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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, 2020

or

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

For the transition period from to

Commission file number 000-26422

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	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 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 16, 2020, there were outstanding 16,921,482 shares of the registrant's common stock, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc., and its 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 and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "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;
- delays in our anticipated clinical timelines and milestones and additional costs associated with COVID-19;
- the results, cost and timing 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 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;
- our plans and ability to successfully execute clinical and business development activities and commercialize our product candidates;
- risks related to manufacturing active pharmaceutical ingredients, drug product, medical devices and other materials we need;
- the size and growth of the potential markets for our product candidates, 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 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 regarding the healthcare system, including changes to the Patient Protection and Affordable Care Act;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the performance of third parties upon which we depend, including third-party contract research organizations, contract manufacturing organizations, contractor laboratories and independent contractors;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers; and
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyberattacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption.

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

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

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

ITEM 1. Financial Statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,356	$ 22,578
Prepaid expenses and other current assets	1,692	1,283
Total current assets	24,048	23,861
Property and equipment, net	702	798
Restricted cash	154	154
Operating lease right-of-use assets	855	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 118,531	$ 118,975
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 726	$ 1,708
Collaboration and device development payable, net	-	1,972
Accrued expenses	4,279	3,226
Operating lease liabilities - current portion	605	750
Loans payable - current portion	704	161
Total current liabilities	6,314	7,817
Operating lease liabilities - non-current portion	358	794
Loans payable - non-current portion	2,364	4,608
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	2,400	-
Deferred tax liabilities	16,370	15,821
Total liabilities	42,806	44,040
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at September 30, 2020 and December 31, 2019; 16,921,506 and 13,697,419 shares issued at September 30, 2020 and December 31, 2019, respectively; 16,921,482 and 13,697,395 shares outstanding at September 30, 2020 and December 31, 2019, respectively	17	14
Additional paid-in capital	788,996	763,097
Accumulated deficit	(710,234)	(685,122)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	75,725	74,935
Total liabilities & stockholders' equity	$ 118,531	$ 118,975

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,	
	2020	2019	2020	2019
Revenues:				
License revenue with affiliate	$ -	$ -	$ -	$ 198
Total revenues	-	-	-	198
Expenses:				
Research and development	3,882	3,792	11,838	10,547
General and administrative	4,823	3,395	11,518	9,990
Total operating expenses	8,705	7,187	23,356	20,537
Operating loss	(8,705)	(7,187)	(23,356)	(20,339)
Other (expense) income:				
Interest income	21	25	115	124
Interest expense	(46)	(105)	(121)	(358)
Other (expense) income, net	(290)	141	(1,750)	473
Total other (expense) income, net	(315)	61	(1,756)	239
Net loss	$ (9,020)	$ (7,126)	$ (25,112)	$ (20,100)
Net loss per common share				
Basic and diluted	$ (0.54)	$ (0.66)	$ (1.65)	$ (1.87)
Weighted average number of common shares outstanding				
Basic and diluted	16,579	10,730	15,228	10,724

See notes to condensed consolidated financial statements

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

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (9,020)	$ (7,126)	$ (25,112)	$ (20,100)
Other comprehensive income:				
Unrealized (loss) gain on marketable securities	-	(12)	-	-
Comprehensive loss	$ (9,020)	$ (7,138)	$ (25,112)	$ (20,100)

See notes to condensed consolidated financial statements

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

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2018	**-**	**$ -**	**10,711**	**$ 11**	**$ 728,804**	**$ (657,647)**	**$ -**	**-**	**$ (3,054)**	**$ 68,114**
Net loss						(6,537)				(6,537)
Vesting of restricted stock units			18							-
Withholding tax payments related to net share settlements of restricted stock units					(151)					(151)
Stock-based compensation expense					1,530					1,530
Unrealized gain on marketable securities							40			40
Balance - March 31, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 730,183**	**$ (664,184)**	**$ 40**	**-**	**$ (3,054)**	**$ 62,996**
Net loss						(6,437)				(6,437)
Stock-based compensation expense					1,739					1,739
Unrealized loss on marketable securities							(28)			(28)
Balance - June 30, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 731,922**	**$ (670,621)**	**$ 12**	**-**	**$ (3,054)**	**$ 58,270**
Net loss						(7,126)				(7,126)
Stock-based compensation expense					1,939					1,939
Unrealized loss on marketable securities							(12)			(12)
Balance - September 30, 2019	**-**	**$ -**	**10,729**	**$ 11**	**$ 733,861**	**$ (677,747)**	**$ -**	**-**	**$ (3,054)**	**$ 53,071**

	Preferred Stock		Common Stock					Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Shares	Amount	Total
Balance - December 31, 2019	**-**	**$ -**	**13,697**	**$ 14**	**$ 763,097**	**$ (685,122)**	**$ -**	**-**	**$ (3,054)**	**$ 74,935**
Net loss						(6,534)				(6,534)
Stock-based compensation expense					1,689					1,689
Balance - March 31, 2020	**-**	**$ -**	**13,697**	**$ 14**	**$ 764,786**	**$ (691,656)**	**$ -**	**-**	**$ (3,054)**	**$ 70,090**
Net loss						(9,558)				(9,558)
Issuance of common stock and common stock warrants, net of issuance costs			3,172	3	20,243					20,246
Modification of warrants					1,112					1,112
Stock-based compensation expense					1,566					1,566
Balance - June 30, 2020	**-**	**$ -**	**16,869**	**$ 17**	**$ 787,707**	**$ (701,214)**	**$ -**	**-**	**$ (3,054)**	**$ 83,456**
Net loss						(9,020)				(9,020)
Vesting of restricted stock units			35	-	-					-
Exercise of common stock warrants			18	-	141					141
Stock-based compensation expense					1,148					1,148
Balance - September 30, 2020	-	$ -	**16,922**	**$ 17**	**$ 788,996**	**$ (710,234)**	$ -	-	**$ (3,054)**	**$ 75,725**

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (25,112)	$ (20,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	-	(198)
Depreciation	123	178
Amortization of debt discount	3	127
Stock-based compensation	4,403	5,208
Non-cash expense related to warrant modifications	1,112	-
Non-cash lease expense	535	741
Realized gain on investments	-	(75)
Changes in:		
Prepaid expenses and other current assets	645	389
Accounts payable	(982)	(2,813)
Collaboration and device development payable	(1,975)	(830)
Accrued expenses	1,053	(1,166)
Operating lease liabilities	(581)	(784)
Other liabilities	-	119
Net cash used in operating activities	(20,776)	(19,204)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	-	13,988
Purchase of property and equipment	(27)	(129)
Net cash (used in) provided by investing activities	(27)	13,859
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	20,246	-
Proceeds from research and development funding arrangement	2,400	-
Proceeds from exercise of common stock warrants	141	-
Proceeds from Payroll Protection Program loan	547	-
Principle payments on Payroll Protection Program loan	(547)	-
Principle payments on loans payable	(2,877)	(820)
Payment for taxes related to net share settlements of restricted stock units	-	(151)
Net cash provided by (used in) financing activities	19,910	(971)
Effect of exchange rate changes on cash and cash equivalents	671	(451)
Net decrease in cash, cash equivalents, and restricted cash	(222)	(6,767)
Cash, cash equivalents, and restricted cash - beginning of period	22,732	11,358
Cash, cash equivalents, and restricted cash - end of period	$ 22,510	$ 4,591
Prepayment of insurance through 3rd party financing	$ 1,056	$ 708

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 and medical device company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Our development programs are primarily focused in the treatment of acute cardiovascular and pulmonary diseases. Our lead cardiovascular product candidate, istaroxime, a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, and early cardiogenic shock 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 two phase 2 clinical trials and has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration. We have also focused on developing AEROSURF (lucinactant for inhalation), a novel drug/medical device combination for non-invasive delivery of our proprietary aerosolized KL4 surfactant, using our proprietary Aerosol Delivery System, or ADS, technology for the treatment of respiratory distress syndrome in premature infants. Our licensee in Asia, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), will conduct the clinical development of AEROSURF in Asia. We are exploring potential licensing agreements with companies ex-Asia. We are also conducting a small pilot study of our proprietary KL4 surfactant for treatment of lung injury resulting from severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the causative agent in novel coronavirus, or COVID-19, infections. Our other drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension, in patients with a specific genetic profile. We also have a number of pipeline preclinical product candidates that we are evaluating for progression into clinical development. These include evaluating and pursuing a number of early exploratory research programs to identify potential product candidates, including oral and intravenous SERCA 2a heart failure compounds and other product candidates utilizing our KL4 surfactant and ADS technologies.

In December 2018, we acquired CVie Investments Limited, or CVie Investments, an exempted company with limited liability incorporated under the laws of the Cayman Islands, which we refer to herein as the CVie Acquisition. Since the CVie Acquisition, we have operated CVie Investments, and its wholly-owned subsidiary, CVie Therapeutics, a Taiwan corporation organized under the laws of the Republic of China, as a subsidiary focused on the development of drug product candidates for cardiovascular diseases.

In May 2020, upon completing a public financing and meeting listing requirements for The Nasdaq Stock Market LLC, our common stock began trading on the Nasdaq Capital Market.

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, 2019 that we filed with the Securities and Exchange Commission, or the SEC, on April 3, 2020, 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

These interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, 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. When necessary, prior year's condensed consolidated financial statements have been reclassified to conform to the current year presentation. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. There have been no changes to our significant accounting policies since December 31, 2019. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2019 contained in our Annual Report on Form 10-K for the year ended December 31, 2019.

The interim unaudited condensed consolidated financial statements reflect the 1-for-3 reverse split of our common stock that was approved by our Board of Directors and controlling stockholders and made effective on April 29, 2020. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

Note 3 – Liquidity Risks and Management's Plans

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 reliance on third party manufacturers.

We have incurred net losses since inception. Our net loss was $9.0 million and $7.1 million, respectively, for the three-month periods ended September 30, 2020 and 2019. Our net loss was $25.1 million and $20.1 million, respectively, for the nine-month periods ended September 30, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of September 30, 2020, we had an accumulated deficit of $710.2 million. Our future success is dependent on our ability to identify 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.

In May 2020, we received net proceeds of approximately $20.2 million related to a public offering, or the May 2020 Offering, of 3,172,413 units, inclusive of 413,793 units related to a fully exercised over-allotment option, at a price per unit of $7.25. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance.

In March 2020, we entered into a binding term sheet, or the Term Sheet, with Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF. In August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, dated and effective as of August 12, 2020, formalizing the terms of the Term Sheet, under which we have received payments of $2.8 million. Pursuant to the PF Agreement, Lee's (HK) agreed to pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. On November 12, 2020, Lee's (HK) provided notice of termination of the PF Agreement. Lee's (HK) will conduct clinical development of AEROSURF in Asia and we will wind-down our clinical development of AEROSURF. Lee's (HK) will fund an additional $1.0 million to us in 2021, repayable pursuant to the terms of the PF Agreement, for certain transition and analytical services to be provided by us with respect to the development of AEROSURF.

