net loss	-	-	-	(8,213)	-	-	(8,213)
Stock-based compensation expense	-	-	1,629	-	-	-	1,629
Balance - September 30, 2021	**26,704**	**$ 27**	**$ 825,457**	**$ (772,251)**	**-**	**$ (3,054)**	**$ 50,179**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance - December 31, 2021	**28,269**	**$ 28**	**$ 830,231**	**$ (785,324)**	**-**	**$ (3,054)**	**$ 41,881**
Net loss	-	-	-	(8,127)	-	-	(8,127)
Stock-based compensation expense	-	-	770	-	-	-	770
Issuance of common stock, ATM Program, net of issuance costs	200	-	205	-	-	-	205
Balance - March 31, 2022	**28,469**	**$ 28**	**$ 831,206**	**$ (793,451)**	**-**	**$ (3,054)**	**$ 34,729**
Net loss	-	-	-	(17,333)	-	-	(17,333)
Stock-based compensation expense	-	-	781	-	-	-	781
Issuance of common stock, ATM Program, net of issuance costs	937	1	1,019	-	-	-	1,020
Balance - June 30, 2022	**29,406**	**$ 29**	**$ 833,006**	**$ (810,784)**	**-**	**$ (3,054)**	**$ 19,197**
Net loss	-	-	-	(4,056)	-	-	(4,056)
Stock-based compensation expense	-	-	744	-	-	-	744
Issuance of common stock, ATM Program, net of issuance costs	3,241	4	1,531	-	-	-	1,535
Balance - September 30, 2022	**32,647**	**$ 33**	**$ 835,281**	**$ (814,840)**	**-**	**$ (3,054)**	**$ 17,420**

See notes to condensed consolidated financial statements

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

(in thousands)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (29,516)	$ (54,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	509	140
Stock-based compensation	2,295	5,616
Non-cash lease expense	417	505
Non-cash expense related to equity consideration for a service agreement	-	494
Loss on impairment of goodwill	12,090	-
Loss on impairment of intangible assets	-	37,770
Loss on sale and disposal of property and equipment	19	-
Deferred income tax benefit	-	(8,332)
Unrealized (gain) loss on foreign exchange rate changes	(941)	331
Changes in assets and liabilities:		
Prepaid expenses and other current assets	687	682
Accounts payable	(283)	(579)
Accrued expenses	(898)	(264)
Operating lease liabilities	(451)	(532)
Net cash used in operating activities	(16,072)	(18,732)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	210	-
Purchase of property and equipment	(13)	(106)
Net cash provided by (used in) investing activities	197	(106)
Cash flows from financing activities:		
Proceeds from ATM Program, net of issuance costs	2,760	1,690
Principal payments on loans payable	(797)	(3,431)
Proceeds from issuance of common stock and warrants, net of issuance costs	-	27,390
Proceeds from research and development funding arrangement	-	800
Net cash provided by financing activities	1,963	26,449
Net (decrease) increase in cash, cash equivalents, and restricted cash	(13,912)	7,611
Cash, cash equivalents, and restricted cash - beginning of period	22,502	17,084
Cash, cash equivalents, and restricted cash - end of period	$ 8,590	$ 24,695
Supplementary disclosure of non-cash activity:		
Prepayment of insurance through third-party financing	$ 1,132	$ 1,321
Operating lease liabilities arising from obtaining right-of-use assets	-	2,000

See notes to condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs. We completed this Phase 2 global clinical study and, in April 2022, announced positive topline results with istaroxime in raising systolic blood pressure. In May 2022, we presented the study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activators which activate SERCA2a. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potential oral agents, these candidates would be developed for chronic heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance this product candidate without securing such an arrangement or partnership.

Previously, we were developing a KL4 surfactant platform, including AEROSURF (lucinactant for inhalation), to address a range of serious respiratory conditions in children and adults. In order to focus our resources on the development of our istaroxime pipeline, we suspended all internal AEROSURF clinical activities in November 2020, and, in January 2022 we began to reduce all other costs related to the KL4 surfactant platform that were not already transferred to our licensee, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Original License Agreement.

On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A&R License Agreement, with Lee's (HK) and Zhaoke, a company organized under the laws of the People's Republic of China, effective as of August 9, 2022. We refer to Zhaoke Pharmaceutical (Hefei) Co. Ltd. and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes the Original License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation, and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A.

Under the Original Agreement, Licensee previously made an upfront payment to us of $1.0 million. Pursuant to the terms of the A&R License Agreement, we may receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income. Further, Licensee is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval, and commercialization of licensed products in the Licensed Territory, including all royalties payable in respect of third-party intellectual property rights sublicensed by us to Licensee and all intellectual property prosecution, maintenance and defense activities and costs.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business, financial condition, and results of operations.

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2021 that we filed with the Securities and Exchange Commission, or the SEC, on March 31, 2022, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Note 2 – Basis of Presentation

The interim unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., or US GAAP, for interim financial information in accordance with the instructions to Form 10-Q and include accounts of Windtree Therapeutics, Inc. and its wholly owned subsidiaries. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. Intercompany balances and transactions have been eliminated in consolidation. All adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The consolidated balance sheet at December 31, 2021 has been derived from the Company's audited consolidated financial statements. There have been no changes to our significant accounting policies since December 31, 2021. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with our annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2021 contained in our Annual Report on Form 10-K for the year ended December 31, 2021.

Note 3 – Going Concern and Management's Plans

We are subject to risks common to companies in the biotechnology industry, including but not limited to, the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international locations and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $4.1 million and $8.2 million, respectively, for the three-month periods ended September 30, 2022 and 2021. Our net loss was $29.5 million and $54.6 million, respectively, for the nine-month periods ended September 30, 2022 and 2021. Included in our net loss for the three and nine months ended September 30, 2022 is a $0.5 million and $12.1 million loss on impairment of goodwill, respectively, and included in our net loss for the nine months ended September 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 – Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of September 30, 2022, we had an accumulated deficit of $814.8 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

We are party to an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the nine months ended September 30, 2022, we sold 4,377,785 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $2.8 million. Subsequent to the end of the third quarter of 2022, we sold 5,963,408 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.5 million (*see*, Note 8 – Stockholders' Equity).

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, under the S-3 during any 12-month period, and, as of November 14, 2022, we have sold the full amount we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

As of September 30, 2022, we had cash and cash equivalents of $8.4 million and current liabilities of $4.0 million. We believe that we have sufficient resources available to support our development activities and fund our business operations into the second quarter of 2023. However, we do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to secure additional capital, potentially through a combination of public or private securities offerings, convertible debt financings, and/or strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. Further, on June 3, 2022, we received a deficiency letter from the Nasdaq Stock Market LLC, or Nasdaq, notifying us that the closing bid price of our common stock had been below the minimum $1.00 per share for 30 consecutive business days, we are out of compliance with the requirements for continued listing on Nasdaq, and are subject to potential delisting. If we are unable to re-achieve compliance with the Nasdaq listing requirements within 180 days, or November 30, 2022, after receipt of a delisting notice, and if we are unable to obtain an extension therefore, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition.

The accompanying condensed consolidated 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.

Note 4 – Summary of Significant Accounting Policies

Principles of Consolidation

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

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or IPR&D, assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three and nine months ended September 30, 2022, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

During the second quarter of 2021, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not impaired and we performed the required quantitative impairment assessment of the related intangible asset. We recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the nine months ended September 30, 2021. No events or changes in the business environment occurred during the nine months ended September 30, 2021 to indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing our annual goodwill impairment assessment as of December 1, 2021, we estimated the fair value of our reporting unit based upon the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium. Based on the quantitative test performed, we determined that the fair value of our reporting unit exceeded its carrying value and no impairment loss was recognized as of December 31, 2021.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock.

During each of the second and third quarters of 2022, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies. Based on the quantitative tests performed, we recorded a loss on impairment of goodwill of $11.6 million in the second quarter of 2022 and an additional $0.5 million in the third quarter of 2022, resulting in a loss on impairment of goodwill of $12.1 million for the nine months ended September 30, 2022, recognized within operating expenses in our condensed consolidated statements of operations.

The closing share price of our common stock has continued to decline subsequent to the end of the third quarter of 2022. If our share price continues to decline during the remainder of the fourth quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

The following table represents identifiable intangible assets and goodwill as of September 30, 2022 and December 31, 2021:

(in thousands)	September 30, 2022	December 31, 2021
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	9,730	9,730
Intangible assets	32,070	32,070
Goodwill	$ 3,592	$ 15,682

Foreign Currency Transactions

The functional currency for our foreign subsidiaries is U.S. Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other income (expense), net. Foreign currency transactions resulted in gains of approximately $0.5 million and losses of approximately $0.1 million for the three-month periods ended September 30, 2022 and 2021, respectively. Foreign currency transactions resulted in gains of approximately $0.9 million and losses of approximately $0.3 million for the nine-month periods ended September 30, 2022 and 2021, respectively.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents are held at domestic and foreign financial institutions and consist of liquid investments, money market funds, and U.S. Treasury notes with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

Severance

In January 2022, in order to focus our resources on the development of our istaroxime pipeline, we began to reduce costs related to KL4 surfactant that were not already transferred to our licensee, Lee's (HK), under the terms of the Original License Agreement. These costs include certain reductions in headcount dedicated to KL4 surfactant and the decommissioning of both our analytical and technical support laboratory, which previously conducted release testing of active pharmaceutical ingredients and supportive research for our lyophilized and aerosolized KL4 surfactant, and our medical device development laboratory, which was previously used to conduct development activities and testing for our aerosol delivery system technologies. In February 2022, management communicated its commitment to provide severance payments to impacted employees, provided that they remain employed with us through their expected termination dates. The total severance cost for impacted employees is approximately $0.4 million, was accrued over the service periods of the employees, and was paid ratably through September 30, 2022. We incurred $0.4 million of expense related to these severance arrangements during the nine months ended September 30, 2022, which is included in research and development expense. During the three and nine months ended September 30, 2022, $0.2 million and $0.4 million was paid, respectively. No further amounts were due as of September 30, 2022.