We believe that our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 are sufficient to fund operations through at least the next twelve months. In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities, and thus they are not considered probable.

Our funding requirements, however, are based on estimates that are subject to risks and uncertainties and may change as a result of many factors currently unknown. Although management continues to pursue the plans described above, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, including as a result of market volatility following the COVID-19 pandemic. Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, strategic partnerships and licensing arrangements. The terms of any future financing may adversely affect the holdings or the rights of our existing stockholders.

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, 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. The following table represents identifiable intangible assets as of September 30, 2020 and December 31, 2019:

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

Goodwill represents the excess of the purchase price over the fair value 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 its carrying value may be impaired.

Foreign Currency Transactions

The functional currency for our foreign subsidiaries is US Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other (expense) income, net. Foreign currency transactions resulted in losses of approximately $0.3 million and gains of approximately $0.1 million for the three-month periods ended September 30, 2020 and 2019. Foreign currency transactions resulted in losses of approximately $0.6 million and gains of approximately $0.4 million for the nine-month periods ended September 30, 2020 and 2019.

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 at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are held 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 July 2020, we entered into separation agreements with two executives, which provide that the former employees will be entitled to receive: (i) a severance amount equal to the sum of their respective base salaries then in effect and their respective annual target bonus amounts, payable in equal installments through August 2021 and (ii) subject to certain exceptions, a pro rata bonus commensurate with the bonus of other contract executives for the year 2020, prorated for the number of days of their respective employment during 2020, and payable at the time that other contract executives are paid bonuses with respect to 2020. The severance amount related to the departure of these executives is approximately $0.9 million, was accrued at the date of the separations, and will be paid ratably through August 2021. During the three months ended September 30, 2020, $0.2 million was paid.

Restructured Debt Liability – Contingent Milestone Payment

In conjunction with the November 2017 restructuring and retirement of long-term debt (see Note 8 – 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 account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical development programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

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, 2020 and 2019, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 9.8 million and 5.2 million shares, respectively. For the three and nine months ended September 30, 2020 and 2019, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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.

COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. As of the date of issuance of these interim unaudited condensed consolidated financial statements, our operations, capital and financial resources and overall liquidity position and outlook have not been materially impacted by COVID-19, while our operations have experienced delays, including in clinical study initiation and productivity. For example, certain of our ongoing clinical trials have experienced delays, including our phase 2 study of istaroxime for early cardiogenic shock in heart failure patients. In addition, travel restrictions and other COVID-19 mitigation efforts have impacted our business development activities with respect to out-licensing certain of our product candidates for which we are seeking partnership. The full extent, duration, or impact that the COVID-19 pandemic will 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 new information that may emerge concerning the severity of the COVID-19 outbreak, including any regional resurgences in one or more markets where our current or intended clinical trial sites, our principal executive offices, research and development laboratories or other facilities are located, and the actions taken to contain it or treat its impact, which may include, among others, the timing and extent of governments reopening activities and the economic impact on local, regional, national, and international markets. The strategic re-implementation of mitigating COVID-19 measures in one or more markets where our clinical trial sites, principal executive offices, research and development laboratories or other facilities are located remains possible and we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials in the fourth quarter of 2020 and beyond.

We are not aware of any specific event or circumstance that would require us to 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. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

Recently Issued Accounting Standards

Recent Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update, or ASU, 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 simplifies the accounting for income taxes by removing exceptions within the general principles of Topic 740 regarding the calculation of deferred tax liabilities, the incremental approach for intra-period tax allocation, and calculating income taxes in an interim period. In addition, the ASU adds clarifications to the accounting for franchise tax (or similar tax). which is partially based on income, evaluating tax basis of goodwill recognized from a business combination, and reflecting the effect of any enacted changes in tax laws or rates in the annual effective tax rate

computation in the interim period that includes the enactment date. The ASU is effective for fiscal years beginning after December 15, 2020 and will be applied either retrospectively or prospectively based upon the applicable amendments. Early adoption is permitted. We are still evaluating the impact this standard will have on our consolidated financial statements and related disclosures, but do not believe there will be a material impact upon adoption.

Note 5 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
(in thousands)	September 30, 2020	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 4,605	$ 4,605	$ -	$ -
U.S. Treasury notes	14,997	14,997	-	-
Total Assets	$ 19,602	$ 19,602	$ -	$ -

	Fair Value	Fair value measurement using		
(in thousands)	December 31, 2019	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 1,819	$ 1,819	$ -	$ -
U.S. Treasury notes	18,230	18,230	-	-
Total Assets	$ 20,049	$ 20,049	$ -	$ -

Note 6 – Collaboration and Device Development Payable

Restructuring of the Battelle Payables

In March 2020, we entered into the first amendment to the December 2018 payment restructuring agreement, or the Amendment, with Battelle Memorial Institute, or Battelle, in which we agreed to amend the payment terms of two milestone payments previously due no later than January 2020. Under the Amendment, we agreed that (i) the first milestone payment would continue to be due upon enrollment of the first patient in the next AEROSURF clinical study but no later than April 15, 2020; and, (ii) the second milestone payment would continue to be due upon completion of technology transfer of our device manufacturing process for the phase 3 ADS to our new medical device manufacturer but no later than September 1, 2020. The Amendment was treated as a debt modification and, in accordance with debt modification accounting, no gain or loss was recognized.

In April 2020, we made the first milestone payment of $0.8 million to Battelle and announced enrollment of the first patient into the AEROSURF phase 2 bridging study. In September 2020, we made the final milestone payment of $0.8 million to Battelle.

Note 7 – Loans Payable

Loans Payable – Current Portion

Loan payable to Bank Direct Capital Finance

In May 2019, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $0.7 million of certain premiums at a 5.35% annual interest rate. As of December 31, 2019, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the quarter ended March 31, 2020.

In June 2020, 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 4.26% annual interest rate. Payments of approximately $117,000 are due monthly from July 2020 through March 2021. As of September 30, 2020, the outstanding principal of the loan was $0.7 million.

Loans Payable – Non-current Portion

Assumption of bank debt as part of the CVie Acquisition

In September 2016, CVie Therapeutics Limited entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd., or O-Bank, to finance operating activities, or the O-Bank Facility. The O-Bank Facility was later renewed and increased to approximately $5.8 million in September 2017. The O-Bank Facility is guaranteed by Lee's Pharmaceutical Holdings Limited, or Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. Interest, payable in cash on a monthly basis, is determined based on the 90-day Taipei Interbank Offer Rate, or TAIBOR, plus 0.91%. The O-Bank Facility expired on September 11, 2019 and the loans were set to mature six months after the expiration date, on March 11, 2020. In March 2020, the O-Bank Facility was amended, among other things, to extend the maturity date to March 2022, to decrease the total amount of the O-Bank Facility to approximately $5.0 million, to change the applicable interest rate to the TAIBOR plus 1.17% and to adjust the term to 24-month non-revolving.

As of September 30, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $2.4 million and $4.6 million, respectively. In the second quarter of 2020, we were informed by Lee's of their desire to reduce the amount of pledged bank deposits with O-Bank by 50%. To remain in compliance with the terms of the O-Bank Facility, we repaid approximately $2.3 million of the outstanding principal in August 2020. In November 2020, Lee's committed to maintain the required level of pledged bank deposits with O-Bank through the date of full repayment of the O-Bank Facility.

Note 8 – Restructured Debt Liability

On November 1, 2017, we and Deerfield entered into the Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield 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 5 – Accounting Policies and Recent Accounting Pronouncements). The liability has been recorded at full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of September 30, 2020 and December 31, 2019, the restructured debt liability balance was $15.0 million.

Note 9 – Stockholders' Equity

Warrant Amendments

On April 24, 2020, we and each of the holders of our Series F Warrants dated as of December 24, 2018, or the Series F Warrants, entered into Amendment No. 1 to the Series F Warrant to Purchase Common Stock whereby the expiration date of the Series F Warrants was extended from June 24, 2020 to December 24, 2020 in consideration for the holders agreeing to be bound by a lock-up provision with respect to any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by the holders. The lock-up provision provides that the holders will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by the holders for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020. The lock-up provision commenced on May 22, 2020 upon closing of the May 2020 Offering discussed below and has expired.

On May 6, 2020, we and certain holders of our Series I Warrants dated as of December 6, 2019, or the Series I Warrants, entered into Amendment No. 1 to the Series I Warrant to Purchase Common Stock pursuant to which the exercise price of the Series I Warrants was amended from $12.09 to $9.67 if the Series I Warrants are exercised, in whole or in part, prior to December 5, 2021. In addition, the certain holders of the Series I Warrants agreed to be bound by a lockup provision with respect to any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock that are beneficially owned, held or acquired by such holders for a period of 90 days following the earlier of (i) the closing date of our next public offering of securities, or (ii) December 24, 2020. During the lock-up period, the certain holders of the Series I Warrants will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock. The lock-up provision commenced on May 22, 2020 upon closing of the May 2020 Offering discussed below and has expired.

While there is no specific guidance that addresses the modification of an equity-classified contract, such as the amendments to the Series F Warrants and the Series I Warrants, it is the practice to determine the accounting for such modifications based on analogy to the share-based compensation guidance. The model for a modified share-based payment award that is classified as equity and remains classified in equity after the modification is addressed in ASC 718-20, *Compensation – Stock Compensation*, or ASC 718-20. Pursuant to that guidance, the incremental fair value from the modification (the change in the fair value of the instrument before and after the modification) is recognized as an expense in the income statement to the extent the modified instrument has a higher fair value.

For the Series F Warrants, the amendment to the terms related to a six-month extension of the expiration date and the incremental fair value from the modification was determined by comparing the Black-Scholes value before and after the modification. The amendment to the Series I Warrants related to a reduced exercise price for an 18-month period and the reversion after that period to the initial exercise price. As a result, the incremental fair value was determined by comparing the Black-Scholes value before the modification to a Monte Carlo valuation after the modification.

We have determined, based on the guidance in ASC 718-20 and our valuation of the Series F Warrants and the Series I Warrants, that the incremental fair value resulting from the modifications is $1.1 million, which was recorded as an increase to equity, with a corresponding expense recognized in the interim unaudited condensed consolidated statement of operations as other expense.

May 2020 Public Offering

On May 20, 2020, we entered into an underwriting agreement, or the Underwriting Agreement, with Ladenburg Thalmann & Co. Inc., or Ladenburg, as representative for the several underwriters named therein, or collectively, the Underwriters, relating to the May 2020 Offering for an aggregate of 2,758,620 units with each unit consisting of one share of our common stock and a Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance. The shares of common stock and the Warrants were immediately separable and were issued separately in the May 2020 Offering.

In addition, we granted the Underwriters a 45-day option, or the Overallotment Option, to purchase up to 413,793 additional shares of common stock and/or Warrants to purchase up to 413,793 additional shares of common stock, which such Overallotment Option was exercised in full.