Property and Equipment

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

During the first quarter of 2022, we determined that certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform would be abandoned by March 31, 2022. We accelerated depreciation of these assets during the first quarter of 2022, resulting in $0.4 million of additional depreciation expense for the three months ended March 31, 2022. During the second quarter of 2022, the abandoned assets and certain other KL4 surfactant platform assets were disposed.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (*see*, Note 7 – Restructured Debt Liability), we have established a $15.0 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017, or the Exchange and Termination Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

Research and Development

We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, consulting, and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical, and regulatory operations expenses, to specific programs. Indirect research and development expenses include personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, regulatory, and medical affairs. Research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 730, Research and Development.

Income Taxes

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

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

For the nine months ended September 30, 2021, we recorded a deferred income tax benefit of $8.3 million. The deferred tax benefit recorded for these periods relates solely to the reduction of the deferred tax liability as a result of the loss on impairment of intangible assets related to rostafuroxin during the same period.

Net Loss per Common Share

Basic net loss per common 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 September 30, 2022 and 2021, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants, as well as the vesting of restricted stock units, was 21.0 million and 20.0 million shares, respectively. For the three and nine months ended September 30, 2022 and 2021, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

COVID-19

The novel coronavirus, or COVID-19, pandemic continues to evolve, and we continue to closely monitor its impact on our business and operations, including its potential impact on our clinical development plans and timelines, and financial condition. There has been intermittent impact of the pandemic in differing geographies, and there may be continued impact. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources, and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The full extent, duration, or continued impact that the COVID-19 pandemic may have directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include the severity and transmissibility of new variants of the virus, information about any resurgences that may occur in one or more geographic locations where our current or intended clinical trial sites, our principal executive offices, research and development laboratories, or manufacturing facilities are located, and the actions taken to contain it or treat its impact. In addition, regional impact and responses to the COVID-19 pandemic have affected where a clinical trial could be executed and how various elements of the clinical trial are performed. Going forward, the pandemic could also impact how monitoring/auditing of clinical trial sites and data occur. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more geographic locations where our clinical trial sites, principal executive offices, research and development laboratories, or other facilities are located remains possible and if realized, there may be further impact on the clinical development of our product candidates, which may include potential delays, halts, or modifications to our ongoing and potential future trials.

We are not aware of any specific event or circumstance that would require us to further update our estimates, judgments, or revise the carrying value of our assets or liabilities as of the date of issuance of these interim unaudited condensed consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

Note 5 – Fair Value Measurements

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

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

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

Fair Value on a Recurring Basis

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

(in thousands)	Fair Value September 30, 2022	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 6,160	$ 6,160	$ -	$ -
Total Assets	$ 6,160	$ 6,160	$ -	$ -

(in thousands)	Fair Value December 31, 2021	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 21,104	$ 21,104	$ -	$ -
Total Assets	$ 21,104	$ 21,104	$ -	$ -

Note 6 – Loans Payable

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% annual interest rate. Payments of approximately $126,000 are due monthly from July 2022 through March 2023. As of September 30, 2022, the outstanding principal of the loan was $0.6 million.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of December 31, 2021, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2022.

Note 7 – Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into an Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield Management Company L.P., or the Deerfield Loan, in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 8,333 shares of our common stock at an exercise price of $2,360.40 per share held by Deerfield were cancelled in consideration for (i) a cash payment in the aggregate amount of $2.5 million, (ii) 23,703 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (iii) the right to receive certain milestone payments based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15.0 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. We established a $15.0 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Exchange and Termination Agreement (*see*, Note 4 – Summary of Significant Accounting Policies). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of September 30, 2022 and December 31, 2021, the restructured debt liability balance was $15.0 million.

Note 8 – Stockholders' Equity

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through the ATM Program. When we issue sales notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the ATM Program. The rate of compensation will not apply when Ladenburg acts as principal.

For the nine months ended September 30, 2022, we sold 4,377,785 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $2.8 million. For the nine months ended September 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million.

Subsequent to the end of the third quarter of 2022, we sold 5,963,408 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.5 million.

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of our public float under the S-3 during any 12-month period, and as of November 14, 2022, we have sold the full amount we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

March 2021 Public Offering

On March 23, 2021, we entered into an underwriting agreement with Oppenheimer & Co. Inc. as representative for the several underwriters named therein, relating to a public offering, or the March 2021 Offering, of an aggregate of 9,230,500 units with each unit consisting of one share of common stock and a warrant, or the March 2021 Warrants. The March 2021 Warrants are immediately exercisable for shares of common stock at a price of $3.60 per share and expire five years from the date of issuance. The shares of common stock and the March 2021 Warrants were immediately separable and were issued separately in the March 2021 Offering.

The closing of the March 2021 Offering occurred on March 25, 2021. The offering price to the public was $3.25 per unit resulting in gross proceeds to us of $30.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the March 2021 Warrants issued pursuant to the March 2021 Offering, the net proceeds to us were approximately $27.4 million.

We have determined that the appropriate accounting treatment under ASC 480, Distinguishing Liabilities from Equity, or ASC 480, is to classify the common stock and the March 2021 Warrants issued in the March 2021 Offering as equity. We have also determined that the March 2021 Warrants are not in their entirety a derivative under the scope of ASC 815, Derivatives and Hedging, or ASC 815, due to the scope exception under ASC 815-10-15-74, nor are there any material embedded derivatives that require separate accounting. We allocated the net proceeds from the March 2021 Offering based on the relative fair value of the common stock and the March 2021 Warrants.

Note 9 – Stock-Based Compensation

We recognize expense in our condensed consolidated financial statements related to all stock-based awards granted to employees and non-employee directors based on their fair value on the date of grant. Compensation expense related to stock options is calculated using the Black-Scholes option-pricing model and is recognized ratably over the vesting period, which is typically three years. Compensation expense related to restricted stock unit, or RSU, awards is also recognized ratably over the vesting period, which typically has been between approximately one to 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, 2022	3,387	$ 9.74	
Granted	880	0.99	
Forfeited or expired	(384)	10.95	
Outstanding at September 30, 2022	3,883	$ 7.64	7.8
Vested and exercisable at September 30, 2022	2,338	$ 10.49	7.2
Vested and expected to vest at September 30, 2022	3,687	$ 7.65	7.8

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2022	-	$ -
Awarded	582	0.99
Cancelled	(24)	1.02
Outstanding at September 30, 2022	558	$ 0.99
Vested and exercisable at September 30, 2022	-	$ -
Vested and expected to vest at September 30, 2022	558	$ 0.99

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

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Research and development	$ 198	$ 688	$ 580	$ 2,257
General and administrative	546	941	1,715	3,359
Total	$ 744	$ 1,629	$ 2,295	$ 5,616

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

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Weighted average expected volatility	106%	104%
Weighted average expected term (in years)	6.9	6.7
Weighted average risk-free interest rate	1.70%	0.49%
Expected dividends	-	-

Note 10 – Licensing and Research Funding Agreements

Term Sheet with Lee's (HK)

In March 2020, we entered into a Term Sheet with Lee's (HK), pursuant to which Lee's (HK) provided financing for the development of AEROSURF. In August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, formalizing the terms of the Term Sheet, and under which we received payments totaling $2.8 million through October 2020. In November 2020, Lee's (HK) provided notice of termination of additional funding under the PF Agreement, and we and Lee's (HK) revised our plans for the continued development of AEROSURF. Lee's (HK) agreed to continue the development of AEROSURF in Asia at its cost. Lee's (HK) agreed to fund an additional $1.0 million to us in 2021 for certain transition and analytical services to be provided by us with respect to the development of AEROSURF, which will be considered "Project Expenses" under the terms of the PF Agreement. In 2021, we received payments totaling $1.0 million from Lee's (HK) and no further amounts were due under the PF Agreement.

To repay the funds provided under the terms of the PF Agreement, until such time as we have repaid 125% of the amounts funded by Lee's (HK) for the development of AEROSURF, we will pay to Lee's (HK) 50% of all revenue amounts and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, excluding (i) payments for bona fide research and development services; (ii) reimbursement of patent expenses and (iii) all amounts paid to us under the Original License Agreement, minus certain deductions and certain reductions for any payments made by us with respect to third party intellectual property not previously funded by Lee's (HK).

As of September 30, 2022, the liability balance related to the payments under the PF Agreement was $3.8 million and is recorded in other liabilities.

A&R License Agreement with Lee's (HK)

Previously, we were developing a KL4 surfactant platform, including AEROSURF (lucinactant for inhalation), to address a range of serious respiratory conditions in children and adults. In order to focus our resources on the development of our istaroxime pipeline, we suspended all internal AEROSURF clinical activities in November 2020, and, in January 2022 we began to reduce all other costs related to the KL4 surfactant platform that were not already transferred to our licensee, Lee's (HK), under the terms of the Original License Agreement.