The closing of the May 2020 Offering occurred on May 22, 2020, inclusive of the Overallotment Option. The offering price to the public was $7.25 per unit. After deducting underwriting discounts and commissions and offering expenses of $2.8 million payable by us, and excluding the proceeds, if any, from the exercise of the Warrants issued pursuant to this May 2020 Offering, the net proceeds to us were approximately $20.2 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 Warrants issued in the May 2020 Offering as equity. We have also determined that the 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 May 2020 Offering based on the relative fair value of the common stock and the Warrants.

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 an at-the-market program, or the ATM Program. We are not obligated to make any sales under the ATM Program, and as of November 16, 2020, we have not sold any shares under the ATM Program. If we issue a sale notice to Ladenburg, we will 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. Sales under the ATM Program will be made pursuant to our "shelf" registration statement on Form S-3 (No. 333-248874) filed with the SEC on September 17, 2020, and declared effective on September 29, 2020, including the base prospectus and the ATM Prospectus filed therein, or the Universal Shelf.

Either party may suspend the offering under the ATM Program by notice to the other party. The ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the ATM Program or (ii) termination of the ATM Program in accordance with its terms. Either party may terminate the ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

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. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $50,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

Note 10 – Stock Options and Stock-Based Employee Compensation

We recognize in our condensed consolidated financial statements all stock-based awards to employees and non-employee directors based on their fair value on the date of grant, calculated using the Black-Scholes option-pricing model. Compensation expense related to stock-based awards is recognized ratably over the vesting period, which for employees is typically three years. We recognize restricted stock unit awards to employees and non-employee directors based on their fair value on the date of grant. Compensation expense related to restricted stock unit awards is recognized ratably over the vesting period, which typically has been between approximately six to 18 months.

A summary of activity under our long-term incentive plan 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, 2020	1,772	$ 17.61	
Granted	537	7.25	
Forfeited or expired	(402)	12.52	
Outstanding at September 30, 2020	1,907	$ 15.76	8.0
Vested and exercisable at September 30, 2020	779	$ 23.23	6.8
Vested and expected to vest at September 30, 2020	1,813	$ 15.76	8.0

During the nine months ended September 30, 2020, 35,000 restricted stock units vested. As of September 30, 2020, there were no unvested restricted stock units.

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

	Nine Months Ended September 30,	
	2020	2019
Weighted average expected volatility	103%	95%
Weighted average expected term (in years)	7.0	6.6
Weighted average risk-free interest rate	0.54%	2.60%
Expected dividends	-	-

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Research and development	$ 309	$ 574	$ 1,619	$ 1,613
General and administrative	839	1,365	2,784	3,595
Total	$ 1,148	$ 1,939	$ 4,403	$ 5,208

Note 11 – Collaboration, Licensing and Research Funding Agreements

In March 2020, we entered into the Term Sheet with Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF and in August 2020, we entered into the PF Agreement with Lee's (HK), under which we have received payments of $2.4 million as of September 30, 2020. We received the final payment under the agreement of $0.4 million in October 2020. Pursuant to the PF Agreement, Lee's (HK) agreed to pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. On November 12, 2020, Lee's (HK) provided notice of termination of the PF Agreement. Lee's (HK) will conduct clinical development of AEROSURF in Asia and we will wind-down our clinical development of AEROSURF. Lee's (HK) will fund an additional $1.0 million to us in 2021, repayable pursuant to the terms of the PF Agreement, for certain transition and analytical services to be provided by us with respect to the development of AEROSURF.

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 License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the 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).

We have determined that the Term Sheet is within the scope of ASC 730-20, *Research and Development Arrangements*, or ASC 730-20. We concluded that there has not been a substantive and genuine transfer of risk related to the Term Sheet as there is a presumption that we are obligated to repay Lee's (HK) based on the significant related party relationship that exists at the time the parties entered into the Term Sheet, including Lee's (HK)'s approximate 29% ownership of the outstanding shares of our common stock.

We have determined that the appropriate accounting treatment under ASC 730-20 is to record the proceeds received from Lee's (HK) as cash and cash equivalents, as we have the ability to direct the usage of funds, and a long-term liability on our condensed consolidated balance sheet when received. The liability will remain on the balance sheet until we repay such amounts as a result of any revenues and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio.

We have also determined that the Term Sheet is not in its entirety a derivative under the scope of ASC 815, due to the scope exception under ASC 815-10-15-59, nor are there any embedded derivatives that require separate accounting.

As of September 30, 2020, the liability balance related to the non-refundable payment was $2.4 million and is recorded in other liabilities.

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 Forward-Looking Statements section, 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, 2019 that we filed with the Securities and Exchange Commission, or SEC, on April 3, 2020, our Quarterly Reports on Form 10-Q 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, 2019. Unless otherwise specified, references to Notes in this MD&A shall refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

OVERVIEW

We are a clinical-stage, biopharmaceutical and medical device company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Our development programs are primarily focused in the treatment of acute cardiovascular and pulmonary diseases. Our lead cardiovascular product candidate istaroxime, a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, and early cardiogenic shock 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 two phase 2 clinical trials and has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. We have also focused on developing AEROSURF (lucinactant for inhalation), a novel drug/medical device combination for non-invasive delivery of our proprietary aerosolized KL4 surfactant, using our proprietary aerosol delivery system, or ADS, technology for the treatment of respiratory distress syndrome, or RDS, in premature infants. Our licensee in Asia, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), will conduct the development of AEROSURF in Asia. We are exploring potential licensing agreements with companies ex-Asia. We are conducting a small pilot study of our proprietary KL4 surfactant for the treatment of lung injury resulting from severe novel coronavirus, or COVID-19, infections. Our other drug product candidates include rostafuroxin, a novel medicine for the treatment of hypertension in patients with a specific genetic profile. We also have a number of pipeline preclinical product candidates that we are evaluating for progression into clinical development. These include evaluating and pursuing a number of early exploratory research programs to identify potential product candidates, including oral and intravenous SERCA 2a heart failure compounds and other product candidates utilizing our KL4 surfactant and ADS technologies.

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, 2019 that we filed with the SEC on April 3, 2020, 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 (AHF)

In April 2020, we announced the presentation at the American College of Cardiology 2020 virtual meeting of a new subset analysis from a phase 2b study of istaroxime in patients hospitalized with AHF. We previously presented the overall results of the study where the primary endpoint demonstrated a significant improvement ($p<0.05$) in cardiac function at both istaroxime study doses. This post-hoc analysis characterized the responses between Caucasian and Asian patients. The istaroxime dose of 0.5 µg/kg/min produced a similar response on E/e', the primary study endpoint, and stroke volume index, an important measure of cardiac performance, in Asian and Caucasian patients.

Istaroxime (Early Cardiogenic Shock)

We have initiated the study of istaroxime for the treatment of early cardiogenic shock in patients with severe heart failure, a presentation of heart failure characterized by very low blood pressure and hypo-perfusion to critical organs which is associated with high mortality and morbidity and is not well treated with current therapies. We believe istaroxime may fulfill an unmet need in early cardiogenic shock based on the profile observed in our phase 2 clinical studies in AHF. Because of the unmet need in the treatment of early cardiogenic shock, we believe there may be an opportunity with a breakthrough therapy designation, which may provide an expedited development program. Receipt of either Fast Track or breakthrough therapy designation may increase the likelihood of receiving priority review of a marketing application, which would provide for an expedited review timeframe.

In October 2020, we announced that we had dosed the first patient in our phase 2 study of istaroxime for the acute treatment of early cardiogenic shock in heart failure patients to evaluate the potential to improve blood pressure and organ perfusion. The study will also evaluate the safety and side effect profile of istaroxime in this patient population. Due to the current global outbreak of COVID-19 and its effect on hospital intensive care units, the location of this study, and the study staff and resources, our study has been impacted and we have experienced some delays in anticipated timelines and milestones.

AEROSURF (lucinactant for inhalation)

In April 2020, as part of the phase 2 clinical program, we enrolled the first patient and commenced our small, approximately 90-patient, phase 2b bridging study in premature infants with RDS to prepare to transition to a phase 3 clinical program by demonstrating the performance of our new ADS, in the neonatal intensive care unit as well as a more intensive dosing regimen. The AEROSURF phase 2b bridging study is a multicenter, randomized, controlled study with masked treatment assignment in up to 90 premature infants 26 to 32 weeks gestational age receiving nasal continuous airway pressure, or nCPAP, for RDS. The trial will leverage the favorable safety profile from the previous phase 2 studies to evaluate higher and more frequent dosing of aerosolized KL4 surfactant compared to premature infants receiving standard care of nCPAP alone. The trial will utilize the new ADS and bridge to data generated in the phase 2 program utilizing a prototype device on the following endpoints: time to nCPAP failure (the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. In June 2020, we announced that all initial European trial sites were active and enrolling or able to enroll patients into the phase 2b bridging study. Most recently, the European study sites were affected by increased rates of COVID-19, which has impacted key study personnel, and resulted in periodic holds on screenings for new patients and dosing. Following termination of the PF Agreement (as defined below), these European trial sites will no longer enroll patients and Lee's (HK) will conduct a clinical trial in Asia. As a result, Asia will be the only location to complete the phase 2b bridging study. Lee's (HK) will conduct, fund and execute the AEROSURF phase 2b bridging study while we focus on the study of lucinactant to prevent lung injury in patients with COVID-19, as described below.

Lyophilized KL4 Surfactant – Lung Injury and Other Studies

We are initiating a study of our proprietary KL4 surfactant for the treatment of lung injury resulting from severe COVID-19 infection. In September 2020, the FDA accepted our investigational new drug, or IND, application for a phase 2 clinical trial to assess the ability of our proprietary KL4 surfactant to impact key respiratory parameters in ventilated COVID-19 patients. The small pilot study will evaluate changes in physiological parameters in patients who are intubated and mechanically ventilated for COVID-19 associated lung injury and acute respiratory distress syndrome, or ARDS. The study will evaluate the dosing regimen, tolerability, and functional changes in gas exchange and lung compliance after KL4 surfactant administration. We plan to enroll up to 20 patients with COVID-19 and ARDS, who are on mechanical ventilation, from four to five U.S. sites. We plan to start the study during the fourth quarter of 2020. We applied to the Biomedical Advanced Research and Development Authority, or BARDA, requesting funding for our development plans of KL4 surfactant in COVID-19 patients and we were granted a meeting to review our proposal with BARDA representatives. With the acceptance of the IND by the FDA and planned start of the trial, we plan to reengage with the federal government on the program. There is no assurance that we will receive funding from BARDA.

Impact of COVID-19

The COVID-19 pandemic continues to evolve, and we are closely monitoring the situation, including its potential impact on our clinical development plans and timelines. As of the date of the filing of this Quarterly Report on Form 10-Q, however, our operations, capital and financial resources and overall liquidity position and outlook have not been materially impacted by COVID-19, while our operations have experienced delays, including in clinical study initiation and early productivity. For example, certain of our ongoing clinical trials have experienced delays, including our phase 2 study of istaroxime for early cardiogenic shock in heart failure patients. In addition, travel restrictions and other COVID-19 mitigation efforts have impacted our business development activities with respect to out-licensing certain of our product candidates for which we are seeking partnership. The full extent, duration, or impact that the COVID-19 pandemic will 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 new information that may emerge concerning the severity of the COVID-19 outbreak, including any regional resurgences in one or more markets where our current or intended clinical trial sites, our principal executive offices, research and development laboratories or other facilities are located, and the actions taken to contain it or treat its impact, which may include, among others, the timing and extent of governments reopening activities and the economic impact on local, regional, national, and international markets. The strategic re-implementation of mitigating COVID-19 measures in one or more markets where our clinical trial sites, principal executive offices, research and development laboratories or other facilities are located remains possible and we believe there could be further impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials in the fourth quarter of 2020 and beyond.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2019. For a discussion of our accounting policies, see Note 4 – Summary of Significant Accounting Policies and, in the Notes to Consolidated Financial Statements (Notes) in our Annual Report on Form 10-K for the year ended December 31, 2019, Note 5 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Operating Loss and Net Loss

The operating loss for the three months ended September 30, 2020 and 2019 was $8.7 million and $7.2 million, respectively. The increase in operating loss from 2019 to 2020 was due to a $1.5 million increase in operating expenses.

The operating loss for the nine months ended September 30, 2020 and 2019 was $23.4 million and $20.3 million, respectively. The increase in operating loss from 2019 to 2020 was due to a $2.8 million increase in operating expenses and a $0.2 million decrease in license revenue with affiliate.

The net loss for the three months ended September 30, 2020 and 2019 was $9.0 million and $7.1 million, respectively. The net loss for the nine months ended September 30, 2020 and 2019 was $25.1 million and $20.1 million, respectively. Included in the net loss for the three and nine months ended September 30, 2020 is $1.1 million in non-cash expenses related to the modification of certain warrants.

Research and Development Expenses

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

Research and development expenses by category are as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Product development and manufacturing	$ 1,002	$ 1,165	$ 3,610	$ 3,262
Clinical, medical and regulatory operations	1,591	1,734	5,009	5,339
Direct preclinical and clinical programs	1,289	893	3,219	1,946
Total research and development expenses	$ 3,882	$ 3,792	$ 11,838	$ 10,547

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.6 million, respectively, for the three months ended September 30, 2020 and 2019 and $1.7 million and $1.7 million, respectively, for the nine months ended September 30, 2020 and 2019.

Product Development and Manufacturing

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

Product development and manufacturing expenses decreased $0.2 million for the three months ended September 30, 2020 compared to the same period in 2019 due to a decrease in analytical testing costs related to our AEROSURF clinical development program. Product development and manufacturing expenses increased $0.3 million for the nine months ended September 30, 2020 compared to the same period in 2019 due to a $0.4 million purchase of raw materials during the second quarter of 2020, partially offset by a decrease in analytical testing costs related to our AEROSURF clinical development program.

Clinical, Medical and Regulatory Operations

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

Clinical, medical and regulatory operations expenses decreased $0.1 million for the three months ended September 30, 2020 compared to the same period in 2019 due to a decrease of $0.2 million in non-cash, stock compensation expense, partially offset by an increase of $0.1 million in personnel costs. Clinical, medical and regulatory operations expenses decreased $0.3 million for the nine months ended September 30, 2020 compared to the same period in 2019 due to (i) a decrease of $0.2 million in personnel and travel costs and (ii) a decrease of $0.2 million in employee-related incentive bonus expense, partially offset by (iii) an increase of $0.1 million in non-cash, stock compensation expense.

Direct Preclinical and Clinical Development Programs

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

Direct preclinical and clinical development programs expenses increased $0.4 million and $1.3 million, respectively, for the three and nine months ended September 30, 2020 compared to the same periods in 2019 due to an increase in costs related to our continued clinical development of istaroxime and AEROSURF.

General and Administrative Expenses

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
General and administrative expenses	$ 4,823	$ 3,395	$ 11,518	$ 9,990

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 increased $1.4 million and $1.5 million, respectively, for the three and nine months ended September 30, 2020 compared to the same periods in 2019 due to (i) an increase of $1.0 million and $1.8 million, respectively, in professional fees, taxes, and insurance and (ii) severance costs of $0.8 million and $0.9 million, respectively, (iii) an increase of $0.1 million and a decrease of $0.4 million, respectively, in employee-related incentive bonus expense, partially offset by (iv) a decrease of $0.5 million and $0.8 million, respectively, in non-cash, stock compensation expense.

Other (Expense) Income

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Interest income	21	25	115	124
Interest expense	(46)	(105)	(121)	(358)
Other (expense) income, net	(290)	141	(1,750)	473
Total other (expense) income, net	$ (315)	$ 61	$ (1,756)	$ 239

Interest income relates to interest on our money market account and U.S. Treasury notes.

For the three and nine months ended September 30, 2020 and 2019, interest expense consists of interest expense associated with the collaboration and device development payables and with the loans payable. The decrease of $0.1 million and $0.2 million, respectively, in interest expense for the three and nine months ended September 30, 2020 to the comparable periods in 2019 is related to the repayment of $2.1 million in loans payable during the year ended December 31, 2019.

For the three months ended September 30, 2020, other (expense) income, net primarily consists of losses on foreign currency translation of $0.3 million. For the nine months ended September 30, 2020, other (expense) income, net primarily consists of $1.1 million in non-cash expenses related to the modification of certain warrants and losses on foreign currency translation of $0.6 million.

For the three and nine months ended September 30, 2019, other (expense) income, net primarily consists of $0.1 million and $0.4 million, respectively, in gains on foreign currency translation.

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 reliance on third party manufacturers.

We have incurred net losses since inception. Our net loss was $9.0 million and $7.1 million, respectively, for the three-month periods ended September 30, 2020 and 2019. Our net loss was $25.1 million and $20.1 million, respectively, for the nine-month periods ended September 30, 2020 and 2019. We expect to continue to incur operating losses for at least the next several years. As of September 30, 2020, we had an accumulated deficit of $710.2 million. Our future success is dependent on our ability to identify 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.

In May 2020, we received net proceeds of approximately $20.2 million related to a public offering, or the May 2020 Offering, of 3,172,413 units, inclusive of 413,793 units related to a fully exercised over-allotment option, at a price per unit of $7.25. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $7.975 per share and expire five years from the date of issuance.

In March 2020, we entered into a binding term sheet, or the Term Sheet, with Lee's (HK), pursuant to which Lee's (HK) will provide financing for the development of AEROSURF and in August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, under which we have received payments of $2.8 million. Pursuant to the PF Agreement, Lee's (HK) agreed to pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. On November 12, 2020, Lee's (HK) provided notice of termination of the PF Agreement. Lee's (HK) will conduct clinical development of AEROSURF in Asia and we will wind-down our clinical development of AEROSURF. Lee's (HK) will fund an additional $1.0 million to us in 2021, repayable pursuant to the terms of the PF Agreement, for certain transition and analytical services to be provided by us with respect to the development of AEROSURF.

We believe that our cash and cash equivalents as of the filing of our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 are sufficient to fund operations through at least the next twelve months. In the future, we will need to raise additional capital to continue funding our operations. We plan to obtain funding through a combination of public or private equity offerings, or strategic transactions including collaborations, licensing arrangements or other strategic partnerships. There is inherent uncertainty associated with these fundraising activities, and thus they are not considered probable.

Our funding requirements, however, are based on estimates that are subject to risks and uncertainties and may change as a result of many factors currently unknown. Although management continues to pursue the plans described above, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, including as a result of market volatility following the COVID-19 pandemic. Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, strategic partnerships and licensing arrangements. The terms of any future financing may adversely affect the holdings or the rights of our existing stockholders.

Cash Flows

Cash outflows for the nine months ended September 30, 2020 consist of $20.8 million used in ongoing operating activities and $19.9 million provided by financing activities. Cash outflows for the nine months ended September 30, 2019 consist of $19.2 million used in ongoing operating activities and $1.0 million used in financing activities, offset by cash inflows for the nine months ended September 30, 2019 of $13.9 million for investing activities.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2020 and 2019 was $20.8 million and $19.2 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital. The increase in net cash used in operating activities from 2019 to 2020 is due to (i) a $5.0 million increase in net loss for the nine months ended September 30, 2020 compared to the same period in 2019; and (ii) a $1.1 million increase in payments related to our collaboration and device development payable with Battelle Memorial Institute as a result of contractual milestone payments during the nine months ended September 30, 2020; partially offset by (iii) costs related to the acquisition of CVie Investments Limited, or the CVie Acquisition, costs from the December 2018 private placement financing and the payment of pre-existing obligations with the proceeds of the December 2018 private placement financing during the nine months ended September 30, 2019.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2019 represents $14.0 million related to the sale of marketable securities, partially offset by $0.1 million in purchase of property and equipment compared with a de minimis amount of net cash used in investing activities for the nine months ended September 30, 2020.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 was $19.9 million and includes the following: (i) $20.2 million in net proceeds from the May 2020 Offering; (ii) $2.4 million in proceeds from our research and development funding arrangement with Lee's (HK); (iii) $0.1 million in proceeds from the exercise of common stock warrants; and (iv) $2.9 million of principal payments on loans payable. Net cash used in financing activities for the nine months ended September 30, 2019 was $1.0 million and represents $0.8 million in principal payments on our loans payable and $0.2 million related to withholding tax payments for net share settlements of restricted stock units.

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

Loans Payable

Loan payable to Bank Direct Capital Finance

In May 2019, we entered into an insurance premium financing and security agreement with Bank Direct Capital Finance, or Bank Direct. Under the agreement, we financed $0.7 million of certain premiums at a 5.35% annual interest rate. As of December 31, 2019, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the quarter ended March 31, 2020.

In June 2020, 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 4.26% annual interest rate. Payments of approximately $117,000 are due monthly from July 2020 through March 2021. As of September 30, 2020, the outstanding principal of the loan was $0.7 million.

Assumption of bank debt as part of the CVie Acquisition

In September 2016, CVie Therapeutics Limited entered into a 12-month revolving credit facility of approximately $2.9 million with O-Bank Co., Ltd., or O-Bank, to finance operating activities, or the O-Bank Facility. The O-Bank Facility was later renewed and increased to approximately $5.8 million in September 2017. The O-Bank Facility is guaranteed by Lee's Pharmaceutical Holdings Limited, or Lee's, which pledged bank deposits in the amount of 110% of the actual borrowing amount. Interest, payable in cash on a monthly basis, is determined based on the 90-day Taipei Interbank Offer Rate, or TAIBOR, plus 0.91%. The O-Bank Facility expired on September 11, 2019 and the loans were set to mature six months after the expiration date, on March 11, 2020. In March 2020, the O-Bank Facility was amended, among other things, to extend the maturity date to March 2022, to decrease the total amount of the O-Bank Facility to approximately $5.0 million, to change the applicable interest rate to the TAIBOR plus 1.17% and to adjust the term to 24-month non-revolving.