On August 17, 2022, we entered into the A&R License Agreement, with Lee's (HK) and Zhaoke, a company organized under the laws of the People's Republic of China, effective as of August 9, 2022. We refer to Zhaoke Pharmaceutical (Hefei) Co. Ltd. and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes Original License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A.

We may receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments under the A&R License Agreement. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income. Further, Licensee is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval, and commercialization of licensed products in the Licensed Territory, including all royalties payable in respect of third-party intellectual property rights sublicensed by us to Licensee and all intellectual property prosecution, maintenance and defense activities and costs.

The A&R License Agreement is considered to be a contract modification in accordance with ASC Topic 606. No additional performance obligations were identified in the contract modification, and no future material performance obligations are due. All revenue related to the $1.0 million upfront payment was appropriately recognized as of the second quarter of 2019. Regulatory and commercialization milestones were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. Consideration related to sales-based milestones and royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Lee's (HK) and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

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, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the section titled "Forward-Looking Statements" and any 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, 2021 that we filed with the Securities and Exchange Commission, or SEC, on March 31, 2022, as supplemented by our Quarterly Reports on Form 10-Q for the three months ended March 31, 2022 and six months ended June 30, 2022 filed thereafter, 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.

This Management's Discussion and Analysis, or MD&A, is provided as a supplement to the accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) to help provide an understanding of our financial condition and 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) and our Annual Report on Form 10-K for the year ended December 31, 2021. Unless otherwise specified, references to Notes in this MD&A refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs. We completed this Phase 2 global clinical study and, in April 2022, announced positive topline results with istaroxime in raising systolic blood pressure. In May 2022, we presented the study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain. We believe that istaroxime has the potential to fulfill an unmet need in early cardiogenic shock. We further believe that the data from our recently completed Phase 2 global clinical study in early cardiogenic shock will not only support that program's continued development but will also support the continued development of our AHF program as well.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activators which activate SERCA2a. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. As potential oral agents, these candidates would be developed for chronic heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance this product candidate without securing such an arrangement or partnership.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred operating losses since our incorporation on November 6, 1992. For the three-month periods ended September 30, 2022 and 2021, we had operating losses of $4.7 million and $8.1 million, respectively. For the nine-month periods ended September 30, 2022 and 2021, we had operating losses of $30.5 million and $62.6 million, respectively. Included in our operating loss for the three and nine months ended September 30, 2022 is a $0.5 million and $12.1 million loss on impairment of goodwill, respectively, and included in our operating loss for the nine months ended September 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin (*see*, Note 4 – Summary of Significant Accounting Policies). As of September 30, 2022, we had an accumulated deficit of $814.8 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock and borrowings from investors and financial institutions.

We expect to continue to incur significant research and clinical development, regulatory, and other expenses as we (i) continue to develop our product candidates; (ii) seek regulatory clearances or approvals for our product candidates; (iii) conduct clinical trials on our product candidates; and (iv) manufacture, market, and sell any product candidates for which we may obtain regulatory approval.

Business and Program Updates

The reader is referred to, and encouraged to read in its entirety, "Item 1 – Business" in our Annual Report on Form 10-K for the year ended December 31, 2021 that we filed with the SEC on March 31, 2022, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.

Istaroxime (Early Cardiogenic Shock)

In September 2020, we initiated a small Phase 2 clinical study of istaroxime for the acute treatment of early cardiogenic shock in heart failure patients with a more severe case of heart failure to evaluate the potential to improve blood pressure. The study also evaluated the safety and side effect profile of istaroxime in this patient population. In April 2022, we announced positive topline results with istaroxime in raising systolic blood pressure, the critical clinical objective in treating patients in cardiogenic shock. In May 2022, we presented data from our positive Phase 2 study of istaroxime in early cardiogenic shock in a late-breaker presentation at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain. There is a significant unmet medical need in the area of early cardiogenic shock and severe heart failure. Istaroxime demonstrated a meaningful improvement in blood pressure in clinical trials of this condition, and we believe there may be an opportunity to apply for a Breakthrough Therapy designation that could provide beneficial opportunities for the development program. In order to continue our development of istaroxime for the acute treatment of early cardiogenic shock, subject to adequate resources, we are planning to extend enrollment in this clinical trial by up to 30 patients. We believe that this extension will advance the characterization of the physiology associated with longer dosing as well as evaluate a dose titration. We also believe that this extension will further characterize the effects and potential benefits associated with SERCA2a activation and will support our clinical regulatory strategy for istaroxime. We currently do not have sufficient capital to fully execute the extension of this clinical trial.

Istaroxime (AHF)

To advance istaroxime for the treatment of AHF potentially through the Phase 2 clinical program and be in a Phase 3-ready position, our strategy includes, subject to adequate resources, planning an additional Phase 2 clinical trial that will enroll approximately 300 patients in approximately 60 clinical sites globally. This trial will focus on treating heart failure patients with low blood pressure, who also tend to be diuretic resistant, as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and increase blood pressure while maintaining or improving renal function. This trial will also collect data on measures that may serve as primary endpoints in a Phase 3 clinical trial, and will include an optimized dosing regimen, potentially extending the infusion time beyond 24 hours. We currently do not have sufficient capital to execute this clinical trial.

Rostafuroxin

Rostafuroxin has demonstrated efficacy in Caucasian patients in treatment naïve hypertension in a Phase 2b trial. During the second quarter of 2021, we concluded an initial process to test the industry's interest in investing in our drug product candidate. We currently have not been able to secure a licensing transaction or other strategic opportunity. As a result, we recorded an impairment of the related intangible asset during the year ended December 31, 2021. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional Phase 2 clinical trial to demonstrate efficacy in African American and Caucasian patients in treatment resistant hypertension. We are continuing to pursue licensing arrangements, other strategic partnerships, and/or grant funding for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement, partnership, or grant funding.

SERCA2a Activators – Preclinical Oral, Chronic, and Acute Heart Failure Product Candidates

We are pursuing several early exploratory research programs to assess potential product candidates, including oral and intravenous SERCA2a activator heart failure compounds, and believe that we can add value to our cardiovascular portfolio by advancing these SERCA2a activator candidates through preclinical studies. To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements, or other strategic opportunities.

KL4 Surfactant Platform

Previously, we were developing a KL4 surfactant platform, including AEROSURF (lucinactant for inhalation), to address a range of serious respiratory conditions in children and adults. In order to focus our resources on the development of our istaroxime pipeline, we suspended all internal AEROSURF clinical activities in November 2020, and, in January 2022 we began to reduce all other costs related to the KL4 surfactant platform that were not already transferred to our licensee, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Original License Agreement.

On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A&R License Agreement, with Lee's (HK) and Zhaoke, a company organized under the laws of the People's Republic of China, effective as of August 9, 2022. We refer to Zhaoke Pharmaceutical (Hefei) Co. Ltd. and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes Original License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation, and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A.

We may receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments under the A&R License Agreement. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income. Further, Licensee is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval, and commercialization of licensed products in the Licensed Territory, including all royalties payable in respect of third-party intellectual property rights sublicensed by us to Licensee and all intellectual property prosecution, maintenance and defense activities and costs.

Impact of COVID-19

The novel coronavirus, or COVID-19, pandemic continues to evolve, and we continue to closely monitor its impact on our business and operations, including its potential impact on our clinical development plans and timelines, and financial condition. There has been intermittent impact of the pandemic in differing geographies, and there may be continued impact. As of the date of the issuance of this Quarterly Report on Form 10-Q, our operations, capital and financial resources, and overall liquidity position and outlook have been impacted by COVID-19, primarily due to delays experienced in our operations, including in clinical study initiation and enrollment. The full extent, duration, or continued impact that the COVID-19 pandemic may have directly or indirectly, on our financial condition and operations, including ongoing and planned clinical trials, will depend on future developments that are highly uncertain and cannot be accurately predicted. These potential future developments include the severity and transmissibility of new variants of the virus, information about any resurgences that may occur in one or more geographic locations where our current or intended clinical trial sites, our principal executive offices, research and development laboratories, or manufacturing facilities are located, and the actions taken to contain it or treat its impact. In addition, regional impact and responses to the COVID-19 pandemic have affected where a clinical trial could be executed and how various elements of the clinical trial are performed. Going forward, the pandemic could also impact how monitoring/auditing of clinical trial sites and data occur. The maintenance, or strategic re-implementation, of mitigating COVID-19 measures in one or more geographic locations where our clinical trial sites, principal executive offices, research and development laboratories, or other facilities are located remains possible and if realized, there may be further impact on the clinical development of our product candidates, which may include potential delays, halts, or modifications to our ongoing and potential future trials.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2021. For a discussion of our accounting policies, *see*, Note 4 – Summary of Significant Accounting Policies and, in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2021, Note 4 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Goodwill and Intangible Assets

We record acquired identified intangibles, which includes intangible assets (such as goodwill and other intangibles), based on estimated fair value. The acquired in-process research and development, or IPR&D, assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three and nine months ended September 30, 2022, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

During the second quarter of 2021, we determined that the fair value of the IPR&D related to our rostafuroxin drug candidate was more likely than not impaired and we performed the required quantitative impairment assessment of the related intangible asset. We recorded a loss on impairment of intangible assets of $37.8 million, recognized within operating expenses in our condensed consolidated statements of operations for the nine months ended September 30, 2021. No events or changes in the business environment occurred during the nine months ended September 30, 2021 to indicate that the fair value of the IPR&D related to our istaroxime drug candidate was impaired.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock.

During each of the second and third quarters of 2022, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies. Based on the quantitative tests performed, we recorded a loss on impairment of goodwill of $11.6 million in the second quarter of 2022 and an additional $0.5 million in the third quarter of 2022, resulting in a loss on impairment of goodwill of $12.1 million for the nine months ended September 30, 2022, recognized within operating expenses in our condensed consolidated statements of operations.

The closing share price of our common stock has continued to decline subsequent to the end of the third quarter of 2022. If our share price continues to decline during the remainder of the fourth quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

The following table represents identifiable intangible assets and goodwill as of September 30, 2022 and December 31, 2021:

(in thousands)	**September 30, 2022**	**December 31, 2021**
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	9,730	9,730
Intangible assets	32,070	32,070
Goodwill	$ 3,592	$ 15,682

RESULTS OF OPERATIONS

Comparison of the Three and Nine Months Ended September 30, 2022 and 2021

(in thousands)	Three Months Ended September 30, 2022	2021	Change	Nine Months Ended September 30, 2022	2021	Change
Expenses:						
Research and development	$ 1,543	$ 4,680	$ (3,137)	$ 9,883	$ 13,311	$ (3,428)
General and administrative	2,653	3,467	(814)	8,548	11,507	(2,959)
Loss on impairment of goodwill	454	-	454	12,090	-	12,090
Loss on impairment of intangible assets	-	-	-	-	37,770	(37,770)
Total operating expenses	4,650	8,147	(3,497)	30,521	62,588	(32,067)
Operating loss	(4,650)	(8,147)	3,497	(30,521)	(62,588)	32,067
Other income (expense):						
Interest income	39	1	38	57	90	(33)
Interest expense	(14)	(14)	-	(40)	(101)	61
Other income (expense), net	569	(53)	622	988	(296)	1,284
Total other income (expense), net	594	(66)	660	1,005	(307)	1,312
Loss before income taxes	(4,056)	(8,213)	4,157	(29,516)	(62,895)	33,379
Deferred income tax benefit	-	-	-	-	8,332	(8,332)
Net loss	$ (4,056)	$ (8,213)	$ 4,157	$ (29,516)	$ (54,563)	$ 25,047

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, contract manufacturing organizations, contract laboratories, consulting and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical and regulatory operations expenses, to specific programs. We also account for research and development and report annually by major expense category as follows: (i) contracted services; (ii) salaries and benefits; (iii) stock-based compensation; (iv) raw materials, aerosol devices and supplies; (v) royalties; (vi) rents and utilities; (vii) depreciation; (viii) travel; and (ix) other. We currently have sufficient capital to execute limited clinical trial work on the extension of our trial of istaroxime for early cardiogenic shock. We expect that our research and development expenses will decrease unless and until we secure additional capital. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates.

Research and development expenses are as follows:

(in thousands)	Three Months Ended September 30, 2022	2021	Increase (Decrease)	Nine Months Ended September 30, 2022	2021	Increase (Decrease)
Istaroxime - early cardiogenic shock	$ 685	$ 945	$ (260)	$ 2,859	$ 2,291	$ 568
Istaroxime - AHF	48	406	(358)	704	1,060	(356)
KL4 surfactant	109	262	(153)	400	769	(369)
Preclinical studies	-	6	(6)	-	6	(6)
Total direct clinical and preclinical programs	842	1,619	(777)	3,963	4,126	(163)
Product development and manufacturing	239	1,094	(855)	2,281	3,266	(985)
Clinical, medical, and regulatory operations	462	1,967	(1,505)	3,639	5,919	(2,280)
Total research and development expenses	$ 1,543	$ 4,680	$ (3,137)	$ 9,883	$ 13,311	$ (3,428)

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.1 million and $0.7 million, respectively, for the three months ended September 30, 2022 and 2021, and $1.1 million and $2.3 million, respectively, for the nine months ended September 30, 2022 and 2021.

Direct Clinical and Preclinical Programs

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

Expenditures related to istaroxime - early cardiogenic shock decreased $0.3 million for the three months ended September 30, 2022 compared to the same period in 2021 as we completed enrollment in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock in March 2022. Costs increased $0.6 million for the nine months ended September 30, 2022 compared to the same period in 2021 due to the timing of costs and enrollment for our Phase 2 global clinical study.

Istaroxime - AHF costs relate to limited ongoing clinical and preclinical development activities, including toxicology studies and drug lot production.

KL4 surfactant costs decreased $0.2 million and $0.4 million, respectively, for the three and nine months ended September 30, 2022 compared to the same periods in 2021 following the completion of enrollment in January 2022 of our Phase 2b study of lucinactant for patients with severe COVID-19 associated acute respiratory distress syndrome. Costs related to the KL4 surfactant platform are expected to continue to decrease as we complete close-out activities on prior KL4 surfactant platform clinical trials and focus our resources on the development of our istaroxime pipeline.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, with our contract manufacturing organization, validation activities, quality assurance; and (ii) pharmaceutical and manufacturing development activities of our drug product candidates, including development of istaroxime. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality assurance activities, and expert consultants and outside services to support pharmaceutical development activities.

Product development and manufacturing expenses decreased $0.9 million for the three months ended September 30, 2022 compared to the same period in 2021 due to (i) a decrease of $0.6 million related to our decision in January 2022 to begin to reduce costs related to the development of the KL4 surfactant platform that were not already transferred to Lee's (HK); and (ii) a decrease of $0.3 million related to reductions in headcount for the KL4 surfactant platform.

Product development and manufacturing expenses decreased$1.0 million for the nine months ended September 30, 2022 compared to the same period in 2021 due to (i) a decrease of $1.0 million related to our decision in January 2022 to begin to reduce costs related to the development of the KL4 surfactant platform that were not already transferred to Lee's (HK); and (ii) a $0.4 million decrease in non-cash stock-based compensation expense; partially offset by (iii) $0.4 million in accelerated depreciation during the first quarter of 2022 following the abandonment and decommissioning of certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform.

Clinical, Medical, and Regulatory Operations

Clinical, medical, and regulatory operations include medical, scientific, preclinical and clinical, regulatory, data management, and biostatistics activities in support of our research and development programs. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Clinical, medical, and regulatory operations expenses decreased $1.5 million for the three months ended September 30, 2022 compared to the same period in 2021 due to (i) the reversal of $0.8 million of royalty expense related to the KL4 surfactant platform; (ii) a decrease of $0.4 million in non-cash stock-based compensation expense; (iii) and a decrease of $0.3 million in personnel costs.

Clinical, medical, and regulatory operations expenses decreased$2.3 million for the nine months ended September 30, 2022 compared to the same period in 2021 due to (i) the reversal of $0.8 million of royalty expense related to the KL4 surfactant platform; (ii) a decrease of $1.3 million in non-cash stock-based compensation expense; and (iii) a decrease of $0.2 million in personnel costs.

General and Administrative Expenses

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 $0.8 million for the three months ended September 30, 2022 compared to the same period in 2021 due to (i) a decrease of $0.4 million in non-cash stock-based compensation expense and (ii) a decrease of $0.4 million in professional fees.

General and administrative expenses decreased $3.0 million for the nine months ended September 30, 2022 compared to the same period in 2021 due to (i) a decrease of $1.7 million in professional fees; and (ii) a decrease of $1.6 million in non-cash stock-based compensation expense; partially offset by (iii) an increase of $0.3 million in personnel costs.

Other Income (Expense), Net

Interest income relates to interest on our money market account for the three and nine months ended September 30, 2022 and 2021, and relates to interest on our U.S. Treasury notes for the nine months ended September 30, 2021.

For the three and nine months ended September 30, 2022 and 2021, interest expense consists of interest expense associated with loans payable.

For the three and nine months ended September 30, 2022, other income (expense), net primarily consists of $0.5 million and $0.9 million, respectively, in gains on foreign currency translation. For the three and nine months ended September 30, 2021, other income (expense), net primarily consists of $0.1 million and $0.3 million, respectively, in losses on foreign currency translation. Foreign currency gains and losses are primarily due to changes in the New Taiwan dollar exchange rate related to activities of our wholly-owned subsidiary, CVie Therapeutics Limited, in Taiwan.

LIQUIDITY AND CAPITAL RESOURCES

We are subject to risks common to companies in the biotechnology industry, including but not limited to, the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international locations and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $4.1 million and $8.2 million, respectively, for the three-month periods ended September 30, 2022 and 2021. Our net loss was $29.5 million and $54.6 million, respectively, for the nine-month periods ended September 30, 2022 and 2021. Included in our net loss for the three and nine months ended September 30, 2022 is a $0.5 million and $12.1 million loss on impairment of goodwill, respectively, and included in our net loss for the nine months ended September 30, 2021 is a $37.8 million loss on impairment of intangible assets related to rostafuroxin and a related $8.3 million deferred income tax benefit (*see*, Note 4 – Summary of Significant Accounting Policies). We expect to continue to incur operating losses for at least the next several years. As of September 30, 2022, we had an accumulated deficit of $814.8 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

We are party to an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through an at-the-market program, or the ATM Program. For the nine months ended September 30, 2022, we sold 4,377,785 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $2.8 million. Subsequent to the end of the third quarter of 2022, we sold 5,963,408 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.5 million (*see*, Note 8 – Stockholders' Equity).