As of September 30, 2020 and December 31, 2019, the outstanding principal of the O-Bank Facility was approximately $2.4 million and $4.6 million, respectively. In the second quarter of 2020, we were informed by Lee's of their desire to reduce the amount of pledged bank deposits with O-Bank by 50%. To remain in compliance with the terms of the O-Bank Facility, we repaid approximately $2.3 million of the outstanding principal in August 2020. In November 2020, Lee's committed to maintain the required level of pledged bank deposits with O-Bank through the date of full repayment of the O-Bank Facility.

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. In September 2020, we filed with the SEC a "shelf" registration statement on Form S-3 (No. 333-248874), or the Universal Shelf, that was declared effective on September 29, 2020, for the proposed offering from time to time of up to $75.0 million of our securities, including common stock, preferred stock, debt securities, warrants, units, subscription rights, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. As of September 30, 2020, approximately $75.0 million remained available under the Universal Shelf. The Universal Shelf will expire upon the earlier to occur of (i) the sale of $75.0 million of our securities or (ii) September 29, 2023.

At-The-Market Program

On September 17, 2020, we entered into 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. We are not obligated to make any sales under the ATM Program, and as of November 16, 2020, we have not sold any shares under the ATM Program. If we issue a sale notice to Ladenburg, we will 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. Sales under the ATM Program will be made pursuant to the Universal Shelf.

Either party may suspend the offering under the ATM Program by notice to the other party. The ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the ATM Program or (ii) termination of the ATM Program in accordance with its terms. Either party may terminate the ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

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. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $50,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at September 30, 2020 and 2019 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 (principal financial officer), does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

ITEM 1A. RISK FACTORS

Investing in our securities involves risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, stockholders and potential 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, 2019 and Part II, Item 1A Risk Factors in our Quarterly Reports on Form 10-Q filed thereafter. These risks are not the only risks that could materialize. 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, 2019 or our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020 actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in *Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources*.

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

Termination of AEROSURF Project Financing Agreement

As previously disclosed, we entered into the Term Sheet with Lee's (HK), pursuant to which the parties agreed that Lee's (HK) would provide financing for the continued development of our product candidate, AEROSURF. On August 12, 2020, we and Lee's (HK) entered into the PF Agreement, formalizing the terms of the Term Sheet, under which we have received payments of $2.8 million.

Pursuant to the PF Agreement, Lee's (HK) agreed to pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. On November 12, 2020, Lee's (HK) provided notice of termination of the PF Agreement. Lee's (HK) will conduct clinical development of AEROSURF in Asia and we will wind-down our clinical development of AEROSURF. Lee's (HK) will 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. We remain responsible for repayment of all amounts received under the PF Agreement pursuant to the terms thereof.

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†	Collaboration Agreement dated as of October 10, 2014, by and between Battelle Memorial Institute and Discovery Laboratories, Inc. (predecessor-in-interest to Windtree).	Filed herewith.
10.2†	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Discovery Laboratories, Inc. (predecessor-in-interest to Windtree) and Laboratorios Del Dr. Esteve S.A.	Filed herewith.
10.3†	Amended and Restated Sublicense and Collaboration Agreement, dated December 3, 2004, by and between Discovery Laboratories, Inc. (predecessor-in-interest to Windtree) and Laboratorios Del Dr. Esteve S.A.	Filed herewith.
10.4†	Project Financing Agreement, dated August 12, 2020, by and between Windtree and Lee's Pharmaceutical (HK) Ltd.	Filed herewith.
10.5#	Employment Agreement, dated July 20, 2020, by and between Windtree and John P. Hamill	Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 23, 2020.
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, 2020, formatted in Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of September 30, 2020 (unaudited) and December 31, 2019, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2020 and September 30, 2019, (iii) Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2020 and September 30, 2019, (iv) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2020 and September 30, 2019, and (v) Notes to Condensed Consolidated Financial Statements.	
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

Compensation Related Contract.
† Certain confidential portions have been omitted from this exhibit 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 16, 2020

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

Date: November 16, 2020

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 WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

COLLABORATION AGREEMENT

BETWEEN

DISCOVERY LABORATORIES, INC.,

AND

BATTELLE MEMORIAL INSTITUTE

REGARDING

DEVELOPMENT OF AEROSURF®

Dated as of October 10, 2014

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (the "Agreement") is made and entered into by and between DISCOVERY LABORATORIES, INC., a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976 USA ("Discovery Labs"), and BATTELLE MEMORIAL INSTITUTE, through its Corporate Operations, a corporation organized and existing under the laws of the state of Ohio having its principal place of business at 505 King Avenue, Columbus, Ohio 43201-2693, USA ("Battelle") as of October 10, 2014 (the "Effective Date"). Discovery Labs and Battelle may be referred to herein individually as a "Party" or collectively as "Parties".

RECITALS:

WHEREAS, Discovery Labs is developing AEROSURF® as a therapy for premature infants with respiratory distress syndrome ("RDS"). AEROSURF is an investigational combination drug/device product that combines Discovery Labs' proprietary technologies: lyophilized synthetic KL4 surfactant for inhalation and its capillary aerosol generator (CAG). By enabling delivery of aerosolized lyophilized KL4 surfactant using less invasive procedures, Discovery Labs believes that AEROSURF will address a serious unmet medical need and enable the treatment of a significantly greater number of premature infants with RDS; and

WHEREAS, over the past two years, Discovery Labs has engaged Battelle to assist in developing the CAG aerosol technology and to manufacture aerosol devices and accompanying disposables that meet the requirements for the AEROSURF phase 2 clinical program. To date, the developmental device and disposables have been deployed in a clinical trial setting in several neonatal intensive care units (NICU's) in the US. The current developmental device and disposable units are expected to be utilized in a planned phase 2b study; and

WHEREAS, further investment in development of the developmental device and disposable units will be required to continue the AEROSURF clinical program into phase 3 and potential commercialization, and the Parties are interested in collaborating to further develop Discovery Labs' CAG technology into a product that will meet the requirements for a phase 3 clinical trial and commercialization of AEROSURF (the "Collaboration");

NOW THEREFORE, IN CONSIDERATION OF THE COVENANTS AND PROMISES CONTAINED IN THIS AGREEMENT, THE PARTIES AGREE AS FOLLOWS WITH THE INTENT TO BE LEGALLY BOUND HEREBY:

1. DEFINITIONS.

Except as otherwise defined herein, the following terms shall have the meanings described below:

A. “AEROSURF” means Discovery Labs’ investigational combination drug/device product that combines Discovery Labs’ proprietary technologies: lyophilized synthetic KL4 surfactant for inhalation and its capillary aerosol generator (CAG). For the purposes of this Agreement, “AEROSURF” means AEROSURF for the treatment of respiratory distress syndrome (RDS) in premature infants.

B. “AEROSURF System” means that particular system described in the Product Requirements Document, being developed for use in the treatment of respiratory distress syndrome (RDS) in premature infants.

C. "Affiliates" means with respect to any Party, any entity who directly or indirectly Controls, or is Controlled by, or is under common Control with such Party. Affiliates include subsidiaries. The term Affiliate or Affiliates, as to Battelle, does not include any person or business operation which manages or operates national laboratories, other laboratories of a third party, or facilities for any of the United States of America, foreign governments or entities, or a third party.

D. “Commercially Reasonable Efforts” means the level of efforts and resources, and the application of the requisite level of skills and experience, commonly used in the medical device industry by a company of similar size and with similar capital resources to the Party with respect to the development and commercialization of a product of similar commercial potential at a similar stage in its development or product life, taking into consideration its safety and efficacy, its cost to develop, manufacture and bring to market, the prevalence of the therapeutic purpose for which it is intended, the competitiveness of alternative devices or systems, the patent and other proprietary position of such device or system, the likelihood of regulatory approval, market size and geographic dispersion, product sales cycle, and its profitability.

E. "Consumables" means disposable dose packet, including a capillary element and other materials that may be included as part of the AEROSURF System as to be detailed in the PRD.

F. “Control” means (a) with respect to any item of Confidential Information (as such term is further defined in the CDA), patent, know how or other intellectual property right, the right to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with, or any legal rights of, any third party, or (b) with respect to any specified party, the possession, directly or indirectly, of the power to direct the management or policies of such party, whether through the ownership of voting equity or by contract relating to voting rights or corporate governance, or otherwise.

G. “Cost Overruns” means any expenses incurred by Battelle that exceed the sum of the Project Plan Fixed Cost and the planned costs set forth in all associated Scope Change Orders.

H. “Device Development Milestone” means successful completion by Battelle of Stage 3 activities as set forth in the Project Plan.

I. "Discovery Labs Fixed Fee" means the fixed fee payable by Discovery Labs to Battelle for Battelle's performance and completion of Stages 2 and 3 of the Project Plan, which amount may be subject to amendment following completion of Stage 1 Work, as provided in Section 3.B(i).

J. "Discovery Labs Default Percent" means, at any time, that portion of the Project Plan performed by Battelle up to the date of termination for material breach by Discovery Labs, expressed as a percent equal to the percentage of the aggregate Discovery Labs Fixed Fee invoiced by Battelle to Discovery Labs up to the date of such termination, plus any amount not yet invoiced by Battelle for the period from the date of the last invoice through the date of such termination [***].

K. "First Commercial Sale" occurs on the date following Registration of AEROSURF in the Territory on which (i) Discovery Labs, an Affiliate or a sublicensee sells AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), to a non-Affiliate and (ii) Discovery Labs or an Affiliate records Net Sales or Net License Revenues in accordance with U.S. (or other applicable) generally accepted accounting principles ("GAAP"), consistently applied.

L. "Net License Revenues" means royalties actually received by Discovery Labs or an Affiliate from third-party licensees or sublicensees on account of commercial sales of AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), including sales of related AEROSURF Consumables, in the Territory in accordance with terms and conditions of the applicable licensing or sublicensing agreement. For monies received by Discovery Labs or an Affiliate in a currency other than U.S. dollars, the monies shall be converted to U.S. dollars based on a commercially reasonable method in the industry then used by Discovery Labs in the preparation of its audited financial statements, consistently applied.

M. "Net Sales" means the amount recognized by Discovery Labs or an Affiliate, in accordance with U.S. GAAP (or by an Affiliate in accordance with applicable GAAP), representing the gross amount invoiced by Discovery Labs or an Affiliate as a result of arms-length, commercial transactions in the Territory on account of the sale of AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), including the sale of related AEROSURF Consumables [***], less all amounts customarily excluded from the calculation of net sales by Discovery Labs or its Affiliate, including by way of example, [***]. For sales denominated in a currency other than U.S. dollars, the sales shall be converted to U.S. dollars based on a commercially reasonable method in the industry then used by Discovery Labs in the preparation of its audited financial statements, consistently applied.

N. "Next Generation System" means any drug-device combination product or medical device, which (i) essentially and in all material respects utilizes, incorporates, derives from, are made using or based on the AEROSURF System for the treatment of RDS in premature infants developed by Battelle under this Agreement, or (ii) [***].

O. "Product Requirements Document" or "PRD" shall mean the detailed device requirements for the AEROSURF System and assumptions and data supplied by Discovery Labs to Battelle, and which is included in the Project Plan.
P. "Project" means the project as more particularly identified in the Project Plan.
Q. "Project Managers" refers to the individuals designated by each of Discovery Labs and Battelle from time to time to manage the overall coordination of the Project.
R. "Project Plan" means the confidential plan attached to this Agreement as Schedule 1, which includes the PRD and identifies appropriate steps contemplated for both Parties and key milestones contemplated to complete development of a device for use in Discovery Labs' planned phase 3 AEROSURF clinical program and, if AEROSURF is Registered, initial commercialization of AEROSURF, and the related timeline, costs and expenses to complete Stages 1 through 3 of the Project, together.
S. "Project Plan Fixed Cost" means the fixed investment amount established by the Parties to fund Stages 2 and 3 of the Project Plan, which may be adjusted after completion of Stage 1 Work. Project Plan Fixed Cost will be used solely to determine the Discovery Labs Fixed Fee, as more particularly set forth in Section 3.B(i).
T. "Registration" or "Register" means obtaining permissions, authorizations, registrations or approvals from the U.S. Food and Drug Administration ("FDA"), the European Commission ("EU") or other applicable regulatory authorities, as necessary to manufacture, use, commercialize and/or sell AEROSURF (or other combination drug/device product comprised of a Next Generation System and Discovery Labs' lyophilized KL4 surfactant for inhalation for the treatment of RDS in premature infants) in the Territory.
U. "Royalty Cap" means the aggregate maximum royalties to be paid by Discovery Labs to Battelle for performance of its obligations under the Project Plan during the Term of this Agreement. The amount of the Royalty Cap is set forth in Section 3.D(ii).
V. "Scope Change" means a change in the scope of the Product Requirements Document, including any assumptions and intentions of the Parties contained therein.
W. "Scope Change Order" means a written modification to this Project Plan agreed to and signed by both Parties reflecting the terms of a Scope Change.
X. "Services Agreement" means the Research and Development Services Agreement entered into between the Parties on June 22, 2012, as amended from time to time.
Y. "Stage 1 Work" means the initial work performed hereunder as agreed by the Parties, which is expected to result in a final, agreed Project Plan and which will be funded according to the terms of Section 3.A of this Agreement.
Z. "Territory" means all countries worldwide.

Unless otherwise defined, all references in this Agreement to sections and clauses refer to sections and clauses in this Agreement.

2. IMPLEMENTATION OF THE PROJECT.

A. General Scope.

This Agreement is in addition to, and not in substitution of, the Services Agreement, which covered work on aspects of the AEROSURF program. Any activities that are ongoing under the Services Agreement and any future proposals included under the Services Agreement by amendment shall be performed in accordance with the terms of the Services Agreement. The activities as defined in the Project Plan of this Agreement are required to further the AEROSURF program and will be performed under the terms of this Agreement.

The general scope of activities under this Agreement will include a three-stage Project Plan which, at a high level, shall consist of an initial stage to define the requirements of the AEROSURF System (Stage 1 Work), Stage 2, which will be devoted to Phase 3 device and disposables development ("Device Development") and Stage 3, which will complete all testing and verification to be in a position to manufacture AEROSURF System(s) for use in Discovery Labs' phase 3 clinical program and, if approved, initial commercial supply. The Parties also may agree from time to time to amend this Agreement to expand the scope or include other projects under this Agreement and will also enter into such other agreements as they deem necessary or appropriate to meet the objectives of this Agreement, including but not limited to a Quality Agreement. Upon completion of the Project Plan, the Parties intend to negotiate in good faith to enter into an agreement covering the manufacture of AEROSURF Systems, including AEROSURF Consumables, for use in the AEROSURF phase 3 clinical program. The Parties contemplate that, if AEROSURF is approved, they will negotiate in good faith to enter into a supply agreement providing for initial commercial supply.

B. Battelle's Contribution to the Project.

i. Battelle will use Commercially Reasonable Efforts to:

a. perform research and development services according to the Project Plan, and to meet the milestones according to the Project Plan and to otherwise perform its obligations pursuant to the Project Plan and under this Agreement. Battelle further agrees to exercise Commercially Reasonable Efforts to meet objectives and comply with directions and guidance with respect to the Project Plan, the PRD, and any Scope Change Order, that may be established from time to time by the Steering Committee or Discovery Labs, as appropriate, and to promptly and thoroughly inform the Steering Committee of the status of development efforts under this Agreement and the Project Plan; and

b. contribute, in accordance with the terms of this Agreement, its labor costs and expenses necessary to complete the work under the Project Plan, in exchange for the payments and other compensation provided by Discovery Labs in accordance with Section 3 herein.

C. Discovery Lab's Contribution to the Project.

i. Discovery Labs will use Commercially Reasonable Efforts to:
   a. perform its obligations set forth in the Project Plan;
   b. adhere to all provisions of this Agreement; and
   c. if Discovery Labs' clinical program achieves the desired results and if Discovery Labs successfully Registers AEROSURF in the U.S. for the treatment of RDS in premature infants, provide for the U.S. commercial launch of AEROSURF (based on the AEROSURF System or a Next-Generation System) following Registration in the U.S.; and perform or provide for all necessary marketing and sales activities to support the distribution of AEROSURF in the U.S. for the duration of the Agreement. Such activities may include, but shall not be limited to, adhering to Registration requirements in the U.S., conducting or providing for the manufacture of devices and drug product, and conducting or providing for marketing, selling, distribution and warranty of AEROSURF.

ii. Discovery Labs shall compensate Battelle according to the terms of Section 3.

D. Scope Change Orders.

i. Following agreement on a final Project Plan at the completion of Stage 1 Work, the Parties may enter into a Scope Change Order for the purpose of (a) incorporating the final Project Plan in this Agreement, (b) adjusting the Project Plan Fixed Cost and the associated Discovery Labs Fixed Fee based on the results of Stage 1 Work, and (c) incorporating such other changes that the Parties agree are necessary and appropriate.

ii. In addition, it may be necessary during the performance of the Project Plan, to enter into one or more additional Scope Change Orders to implement changes determined by Discovery Labs as being necessary or appropriate under the circumstances to meet its objectives. In that event, the Parties will negotiate in good faith to agree upon an appropriate cost and implementation plan for such Scope Change and enter into a Scope Change Order. To the extent that implementation of a Scope Change, as set forth in the related Scope Change Order, causes the date for completion of the Project Plan to be extended beyond the then current Milestone Date (as defined in Section 3.E(ii), below), then such Milestone Date shall be delayed for the period of such extension. By way of example, if implementation of a Scope Change Order would cause the Project Plan to be extended by one month, then the Milestone Date would be similarly extended to June 30, 2016.

E. Establishing Project Managers.

i. Each Party shall appoint an individual to serve as such Party's Project Manager, who shall be responsible for the day to day management of the Project and communications with the other Party and the Steering Committee, as may be appropriate to advance the purposes of this Agreement.

ii. Project Managers and their respective teams will be in frequent communications and contact as required to perform the Project Plan.

iii. Project Managers shall keep up to date, and otherwise maintain, the Project Plan, including, if appropriate, forecasts for Project spending, and will provide periodic updates, in such form as is acceptable to the Steering Committee.

iv. Each Project Manager will immediately notify the other of any event which is likely to substantially affect the Project or the timely completion of the Device Development Milestone.

v. The Parties will appoint initial Project Managers within 72 hours of the Effective Date. Each Party shall appoint and replace its Project Manager as it deems appropriate during the term of this Agreement. When possible, a Party will allow for a minimum of a week's transition if it elects to appoint a new Project Manager.

F. Establishing the Steering Committee.

i. Membership. The Steering Committee shall initially consist of a maximum of six members, with an even number of members from each Party, with all initial members to be appointed within fourteen calendar days after the Effective Date. A Discovery Labs member will serve as Chairman of the Steering Committee. The Chairman shall be responsible for scheduling special meetings, circulating the agenda and presiding as chair at each meeting. The size of the Steering Committee can be amended upon mutual agreement of the Parties. Each Party shall appoint and replace its representatives to the Steering Committee as it deems appropriate during the term of this Agreement.

ii. Meetings. During the period beginning with the Effective Date through the completion of Stage 3, the Steering Committee will meet in-person at a minimum of once each calendar quarter according to a schedule agreed by the Parties. After that period of time, in-person meetings shall be held as requested by a Party on no less than three (3) business days' advance notice (unless such notice is waived by all members). A majority of members must be present or otherwise available for a meeting to be constituted. Each Party may appoint a replacement or delegate for any member who is unable to attend a meeting of the Steering Committee. The location for each in-person meeting will alternate between Columbus, Ohio and Warrington, Pennsylvania. Each Party will bear its own expenses to prepare for and attend in-person Steering Committee meetings and these shall not be considered Project-related expenses for any purpose. The Steering Committee may conduct meetings (other than in-person meetings) by telephone or video conference and may act without a meeting by written consent signed by both Parties. Both Parties may contribute to the agenda for any upcoming Steering Committee meeting and meeting minutes must be taken during every meeting, however held. All such minutes and other records of the Steering Committee shall be available at all times to either Party. Employees of each Party who are not on the Steering Committee or delegates of a Party may attend meetings of the Steering Committee, as required to further the Project. Neither Party shall be entitled to instruct its representatives to refuse to attend or to convene any properly noticed and scheduled meeting as a means of avoiding the establishment of a quorum, and a deemed quorum shall exist if a Party shall fail for any reason to have its representatives in attendance (in person or by telephone or video conference) more than twice at any properly noticed and scheduled (or adjourned) meeting. The Steering Committee will establish such standing rules as it deems appropriate to conduct its work, to the extent that such rules are not inconsistent with this Agreement.

iii. At each quarterly meeting, and otherwise as needed, the Steering Committee will:
   a. Require members to indicate whether their respective Parties are pursuing the Project Plan in compliance with this Agreement;
   b. Hear updates on the Project Plan from the Project Managers;
   c. Evaluate the progress made since the date of the prior meeting and approve the results of the Project to date, in writing;
   d. Discuss and decide any issues brought to its attention by the Project Managers including without limitation those brought under Section 3 and Section 9.E or which a member of the Steering Committee wishes to raise; and
   e. Discuss and decide how to proceed with the Project if the Steering Committee does not approve the results to date.