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and as of November 14, 2022, we have sold the full amount we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

As of September 30, 2022, we had cash and cash equivalents of $8.4 million and current liabilities of $4.0 million. We believe that we have sufficient resources available to support our development activities and fund our business operations into the second quarter of 2023. However, we do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to secure additional capital, potentially through a combination of public or private securities offerings, convertible debt financings, and/or strategic transactions, including potential licensing arrangements, alliances, and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. Further, on June 3, 2022, we received a deficiency letter from the Nasdaq Stock Market LLC, or Nasdaq, notifying us that the closing bid price of our common stock had been below the minimum $1.00 per share for 30 consecutive business days, we are out of compliance with the requirements for continued listing on Nasdaq, and are subject to potential delisting. If we are unable to re-achieve compliance with the Nasdaq listing requirements within 180 days, or November 30, 2022, after receipt of a delisting notice, and if we are unable to obtain an extension therefore, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition.

The accompanying condensed consolidated 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.

Cash Flows

Cash flows for the nine months ended September 30, 2022 primarily consist of $16.1 million of net cash used in operating activities, $0.2 million of net cash provided by investing activities, and $2.0 million of net cash provided by financing activities. Cash flows for the nine months ended September 30, 2021 consist of $18.7 million of net cash used in operating activities and $26.4 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $16.1 million for the nine months ended September 30, 2022 and consisted primarily of (i) a net loss of $29.5 million; (ii) changes in operating assets and liabilities of $0.9 million; and (iii) an unrealized gain on foreign exchange rate changes of $0.9 million; partially offset by (iv) a non-cash loss on impairment of goodwill of $12.1 million; (v) non-cash stock-based compensation of $2.3 million; (vi) depreciation and amortization of $0.5 million; and (vii) non-cash lease expense of $0.4 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in operating activities was $18.7 million for the nine months ended September 30, 2021 and consisted primarily of (i) a net loss of $54.6 million; (ii) a non-cash deferred income tax benefit of $8.3 million; and (iii) changes in operating assets and liabilities of $0.7 million; partially offset by (iv) a non-cash loss on impairment of intangible assets of $37.8 million; (v) non-cash stock-based compensation of $5.6 million; (vi) non-cash expense related to equity consideration for a financial advisory service agreement of $0.5 million; (vii) non-cash lease expense of $0.5 million; (viii) an unrealized loss on foreign exchange rate changes of $0.3 million; and (ix) depreciation and amortization of $0.1 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Investing Activities

Net cash provided by investing activities was $0.2 million for the nine months ended September 30, 2022 and primarily includes proceeds from sale of property and equipment related to the decommissioning and sale of certain manufacturing and laboratory equipment assets previously used for the KL4 surfactant platform.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was $2.0 million and includes (i) $2.8 million in net proceeds from the ATM Program; partially offset by (ii) $0.8 million of principal payments on loans payable.

Net cash provided by financing activities for the nine months ended September 30, 2021 was $26.4 million and includes (i) $27.4 million in net proceeds from the March 2021 public offering; (ii) $1.7 million in net proceeds from the ATM Program; and (iii) $0.8 million in proceeds from our research and development funding arrangement with Lee's (HK); partially offset by (iv) $3.4 million of principal payments on loans payable.

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

Loan Payable to Bank Direct Capital Finance

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% annual interest rate. Payments of approximately $126,000 are due monthly from July 2022 through March 2023. As of September 30, 2022, the outstanding principal of the loan was $0.6 million.

In June 2021, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.3 million of certain premiums at a 3.37% annual interest rate. Payments of approximately $147,000 are due monthly from July 2021 through March 2022. As of December 31, 2021, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2022.

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings.

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal under the ATM Program. When we issue sales notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

For the nine months ended September 30, 2022, we sold 4,377,785 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $2.8 million. For the nine months ended September 30, 2021, we sold 552,474 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.7 million (*see*, Note 8 – Stockholders' Equity).

Subsequent to the end of the third quarter of 2022, we sold 5,963,408 shares of our common stock under the ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.5 million.

The shares of common stock issued and sold under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of our public float during any 12-month period, and as of November 14, 2022, we have sold the full amount we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

March 2021 Public Offering

On March 23, 2021, we entered into an underwriting agreement with Oppenheimer & Co. Inc. as representative for the several underwriters named therein, relating to a public offering, or the March 2021 Offering, of an aggregate of 9,230,500 units with each unit consisting of one share of common stock and a warrant, or the March 2021 Warrants. The March 2021 Warrants are immediately exercisable for shares of common stock at a price of $3.60 per share and expire five years from the date of issuance. The shares of common stock and the March 2021 Warrants were immediately separable and were issued separately in the March 2021 Offering.

The closing of the March 2021 Offering occurred on March 25, 2021. The offering price to the public was $3.25 per unit resulting in gross proceeds to us of $30.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the March 2021 Warrants issued pursuant to the March 2021 Offering, the net proceeds to us were approximately $27.4 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at September 30, 2022 and 2021 or during the periods then ended.

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

Our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer and Treasurer 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 and Treasurer 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 and Treasurer, 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 September 30, 2022 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 certain risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, investors should carefully consider the risks and uncertainties discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, as supplemented by risk factors included in our Quarterly Reports on Form 10-Q filed thereafter. These risks are not the only risks that could materialize. Other than as set forth below, there have been no material changes in our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021 or our Quarterly Reports on Form 10-Q filed thereafter. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations and development activities. Should any of the risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2021, as supplemented by our subsequent filings with the SEC, 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 an investor could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in *Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources*.

Our common stock is listed on the Nasdaq Capital Market. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on the Nasdaq Capital Market.

On June 3, 2022, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock has been below the minimum $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Capital Market under the symbol "WINT" at this time. We have been given 180 calendar days, or until November 30, 2022, to regain compliance with Rule 5550(a)(2). If at any time before November 30, 2022, the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Staff will provide written confirmation that we have achieved compliance. If we do not regain compliance with Rule 5550(a)(2) by November 30, 2022, we may be afforded a second 180 calendar day period to regain compliance, if we meet certain other conditions. If we fail to maintain compliance, Nasdaq may take steps to de-list our common stock. If such delisting should occur, it would likely have a negative effect on the price of our common stock and would impair an investor's ability to sell or purchase our common stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

We have a significant amount of intangible assets, including goodwill, recorded on our condensed consolidated balance sheets which may lead to potentially significant impairment charges.

We have recorded significant goodwill and intangible assets on our condensed consolidated balance sheets as a result of a previous acquisition, which could become impaired and lead to material charges in the future. The amount of identifiable intangible assets and goodwill in our condensed consolidated balance sheets is significant due to the acquisition of CVie Therapeutics Ltd., or CVie Therapeutics, in December 2018. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin, which, as of September 30, 2022, are $22.3 million and $9.7 million, respectively, recorded in aggregate on our condensed consolidated balance sheets as intangible assets of $32.1 million. At September 30, 2022, goodwill recorded on our condensed consolidated balance sheets was $3.6 million.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that intangible assets or goodwill may be impaired. If an impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict, including the uncertainties associated with the development of product candidates and the success of business development activities, and are an inherent risk in the pharmaceutical industry.

We have experienced a declining trend in the closing share price of our common stock following the announcement in April 2022 of positive topline results in our Phase 2 global clinical study of istaroxime for the treatment of early cardiogenic shock due to, we believe, both market conditions and our need to secure additional capital in the near term to advance our development programs.

During each of the second and third quarters of 2022, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies. Based on the quantitative tests performed, we recorded a loss on impairment of goodwill of $11.6 million in the second quarter of 2022 and an additional $0.5 million in the third quarter of 2022, resulting in a loss on impairment of goodwill of $12.1 million for the nine months ended September 30, 2022, recognized within operating expenses in our condensed consolidated statements of operations.

The closing share price of our common stock has continued to decline subsequent to the end of the third quarter of 2022. If our share price continues to decline during the remainder of the fourth quarter of 2022, we may be at risk for future impairment to goodwill in the near term.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report on Form 10-Q. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
10.1 †	Amended and Restated License, Development and Commercialization Agreement, by and among Lee's Pharmaceutical (HK) Ltd., Zhaoke Pharmaceutical (Hefei) Co. Ltd., and Windtree Therapeutics, Inc., effective as of August 9, 2022.	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.	Furnished herewith.
101.1	The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of September 30, 2022 (unaudited) and December 31, 2021, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2022 and September 30, 2021, (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2022 and September 30, 2021, and (iv) Notes to Condensed Consolidated Financial Statements.	
101.INS	Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) (1).	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1).	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1).	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1).	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1).	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1).	Filed herewith.
104	Cover Page Interactive Data File (formatted as Inline XBRL and combined in Exhibit 101.1)	Filed herewith.

(1) These Interactive Data Files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Act of 1934, as amended, or otherwise subject to liability under those sections.

† Portions of this exhibit are redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: November 14, 2022

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

Date: November 14, 2022

By: /s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS SUCH INFORMATION AS PRIVATE AND CONFIDENTIAL.

EXECUTION COPY

AMENDED AND RESTATED

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

by and among

WINDTREE THERAPEUTICS, INC.,

LEE'S PHARMACEUTICAL (HK) LTD.

and

ZHAOKE PHARMACEUTICAL (HEFEI) CO. LTD.

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AMENDED AND RESTATED
LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amended and Restated License, Development and Commercialization Agreement (this "***Agreement***") is entered into as of August 9, 2022 (the "***Effective Date***"), by and among Windtree Therapeutics, Inc., a Delaware corporation with its principal offices at 2600 Kelly Rd., Suite 100, Warrington, PA 18976 ("***Licensor***"), 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 ("***Lee's***"), and Zhaoke Pharmaceutical (Hefei) Co. Ltd., a company organized under the laws of the People's Republic of China ("***Zhaoke***" and together with Lee's, "***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, Manufacture and Commercialize Aerosurf in the Licensed Territory;

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

Whereas, Licensor and Licensee are parties to that certain License, Development and Commercialization Agreement dated as of June 12, 2017 (as amended by Amendment No. 1 thereto dated August 14, 2017 by and between Licensor and Lee's, the "***Original Agreement***"), pursuant to which they have collaborated with the aim of advancing the Development, registration and Commercialization of the Surfaxin Product, Surfaxin LS, Aerosurf, and any other pharmaceutical composition containing synthetic KL_4 Surfactant in various jurisdictions; and

Whereas, Licensor and Licensee desire to amend and restate the Original Agreement, as set forth in this Agreement, in order to grant to Licensee exclusive worldwide (subject to certain exceptions) rights to Develop, Manufacture and Commercialize the Surfaxin Product, Surfaxin LS, Aerosurf, and any other pharmaceutical composition containing synthetic KL_4 Surfactant.

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.

"*Active Ingredient*" means Licensor's active ingredient disclosed by the Licensor Patents, together with any of the foregoing that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of a human.

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

"*Aerosolized Product(s)*" means any combination drug/device product (or any component or ingredient thereof) that utilizes a pharmaceutical composition containing synthetic KL_4 Surfactant and the Device to produce aerosolized KL_4 Surfactant and includes Aerosurf.

"*Aerosurf*" means AEROSURF® (lucinactant for inhalation), a combination drug/device product that utilizes lyophilized synthetic KL_4 Surfactant and the Device to produce aerosolized KL_4 Surfactant for non-invasive aerosolized delivery.

"*Affiliate*" means, with respect to a 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.

"Battelle Agreement" means the Collaboration Agreement between Licensor and Battelle Memorial Institute date October 10, 2014, as amended by the Payment Restructuring Agreement dated December 7, 2018.

"Breaching Party" has the meaning set forth in Section 12.4.

"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" or "***Commercializing***," with a correlative meaning for "***Commercialize***" and "***Commercializing***," means all activities undertaken, whether before or after obtaining Regulatory Approvals directed to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale and distribution of a Product in the Licensed Territory, including Medical Affairs Activities, scientific activities, strategic marketing, sales, 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 Development or Manufacture.

"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 a 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 12.4.

"Detail" or "***Detailing***," as applicable, means a face-to-face discussion or other direct communication (e.g., e-detailing) with a physician or other health care practitioner who is permitted under applicable Laws to prescribe a Product for the purpose of promoting such Product to such physician and/or other health care practitioner.

"Development Data" means all data generated from any Development activities by or on behalf of Licensee or any of its Affiliates or Sublicensees.

"Develop" or "***Development***" means all activities relating to preparing and conducting non-clinical or pre-clinical studies, Clinical Studies and regulatory activities (*e.g.*, preparation of regulatory applications) that are necessary or useful to seek, obtain or maintain Drug Approval of Product in the Licensed Territory. Development does not include Commercialization but may include Manufacturing to the extent applicable.

"Development Plan" has the meaning set forth in Section 4.2.

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

"Distributor" means a Third Party that sells Product to the trade but to which a sublicense is not granted pursuant to Section 2.2.

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

"Drug" means KL_4 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.

"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 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, 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, 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.

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

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

"KL$_4$ Surfactant" means a pharmaceutical composition containing the peptide known as KL_4 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, as of the Effective Date, the world excluding Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain; provided that if and to the extent that the Amended and Restated Sublicense and Collaboration Agreement between Licensor and Laboratorios Del Dr. Esteve, S.A. dated December 3, 2004 is terminated in whole or as to one or more of Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain, then the country(ies) no longer licensed to Laboratorios Del Dr. Esteve, S.A. automatically become a part of the Licensed Territory.

"Licensed Territory Development Costs" means all costs and expenses, including all internal, human capital and out-of-pocket costs, incurred after the Effective Date and attributable to the Development of the Products in the Field in the Licensed Territory including costs and expenses for Drug Approvals and Pricing Approvals and/or Reimbursement Approvals, and costs incurred after any of the foregoing approvals, including Phase 4 Study costs, costs of non-clinical studies, costs of clinical studies, costs of clinical supply and comparator drugs, insurance costs and any other development and regulatory costs incurred in connection with Development activities.

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

"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, Manufacture or Commercialization of a Product, the Drug or the Device in the Field, and (b) is (i) Controlled by Licensor or its Affiliates as of the Effective Date or (ii) subject to Section 2.5, 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 2.5, 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 2.5, 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 Technology" means, subject to Section 8.1, the Licensor Know-How and Licensor Patents.

"Manufacture" or "***Manufacturing***" means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of Product and including without limitation process and formulation development, process validation, stability testing, process development, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control.

"Marketed" has the meaning set forth in Section 7.3(e).

"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 such 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:

(a) [***]

(b) [***]

(c) [***]

(e) [***]

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 (or any component or ingredient thereof) and any other pharmaceutical composition containing the synthetic KL_4 Surfactant, in each case to be administered in any form other than as aerosol.

"Non-Breaching Party" has the meaning set forth in Section 12.4.

"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.

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

"Patent Challenge" means any challenge to the validity or enforceability of a Licensor Patent, including by (a) filing a declaratory judgment action in which the applicable Licensor Patent is alleged to be invalid or unenforceable, (b) becoming party to an interference with the applicable Licensor Patent pursuant to 35 U.S.C. §135 or (c) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against the applicable Licensor Patent, or petitioning for any form of administrative or judicial (or arbitration) review of the applicable Licensor Patent, including post-grant review, inter partes review, or opposition proceedings.

"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 7.6.

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

"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.

"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.

"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.

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

"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 2.2. "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 2.2. For clarity, a Distributor shall not be considered a Sublicensee.

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

"Surfaxin Product" means Surfaxin® (lucinactant) intratracheal suspension, a pulmonary KL_4 Surfactant, based on NDA No. 21-746, as approved by the FDA on March 6, 2012.

"Technology Transfer Agreement" means the Technology Transfer Agreement between Licensor and Lee's dated August 1, 2017.

"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 IP 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

LICENSE GRANT; OTHER RIGHTS

2.1. License Grant. 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 2.2, under the Licensor Technology, to Develop, register, Manufacture, use, sell, offer for sale, import, distribute and otherwise Commercialize Products in the Field in the Licensed Territory. Licensee's right to manufacture Products is not sublicensable other than to its Affiliates in accordance with Section 2.2. For the avoidance of doubt, the license granted by this Section 2.1 includes the right to Develop, register, Manufacture, use, sell, offer for sale, import, distribute and otherwise Commercialize the Device in the Field in the Licensed Territory solely for use with the Aerosolized Product and not on a standalone basis or for use with any product that is not an Aerosolized Product.

2.2. Sublicense Rights. Subject to Section 2.7, Licensee may sublicense the rights granted in Section 2.1 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 rights granted in Section 2.1 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 2.2 shall not include the right to sublicense.

2.3. 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.

(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.

2.4. 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.

2.5. 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.

2.6. In-Licenses.

(a) 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 and to perform on behalf of Licensor all of Licensor's obligations under the In-License Agreements. Without limiting the generality of the foregoing, Licensee shall perform all of Licensor's obligations set forth in:

(i) Sections [***];

(ii) Sections [***];

(iii) Sections [***]; and

(iv) Section [***].

(b) In addition, the sublicense to Licensee of the Licensor Technology, to the extent such Licensor Technology is licensed to Licensor under any 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.

(c) If Licensee fails to perform on behalf of Licensor any of Licensor's obligations under any of the In-License Agreements and refuses to cure such failure, Licensor may at its option (a) cure the failure at Lee's cost and expense (with Lee's indemnifying Licensor for such costs and expenses) and/or (b) exercise any termination rights it has under the affected In-License Agreement including a termination negotiated with the relevant contract party as a result of Lee's failure to perform the obligations under the applicable In-License Agreement.

2.7. Right of First Negotiation and Right of First Refusal

. If Licensee desires to sublicense the right to Commercialize any Product in the United States to any Third Party, then Licensee must comply with this Section before Licensee may do so, and if Licensor exercises its rights under this Section 2.7, then Licensee may not sublicense its rights to the Third Party in respect of the Product in the United States.

(a) Before entering into discussions with any Third Party regarding the Third Party Commercializing the applicable Product in the United States, Licensee shall first offer Licensor the right to Commercialize the applicable Product in the United States. Such offer shall be in writing and include the proposed economic terms under which Licensor would Commercialize the applicable Product in the United States. Within [***] after the date on which Licensee delivers such offer to Licensor, Licensor shall notify Licensee that (i) Licensor declines the opportunity to negotiate such offer, in which case the remainder of this Section 2.7 shall remain in effect or (ii) Licensor accepts the opportunity to negotiate such offer. If Licensor so accepts the Licensee's offer to negotiate, then for no more than [***] after Licensor's acceptance, the Parties shall negotiate in good faith definitive agreements, including economic terms, that would allow Licensor the right to exclusively Commercialize the applicable Product in the United States. If the Parties do not enter into such definitive agreements within such [***] (as may be extended with the agreement of both Parties), then such negotiations shall cease and Licensee shall be deemed to have satisfied its obligations under this Section 2.7(a) and the remainder of this Section 2.7 shall remain in effect.