G. Decision Making Generally.

i. For the duration of the Project, the Project Managers may resolve issues that arise in day-to-day operations under the Project Plan unless otherwise stated in this Section.

ii. The Steering Committee shall be responsible for resolving outstanding issues regarding the following:
   a. Any day-to-day issue or other matter that Project Managers cannot decide;
   b. Any and all changes in Project Plan dates and the Product Requirements Document and any updates or amendments thereto; and
   c. All other matters of any kind brought to its attention by a Party.

iii. The Steering Committee will use Commercially Reasonable Efforts to reach consensus on all matters before it. The Steering Committee will duly consider the input of the Project Managers in reaching its decisions. If the Steering Committee is unable to reach consensus on any matter within a reasonable time under the circumstances, either Party may escalate the matter in accordance with the terms of Section 6(A)(viii) (Dispute Resolution).

iv. Notwithstanding the foregoing, Discovery Labs shall have final decision-making authority and the final say on all matters relating to the design, Registration, manufacture, packaging, marketing, distribution and sale of the AEROSURF System, and any final decision made by Discovery Labs on such matters shall not be subject to any further review under the dispute resolution provisions of Section 6.A(ix) of this Agreement or in any court or other forum either at law or in equity.

3. COMPENSATION TO BATTELLE.

A. Stage 1 Work.

With respect solely to Stage 1 Work, Discovery Labs will pay Battelle fifty percent (50%) of Battelle's costs and expenses incurred, including Cost Overruns and Scope Changes, according to [***] invoices prepared by Battelle for all Stage 1 Work performed by Battelle under the Project Plan. Based on an estimated cost for Stage 1 Work of approximately [***], Discovery Labs expects that its share of Stage 1 Work will be approximately [***]. Battelle Invoices will indicate all costs incurred by Battelle for Stage 1 Work performed, and Battelle will provide further detail [***], through [***] detailed project plan reports. Discovery Labs shall pay all Battelle invoices in accordance with Section 3.C.

B. Stages 2 – 3 Work.

i. Discovery Labs Fixed Fee. The estimated Project Plan Fixed Cost as of the Effective Date is [***]. The estimated Discovery Labs Fixed Fee as of the Effective date is 50% of the Project Plan Fixed Cost, or [***]. The Project Plan Fixed Cost may be revised once by mutual agreement of the Parties following completion of the Stage 1 Work, to take into account any increase or decrease in anticipated costs of the Project Plan based on the results of the Stage 1 Work. If the Project Plan Fixed Cost is revised, the Discovery Labs Fixed Fee will be similarly revised to equal 50% of the revised Project Plan Fixed Cost. [***]. Battelle shall be solely responsible for any and all Cost Overruns related to its performance of its obligations under the Project Plan.

ii. Scope Changes. Discovery Labs shall be responsible for any increase in the Project Plan costs that result from Scope Changes detailed in Scope Change Orders approved under Section 2.D(ii). The Parties shall agree to [***]. In addition, [***], the Parties shall agree to [***]. Battelle shall be responsible for any Cost Overruns associated with any Scope Changes affecting Stages 2 and 3.

iii. Stages 2 – 3 Work Invoices. Discovery Labs Fixed Fee shall be payable in [***] over the period of performance set forth in the final Project Plan established following the Stage 1 Work. Battelle shall prepare [***] invoices, each of which shall reflect the Discovery Labs Fixed Fee [***] amount due, [***]. The [***] detailed project plan report shall also include such other information as may be agreed by the Parties.

iv. Detailed Project Plan Report. In addition, invoices shall be accompanied by a detailed report of actual work performed by Battelle in performing its obligations under the Project Plan, and, for Stage 1 Work, shall include [***].

v. Taxes. For all payments hereunder, [***] shall pay any [***], or similar taxes arising out of or in connection with the performance of this Agreement (other than those [***]), imposed by any authority, government or governmental agency, unless a valid exemption certificate, if applicable, is received. [***] shall be responsible for taxes based on [***].

C. Payment of Invoices; Financial Covenant.

i. Under no circumstances shall the amount payable by Discovery Labs for Battelle's performance under the Project Plan exceed the sum of the Discovery Labs Fixed Fee plus, [***] Scope Change Orders approved under Section 2.D(ii).

ii. [***] invoiced amounts shall be payable on a date no later than [***].

iii. All payments made to Battelle under this Agreement shall be in U.S. dollars and shall be made without reduction for, or withholding of, any tax assessment, fee, levy, or similar charge in lieu of tax of any nature, by bank wire transfer in immediately available funds to an account designated by Battelle.

iv. Discovery Labs shall maintain at all times aggregate available cash and cash equivalents (as reflected in its financial statements) sufficient to satisfy the amounts that would be due Battelle if invoices were [***]. If as of the last business day of a calendar quarter, any Battelle invoices to Discovery Labs are outstanding [***].

D. Royalties.

i. As consideration for Battelle's achievement of the Device Development Milestone, Discovery Labs will pay royalties to Battelle in an amount equal to [***] of Net Sales and Net License Revenues in the Territory. Royalty payments based on Net Sales or Net License Revenues in the U.S. shall be made [***]. Royalty payments based on Net Sales or Net License Revenues outside the U.S. shall be made [***].

ii. The payment of royalties by Discovery Labs to Battelle shall be subject to a Royalty Cap of Twenty Five Million dollars ($25,000,000). Upon payment of aggregate royalties equal to the Royalty Cap, Discovery Labs obligations to pay royalties under this Section 3.D shall terminate.

E. Warrants.

i. As consideration for Battelle's investment in the Project under this Agreement, on the Effective Date, Discovery Labs shall execute and deliver to Battelle a warrant, in the form of Exhibit A (the "Initial Warrant"), granting Battelle the right to purchase One Million (1.00M) shares of Discovery Labs common stock, par value $0.001 per share ("Common Stock"), at an exercise price per share equal to Five Dollars ($5.00), exercisable upon achievement of the Device Development Milestone, and expiring on the tenth anniversary date of the Effective Date.

ii. As consideration for the achievement of the Device Development Milestone on or before May 31, 2016 ("Milestone Date"), or such later date as may be determined under Section 2.D(ii), on the Effective Date, Discovery Labs will execute and deliver to Battelle a second Warrant, in the form of Exhibit B, granting Battelle the right to purchase 500,000 shares of Common Stock, at an exercise price per share equal to Five Dollars ($5.00), exercisable upon achievement of the Device Development Milestone, provided such event occurs no later than the Milestone Date, and expiring on the tenth anniversary date of the Effective Date.

4. SALES REPORTS, RECORD KEEPING AND AUDITS.

A. Battelle Records. Battelle shall keep complete, true and accurate books of account and records for the purpose of determining Stage 1 Work [***] invoices to be delivered by Battelle to Discovery Labs under this Agreement. Such books and records relating to all costs billed to Discovery Labs shall be kept at the principal place of business of Battelle or at such reasonably accessible location acceptable to Discovery Labs, as the case may be, [***] following the end of the [***] period to which they pertain. Such records, excluding Battelle's proprietary indirect rates and their associated calculations, will be open for inspection during such [***] period by a public accounting firm to whom Battelle has no reasonable objection. Such inspections may be made no more than [***], at reasonable times, on reasonable notice and at Discovery Labs' expense which shall include Battelle's direct costs, including labor costs, in providing for such an audit. Any under- or over-payment that is discovered shall be promptly reconciled.

B. Discovery Labs Reports. Beginning [***] with respect to which the first royalty payment to Battelle is made, Discovery Labs shall provide written reports [***] with respect to Net Sales and Net License Revenues in the U.S., and [***] with respect to Net Sales and Net License Revenues from outside the U.S., and shall state in each such report, separately for Discovery Labs, Affiliates and each sublicensee, the number, description, and aggregate Net Sales and Net License Revenues, by region, sold during [***].

C. Discovery Labs Records. Discovery Labs and its agents shall keep complete, true and accurate books of account and records for the purpose of determining the payments to be made to Battelle under this Agreement. Such books and records shall be kept at Discovery Labs' principal place of business for [***] following the end of [***] to which they pertain. Such records will be open for inspection during such [***] period by a public accounting firm to whom Discovery Labs has no reasonable objection, solely for the purpose of verifying payment obligations hereunder. Such inspections may be made no more than [***], at reasonable times, on reasonable notice and at Battelle's expense. Any under- or over-payment that is discovered shall be promptly reconciled.

5. TERM AND TERMINATION.

A. Term. This Agreement shall have a term ("Term") that shall begin as of the Effective Date and expire upon the fulfillment of all payment obligations of Discovery Labs to Battelle under this Agreement, unless sooner terminated as provided in this Section 5.

B. Bankruptcy.

With respect to bankruptcy or insolvency, if a Party shall:

i. admit in writing its inability to pay its debts generally as they become due;
ii. file a petition in bankruptcy or a petition to take advantage of any insolvency act which are not be dismissed within [***] after the filing thereof;
iii. make an assignment for the benefit of creditors;

iv. consent to the appointment of a receiver of the whole or any substantial part of its property;
v. on a petition in bankruptcy filed against it, be adjudicated a bankrupt, which is not dismissed within [***] after the filing thereof;
vi. file a petition or answer seeking reorganization or similar arrangement under applicable law;
vii. if a court of competent jurisdiction shall enter an order, judgment, or decree appointing, without the consent of the Party, a receiver of the whole or any substantial part of the Party's property, and such order, judgment or decree shall not be vacated or set aside or stayed within [***] from the date of entry thereof; or
viii. if, under the provisions of any other law for the relief or aid of debtors, any court of competent jurisdiction shall assume custody or control of the whole or any substantial part of a Party's property and such custody or control shall not be terminated or stayed within [***] from the date of assumption of such custody or control,

then, for any of the foregoing scenarios, the other Party shall have the right to terminate this Agreement upon [***] written notice to the Party subject to such circumstances.

C. ‘Failure of Purpose’ Termination Rights.

Either Party may terminate this Agreement on thirty (30) calendar days’ written notice to the other Party upon the occurrence of one or more of the following events (each, a “Failure of Purpose”):

i. After a good faith negotiation, the Parties fail to agree on a final Project Plan within [***] of the Stage 1 Work;
ii. Discovery Labs determines in good faith that (a) the AEROSURF clinical program (including with respect thereto, related preclinical studies) has failed or will fail to demonstrate the results needed to proceed with the AEROSURF development program based on the AEROSURF System, or (b) Discovery Labs is unable to achieve Registration of AEROSURF in the U.S.;
iii. After consultation, the Parties determine in good faith that, for reasons other than a material breach by a Party, the Project Plan cannot be completed for the reason of technical infeasibility;
iv. After consultation with Battelle, Discovery Labs determines in good faith that, for reasons other than a material breach by a Party, the Parties will be unable to complete the Project Plan within [***] after the then-current Milestone Date; or
v. Extended Force Majeure exceeding six months.

Other than as specifically set forth in this Agreement, including Discovery Labs’ obligation to pay Battelle invoices, [***]; provided that, if Discovery Labs terminates this Agreement pursuant to Clause (ii) of this Section 5.C after Battelle has successfully completed Stage 3, and if Discovery Labs or an Affiliate subsequently Registers AEROSURF based on the AEROSURF System developed by Battelle in the Territory [***], then Discovery Labs or an Affiliate [***] provided in Section 3.D(ii).