(b) Licensee may offer a sublicense of the right to Commercialize the applicable Product in the United States only on a completely standalone basis and without any connection, term or condition applicable to countries other than the United States;

(c) Licensee must provide Licensee with a copy of the final term sheet (or unsigned definitive agreement) with the Third Party outlining the material terms of the sublicense for the United States, which terms must comply with the requirements of Section 2.7(a) (the "***Third Party Offer***");

(d) Licensor shall have [***] from its receipt of the Third Party Offer to decide whether to match the Third Party Offer, and if Licensor timely notifies Licensee in writing that it will match the Third Party Offer, then Licensee may not sublicense the right to Commercialize the applicable Product in the United States and instead the Parties shall negotiate in good faith and enter into a definitive agreement consistent with the Third Party Offer within [***]; and

(e) if Licensor does not timely notify Licensee in writing that it will match the Third Party Offer or if no definitive agreements are entered into within the time period set forth in Section 2.7(d), then Licensee may sublicense the right to Commercialize the applicable Product in the United States on the terms set forth in the Third Party Offer; provided that if the terms of the definitive agreement is materially more beneficial to the Third Party than the terms in the Third Party Offer, then Licensee must again comply with the procedures and obligations of this Section 2.7 as a condition to consummating the transaction with the Third Party.

ARTICLE 3

TECHNOLOGY TRANSFER

3.1. Licensor hereby agrees to provide to Licensee all the technologies, software, application, information, documentation, equipment, devices, and materials as set forth on Schedule 3.1 attached hereto within 15 days upon execution of this Agreement (unless previously provided) in order for Licensee to Develop, register, Manufacture, use, sell, offer for sale, import, distribute and otherwise Commercialize Products in the Field in the Licensed Territory.

ARTICLE 4

PRODUCT DEVELOPMENT

4.1. **Overview**. As between the Parties, Licensee shall be solely and exclusively responsible for Development of Product in the Licensed Territory.

4.2. **Diligence**. Licensee shall use Commercially Reasonable Efforts to Develop each Product in the Field in the United States, the PRC and the European Union in accordance with a comprehensive written development plan that specifies all material Development activities for Product in the Field in the United States, PRC, the European Union (the "***Development Plan***"). No later than September 30th of each Calendar Year during the Term, starting with the year 2022, Licensee shall provide Licensor with a copy of the then-current Development Plan.

4.3. **Performance**. Licensee 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. For the avoidance of doubt, Licensor shall have no obligation to engage in any Development activities.

4.4. **Licensed Territory Development Costs**. Licensee shall pay 100% of all Licensed Territory Development Costs.

4.5. **Development Reports**. Licensee shall provide Licensor with written reports detailing its Development activities under this Agreement and the results of such activities within thirty (30) days after the conclusion of each Calendar Year. The Parties shall discuss the status, progress and results of Licensee's Development activities under this Agreement at least once per Calendar Year.

4.6. Development Records. Licensee 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.

ARTICLE 5

REGULATORY MATTERS

5.1. Regulatory Responsibilities in the Licensed Territory.

(a) Licensee shall be responsible to conduct all regulatory activities and pricing and reimbursement negotiations in the Licensed Territory with respect to Product in the Field as necessary and appropriate in Licensee's sole discretion. Licensee shall use Commercially Reasonable Efforts in respect of Product as the 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 as necessary and appropriate in Licensee's sole discretion at its sole expense.

(b) Licensee shall keep Licensor informed of material regulatory developments relating to Product in the Field in the Licensed Territory and shall promptly notify Licensor in writing of any material action or decision by any Regulatory Authority in the Licensed Territory regarding Product.

5.2. 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.

ARTICLE 6

COMMERCIALIZATION

6.1. Overview of Commercialization in the Licensed Territory. Subject to the terms and conditions of this Article 6, 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 provide Licensor with a copy of the Commercialization Plan no later than [***] before the anticipated launch of the first Product to be Commercialized in the Licensed Territory, on an informational basis. On at least an annual basis, Licensee shall prepare and provide to Licensor an amendment, as appropriate, to the then-current Commercialization Plan. Licensee shall provide to Licensor a copy of any material amendment to the Commercialization Plan.

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.

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, in a given country within [***] 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, in such country; and (ii) Aerosurf in a given country within [***] after Drug Approval therefor has been obtained from the appropriate Regulatory Authority (or pricing and reimbursement approval where applicable) to Commercialize Aerosurf in such country.

(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 any countries excluded from the Licensed Territory. As to such countries excluded from the Licensed Territory and except to the extent inconsistent with Law in the relevant country, 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.

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, Licensee previously paid to Licensor a one-time upfront fee of One Million Dollars ($1,000,000) in accordance with the Original Agreement. Such fee was and remains non-creditable and non-refundable.

7.2. 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 [***].

7.3. Royalties.

(a) Royalties Under the In-License Agreements. Licensee shall pay all royalties when and as due under each of the In-License Agreement directly to the applicable licensor under such In-License Agreements.

(b) Running Royalty. In addition to the royalties payable under Section 7.3(a), 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; provided that [***].

(i) Royalty Rates for [***]

Annual Net Sales of the Surfaxin Product and/or Surfaxin LS in the Licensed Territory	**Royalty Rate, %**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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

Annual Net Sales of all Products (other than the Surfaxin Product and/or Surfaxin LS) in the Licensed Territory	**Royalty Rate,%**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(c) Duration. Licensee shall pay to Licensor royalties under Section 7.3(b) on a country-by-country and Product-by-Product basis as follows:

(i) [***]. In consideration of licensed rights to Regulatory Materials 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 7.3(b)(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 7.3(b)(i) for a period of [***], and (y) [***] of the royalty rates set forth in Section 7.3(b)(i) thereafter.

(ii) [***]. With respect to 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 7.3(b)(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 [***] of the rates set forth in Section 7.3(b)(ii) for a period of [***] and, thereafter, of [***] of the royalty rates set forth in Section 7.3(b)(ii).

(d) 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 7.3(a) or 7.3(c). Concurrent with the delivery of the applicable quarterly report, Licensee shall pay in Dollars all amounts due to Licensor pursuant to this Section 7.3 with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such Calendar Quarter.

(e) 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 in Section 7.3(b) 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. Prior to any royalty reduction pursuant to this Section 7.3(e), Licensee shall provide evidence of such Generic/Branded Generic of Product in such country. Solely for purposes of this Section 7.3(e), "***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.

7.4. 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 sixty (60) days 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 7.4 for such Calendar Quarter, including the method and currency exchange rates (if any) used to calculate Sublicense Income.

7.5. 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.

7.6. 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.

7.7. Records. Licensee 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 Net Sales and Sublicense Income. Licensee and its Affiliates and Sublicensees 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 7.8.

7.8. Audits. Licensor may have an independent certified public accountant, reasonably acceptable to Licensee, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the Licensee (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 Licensor'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 Licensee'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 Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 7.6 or (ii) excess payments were made by License, Licensor 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. Licensor 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 Licensor of more than five percent (5%) from the amount of the original report, royalty or payment calculation, in which case Licensee shall bear the full cost of the performance of such audit. The results of such audit will be final, absent manifest error.

7.9. 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 the Device, 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 or 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 including all Development Data ("***Licensee Improvements***").

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

(f) 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) As between the Parties, Licensee shall file, prosecute and maintain the Licensor Patents and any Patents arising under Section 8.1(b) (the "***Licensee Prosecuted Patents***") using counsel of its choosing and reasonably acceptable to Licensor. As between the Parties, Licensee shall bear all costs incurred after the Effective Date in connection with the preparation, filing, prosecution and maintenance of any Licensee Prosecuted Patent including the fees and costs of Licensor's counsel. Licensee shall not abandon any Licensee Prosecuted Patents without giving Licensor at least thirty (30) days prior written notice that identifies the Licensee Prosecuted Patent Rights that Licensee wishes to abandon and allowing Licensor, at its option, to assume prosecution and maintenance of the Licensee Prosecuted Patent Rights that Licensor wishes to so assume; provided that each Licensee Prosecuted Patent for which Licensor assumes prosecution and maintenance shall no longer be a Licensor Patent or a Licensee Prosecuted Patent and no longer licensed to Licensee.

(b) Subject to Section 8.2(c), as between the Parties, Licensee may prepare, file, prosecute and maintain all Licensee Patents that are not assigned to Licensor pursuant to Section 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.

(c) If Licensee decides anywhere in the Licensed 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 Licensed Territory.

(d) 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, Licensee may bring an appropriate suit or other action against any person or entity engaged in such Licensed Territory Infringement, at Licensee's cost and expense. Licensee 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 Licensee 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 Licensor may commence a suit or take action to enforce such Joint Patents or Licensor Patents against such Licensed Territory Infringement at its own cost and expense. In this case, Licensee shall take appropriate actions to enable Licensor to commence a suit or take the actions set forth in the preceding sentence, at Licensor'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. The Party controlling any Action pursuant to Section 8.3(b) 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, without the prior written consent of Licensor, which consent will not be unreasonably withheld or delayed. Nothing in this Article 8 requires the non-enforcing Party to consent to any settlement that is reasonably anticipated by such Party to have a substantially adverse impact upon any Licensor Patent, Joint Patent or Licensee Patent, or on 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 7.3.

8.4. Infringement of Third Party Rights in the Licensed Territory. Each Party shall promptly notify the other Party upon becoming aware of any actual or threatened claim that the Development, Manufacture, or Commercialization of any Product infringes or misappropriates the Intellectual Property Rights (including Trademarks) of a Third Party in the Field in the Licensed Territory (each, a "***Third Party IP Claim***"). If either Party is entitled to indemnification under Article 10 with respect to any Third Party IP Claim, then the terms and conditions of Article 10 will apply to such Third Party IP Claim. In all other cases, each Party may defend itself from any such Third Party IP Claim brought against such Party or its Affiliates or licensees (or in the case of Licensee, Sublicensees) at its own expense and with counsel of its choosing; *provided*, *however*, that Section 8.3 will govern the right to assert a counterclaim of infringement or misappropriation of any Licensed Technology, and Licensee is solely responsible for any and all claims related to trademarks. Each Party shall keep the other Party reasonably informed of all material developments in connection with any Third Party IP Claim, and the other Party shall consult with and offer reasonable assistance to the Party defending against such Third Party IP Claim, at the defending Party's cost and expense.

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, as well as establish a global brand. For the avoidance of doubt, Licensee has no obligation to use the Licensed Marks with any Product in any jurisdiction in the Licensed Territory.

(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** with the Products (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.

(c) Prosecution and Maintenance. As between the Parties, Licensee shall file, prosecute and maintain the Licensed Marks using counsel of its choosing and reasonably acceptable to Licensor. As between the Parties, Licensee shall bear all costs incurred after the Effective Date in connection with the preparation, filing, prosecution and maintenance of the Licensed Marks including the fees and costs of Licensee's counsel. Licensee shall not abandon any Licensed Marks without giving Licensor at least thirty (30) days prior written notice that identifies the Licensed Marks that Licensee wishes to abandon and allowing Licensor, at its option, to assume prosecution and maintenance of the Licensed Marks that Licensor wishes to so assume; provided that each Licensed Mark for which Licensor assumes prosecution and maintenance shall no longer be a Licensed Mark and no longer licensed to Licensee.

(d) 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, Manufacture and Commercialize Product in the Field in the Licensed Territory. Licensor has not granted, assigned, transferred, conveyed, and is not under any obligation to grant, assign, transfer or convey, 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 disclosed by Licensor in its SEC filings, there is no actual or threatened infringement of the Licensor Technology or Licensed Mark in the Field in the Licensed Territory by any Third Party.

(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 Patent, and no claim or litigation has been brought or, to the Knowledge of Licensor, 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.

(e) To the Knowledge of Licensor, the Development, Manufacture, or Commercialization of the Active Ingredient or any Product in the Field in the Licensed Territory does not infringe, misappropriate, or otherwise violate any Patent Right or Know-How of any Third Party, and to Licensor's Knowledge, there is no factual, legal, or other reasonable basis for any such claim, litigation, or proceeding.

(f) to Licensor's knowledge, (i) all Development activities for the Active Ingredient conducted by Licensor or its Affiliates or its or their contractors prior to the Effective Date have been in compliance in all material respects with all applicable Laws; and (ii) it has not employed or used the services of any Person who has been debarred or disqualified, threatened to be debarred or disqualified, or convicted of a crime for which a Person can be debarred or disqualified, under any applicable Law in connection with such Development activities; and

(g) all information provided by Licensor to Licensee for due diligence purposes in relation to this Agreement is, to Licensor's Knowledge, accurate in all material respects, and Licensor has not failed to disclose (or cause to be disclosed) any material information or data that could reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect.

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, or will obtain, as applicable, 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.

(c) Notwithstanding anything to the contrary in this Agreement, Licensee makes no representation, warranty, or covenant, either express or implied, that any Product will be successfully Developed or, if Regulatory Approval is obtained, will achieve any Regulatory/Commercial Milestone Event, Milestone Event or any level of Net Sales, or that any other Development or Commercialization results will be achieved. Nothing in this Agreement will be construed as representing an estimate or projection of: (a) the number of Products that will or may be Developed or Commercialized under this Agreement; (b) the successful Development or Commercialization of any Product; or (c) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement.

9.4. Covenants

(a) In the course of the Development and Commercialization of Product in the Licensed Territory, Licensee shall not use any employee, consultant or contractor:

(i) who, to Licensee's Knowledge, 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 Licensee'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 Licensee; and

(iii) who, to Licensee's Knowledge, 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.

Licensee shall notify Licensor 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) Licensee 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) Licensee shall not practice or exploit the intellectual property licensed 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, or any failure to comply with applicable Law, 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) Manufacturing of Product by or on behalf of Licensee or its Affiliates or its or their Sublicensees, (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. 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. Licensor shall maintain clinical trial insurance (or product liability insurance that includes clinical trial insurance) in respect of its Development of the Products prior to the Effective Date for three (3) years after the Effective Date; provided that Licensor may purchase an extended reporting privilege (sometimes called a tail) that covers such three (3) year period in lieu of maintaining such insurance. Licensee 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 Licensee. Such insurance does not create a limit on such Party's liability with respect to its indemnification obligations under this Article 10. Each of Licensor and Licensee shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each of Licensor and Licensee 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 four (4) years 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 at least as restrictive as those set forth in 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 cooperate with the disclosing Party's efforts to obtain 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 any mutually agreed strategy established by the Parties. 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 Section 11.2(d) and 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) 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. All Information disclosed by a Party or its Affiliate to the other Party or its Affiliate pursuant to any prior confidentiality agreements related to any Products 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 Licensor or Licensee shall have the right to terminate this Agreement in its entirety upon immediate written notice to the other Parties in the event Licensor or Licensee, as applicable (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. Any Party may, at its discretion and upon written notice to the other Parties, 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 sixty (60) days after delivery of the Default Notice (or within thirty (30) days 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. Licensee's Termination for Convenience. At any time after the second anniversary of the Effective Date, Licensee may terminate this Agreement in its entirety or in part on a Product-by-Product basis, in its discretion and with or without cause, by providing written notice to Licensor, and such termination will be effective sixty (60) days after the date of such notice.

12.6. Termination for Patent Challenge. In the event of a Patent Challenge, Licensor may terminate this Agreement in its entirety immediately upon notice to Licensee in accordance with Section 14.3.

12.7. 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 12.8), 12.3 or 12.4, or by Licensee pursuant to Sections 12.2 (subject to Section 12.8),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 12.7(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 12.7(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, Manufacturing, 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 12.7(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 12.8, 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 occurring 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 12.7 will be borne by Licensee.

(i) Transition Assistance. In addition to the obligations of Licensee set forth above in this Section 12.7, 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.

12.8. Intellectual Property. Notwithstanding Sections 12.2 and 12.7, the Parties acknowledge and agree that the licenses granted by the Parties pursuant to Section 2.1 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), 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 12.8 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other applicable Laws.

12.9. Termination by Licensee; Liquidated Damages. Notwithstanding Sections 12.4 and 12.7, 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 12.7 shall apply, or (b) not terminate this Agreement, [***]. For clarity, such liquidated damages 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.

12.10. 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 7.7 (Records), 7.8 (Audits) and 7.9 (Taxes), 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 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. Equitable Relief. Notwithstanding Section 13.1, 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 Section 13.1, 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.

13.3. 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.

13.4. 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 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, including the Original Agreement and the Technology Transfer Agreement. 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 and the Development Plan. 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 ninety (90) days, 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 by a reputable courier service or by E-mail, 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
USA
Attn: Diane Carman, SVP & General Counsel
Email: dcarman@windtreetx.com

With copies to (which will not constitute notice):

Troutman Pepper Hamilton Sanders LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312
USA
Attn: Timothy C. Atkins
Email: timothy.atkins@troutman.com

If to Zhoake: Zhaoke Pharmaceutical (Hefei) Co. LTD.
_____
_____
_____
_____
Attn: _____
Email: _____

If to Lee's or Licensee: Lee's Pharmaceutical (HK) Ltd.
1/F, Building 20E, Phase 3
Hong Kong Science Park
Shatin, N.T.
Hong Kong
Attn: Managing Director
Email: info@leespharm.com

With copies to (which will not constitute notice)

King & Wood Mallesons LLP
500 5th Ave., 50th Floor
New York, New York 10022
Attn: Laura Hua Luo-Hemmann
Email: laura.luo-hemmann@us-kwm.com

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.

[*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 E. Fraser
Name: Craig E. Fraser
Title: President and Chief Executive Officer

LEE'S PHARMACEUTICAL (HK) LTD.

By: /s/ Leelalertsuphakun Wanee
Name: Leelalertsuphakun Wanee
Title: Director

ZHAOKE PHARMACEUTICAL (HEFEI) CO. LTD.

By: /s/ Leelalertsuphakun Wanee
Name: Leelalertsuphakun Wanee
Title: Director

EXHIBIT A

LICENSED MARKS

Mark	Country	Status	Application No.	Registration No.	Filing Date	Reg. Date	Renewal Date	Class	Goods and Services
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

SCHEDULE 1

LICENSOR PATENTS

[***]

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

[***]

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

SCHEDULE 1

LICENSOR PATENTS

[***]

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

[***]

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

Exhibit 31.1

CERTIFICATION

I, Craig E. Fraser, certify that:

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

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

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

4. The registrant's other certifying officers and I are 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 reports (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including 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 registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 14, 2022

/s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, John P. Hamill, certify that:

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including 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 registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 14, 2022

/s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report of Windtree Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

/s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer)

/s/ John P. Hamill
John P. Hamill
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.