D. Termination for Breach.

If either Party believes the other is in material breach of its obligations under this Agreement, including failure to pay an undisputed amount due under this Agreement, it may give notice of such breach or payment failure to the other Party, which Party shall have thirty (30) calendar days after receipt of such notice in which to remedy such breach. If such alleged breach is not remedied in the time period set forth above, the non-breaching Party may terminate this Agreement and receive the liquidated damages set forth below, as their respective sole and exclusive monetary remedy, which liquidated damages are agreed in light of the difficulty in forecasting damages as of the Effective Date. Nothing in the foregoing shall preclude equitable remedies in addition to monetary remedies.

i. In the event Discovery Labs terminates this Agreement because of an uncured material breach by Battelle:
   a. Discovery Labs' obligation to pay royalties to Battelle shall cease;
   b. any outstanding warrants delivered to Battelle pursuant to this Agreement shall expire immediately and be of no further effect;
   c. At its expense, Battelle shall cooperate with Discovery Labs to complete the activities provided in Section 5.F; and
   d. Battelle shall pay to Discovery Labs within [***] (after receipt of an invoice from Discovery Labs) [***] of the amount paid by Discovery Labs to Battelle under Section 3 of this Agreement up to the effective date of termination, plus reasonable costs to cover transition to a successor.

ii. In the event Battelle terminates this Agreement because of an uncured material breach by Discovery Labs:
   a. Discovery Labs shall pay to Battelle all outstanding amounts then due from Discovery Labs under this Agreement, including unpaid invoiced amounts, and reasonable transition costs [***];
   b. Discovery Labs shall pay to Battelle within [***] (after receipt of an invoice from Battelle) [***] of the amount of the Project Plan Fixed Cost actually contributed by Battelle under the Project Plan up to the effective date of termination;
   c. if Discovery Labs or an Affiliate (i) completes the Project Plan without the assistance of Battelle, and (ii) [***]; and
   d. that percent of the Initial Warrant issued to Battelle on the Effective Date that equals the Discovery Labs Default Percent shall immediately become exercisable and remain outstanding for the period therein provided.

E. Section 365(n) of the Bankruptcy Code.

All grants, rights and licenses granted or created under or pursuant to this Agreement by Discovery Labs or Battelle are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non- subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

F. Post-Termination Activities.

In the event that either Party issues a notice of termination of this Agreement, the Parties will exercise Commercially Reasonable Efforts during the [***] period following issuance by a Party of such notice of termination to reach agreement regarding an appropriate wind-down plan, taking into account ethical responsibilities to patients in clinical trials (if any), control of any trailing project costs, and the stewardship of intellectual property and other assets created by the Parties hereunder. Battelle shall promptly transfer or return to Discovery Labs all data, reports, materials, Discovery Labs Inventions, designs, models, working embodiments, prototypes etc. of the device, and must take continuing action to disclose and transfer the know-how and technical information relating to the Project to Discovery Labs and to cooperate and take measures to assign to Discovery Labs and execute such documents as Discovery Labs may reasonably request to perfect Discovery Labs' title as sole owner of all Discovery Labs' Inventions. Except as provided in Section 5.D(i), Discovery Labs shall pay Battelle's reasonable expenses in complying with this Section 5.F. Battelle shall issue to Discovery Labs detailed invoices in a manner consistent with those prepared for Stage 1 Work described in Section 3.A.

6. TERMS AND CONDITIONS INCORPORATED BY REFERENCE.

A. The following provisions of the Services Agreement are incorporated herein by reference, provided that references in the Services Agreement to "Agreement", "Project", "Services" and other defined terms shall be construed to refer to such terms as defined in this Agreement or, if not so defined, in a manner to be consistent with the terms and conditions of this Agreement:

i.	Section 3	Intellectual Property
ii.	Section 4	No Endorsement: Public Announcement
iii.	Section 5	Confidentiality (excluding Section 5.3)
iv.	Section 7	Warranties; Limitation of Liability (excluding Section 7.2)
v.	Section 8	Indemnities
vi.	Section 13	U.S. Export Control
vii.	Section 14	Client Furnished Materials
viii.	Section 16	Dispute Resolution

B. [***].

C. Discovery Labs assumes responsibility for its use, misuse, or inability to use the Project results, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Battelle. Except as necessary to satisfy Third Party Claims (as defined in Section 8.1 of the Services Agreement) indemnified hereunder, [***], Battelle's total liability to Discovery Labs arising out of or related to this Agreement [***]. Except for a breach of Section 6.B or its confidentiality obligations hereunder and as set forth in the CDA, neither Party shall be liable to the other Party for any indirect, incidental, consequential, special, punitive or exemplary damages in connection with this Agreement or the Project, however caused, under any theory of liability. [***].

7. **INSURANCE**

Discovery Labs shall purchase and maintain, at its own expense, insurance in amounts reasonable and customary for the industry in which they operate. Discovery Labs shall maintain all insurance which is required by any law, statute, ordinance or regulation of any jurisdiction having authority in whole or in part over their operations. Nevertheless, the following minimum insurance coverage shall be maintained:

a. Clinical Trials Insurance: If any AEROSURF System or Next Generation System developed under this Agreement is used by Discovery Labs in clinical trial(s), prior to the first activity involving human subjects, Discovery Labs shall maintain no less than [***] of clinical trials liability insurance related to the AEROSURF System or Next Generation System in all territories (on a country-by-country basis) in which the Device is used in clinical trials involving human subjects.

b. Product Liability Insurance: Prior to the commercial sale of any AEROSURF System or Next Generation System, Discovery Labs shall maintain no less than [***] of product liability insurance related to the AEROSURF System or Next Generation System in all territories (on a country-by-country basis) in which the Device is commercially available. Such insurance shall cover any Discovery Labs products that may be developed in whole or in part based on Battelle's work under this Agreement and shall name Battelle Memorial Institute as an additional insured.

Discovery Labs shall maintain coverage with insurance companies that [***]. Should any of the insurance policies agreed to herein provide coverage on a claims-made basis, such insurance shall be kept in force for a period of [***]. Discovery Labs shall provide a certificate of insurance to Battelle evidencing such coverage prior to the first administration to a human subject of such product and prior to the sale of such product. Such certificate shall provide that, if a policy is cancelled, notice will be delivered as provided in the policy provisions. Discovery Labs shall use commercially reasonable efforts to provide at least thirty (30) days prior notice to Battelle of any cancellation, non-renewal, or relevant reduction in coverage.

8. REPRESENTATIONS AND WARRANTIES OF THE PARTIES.

Battelle and Discovery Labs each hereby represent and warrant to each other, as of the Effective Date, as set forth below:

i. It is duly organized and validly existing and in good standing under the laws of its jurisdiction of incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

ii. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.

iii. Its legal team (i) is not aware of any pending or threatened litigation involving the AEROSURF System and (ii) has not received any communications alleging that it has violated or would violate any rights (including intellectual property rights) of any third party; in each case, which if decided adversely, would reasonably be expected to have a material adverse effect upon such Party, its condition, financial or otherwise, or its business affairs or business prospects, or its ability to perform its obligations under this Agreement.

iv. To its knowledge, there is no material unauthorized use, infringement or misappropriation of any of its patents, copyrights, trademarks, trade secret rights or know-how necessary or useful to make, use or sell the AEROSURF System.

v. All of its employees, officers, contractors and consultants performing research and development services related to this Agreement have executed agreements requiring assignment to the Party of all inventions made during the course of and as a result of their association with such Party and obligating the individual to maintain as confidential the Confidential Information of such Party.

vi. It has the power, authority and legal right, and is free to enter into this Agreement and, in so doing, will not violate any other agreement to which it is a party as of the Effective Date.

vii. Battelle represents and warrants that, after due inquiry, it has not and will not knowingly employ, contract with or retain any person directly or indirectly to perform services under this Agreement, if such person is debarred by the FDA under 21 USC 335a(k) of the FDA Act or a regulator in the EU under similar laws. Upon written request from Discovery Labs, Battelle shall within five (5) business days confirm in writing that it has complied with the foregoing obligation.

viii. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not and will not, whether with the giving of notice or passage of time or both, conflict with or violate any requirement of any obligation, agreement, covenant or condition contained in any contract, indenture, credit agreement, or other agreement or instrument to which it is a party ("Agreements/Instruments"), (b) nor will such actions result in any violation of any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, as applicable, (c) nor will such actions result in any violation of any applicable law, statute, rule, regulation, judgment, order, writ or decree of any government, government instrumentality or court, domestic or foreign, having jurisdiction over the Company or any Affiliate or any of their assets, properties or operations; do not conflict with, violate, or breach or constitute a default or require any consent under, any applicable law or any Agreements/Instruments or court or administrative order by which such Party is bound; except, with respect to each of the foregoing clauses viii(a)-(c), for those or under those circumstances that would not reasonably be expected to have a material adverse effect upon such Party, its condition, financial or otherwise, or its business affairs or business prospects, or its ability to perform its obligations under this Agreement.

ix. Battelle acknowledges that the success of the Project Plan, and the efforts by Discovery Labs to secure Registration, and execute a commercial launch for, AEROSURF in the U.S. are subject to a variety of risks and uncertainties that could cause results to differ materially from those set forth in the Project Plan or otherwise anticipated by the Parties. Examples of such risks and uncertainties are set forth in Discovery Labs' Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 15, 2014 and in Discovery Labs' periodic and other reports filed with the SEC from time to time.

x. Discovery Labs acknowledges that its business strategy includes seeking to enter into a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise as well as financial resources for the AEROSURF development program, and, if AEROSURF is approved, support the commercial introduction of AEROSURF and/or AEROSURF System(s) in the EU and other selected markets outside the U.S. However, there can be no assurance that Discovery Labs will succeed, if at all, during the performance of this Agreement.

With respect to the foregoing, the term "knowledge" shall be deemed to refer to the personal knowledge of the respective Parties management and the legal team

9. MISCELLANEOUS.

A. Assignment. Except as otherwise provided for herein, neither Party may assign this Agreement without the written consent of the other Party, which consent may be granted or withheld in the other Party's sole discretion. Notwithstanding the foregoing, [***]. In any event, this Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 8(A) shall be void.

B. Compliance with Law. The Parties shall comply with appropriate legal, ethical and professional standards of behavior and conduct, and will exercise diligence in complying with all laws applicable to their relationship and to each Party's performance as described herein, including, but not limited to, the following U.S. laws: Foreign Corrupt Practices Act, the Export Administration Act, the Export Administration Regulations including the Anti-boycott Regulations and Guidelines, and any other applicable export regulations.

C. Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be effective on receipt, when sent via Internet email, hand-delivered, transmitted by facsimile, or sent by registered airmail or overnight courier and addressed to the Parties as noted below (or to such other address as may be provided in writing by a Party to the other Party in accordance with this Section).

For Battelle: Battelle Memorial Institute
Attn: General Counsel 505 King Avenue
Columbus, Ohio 43201

For Discovery Labs: Discovery Laboratories, Inc.
Attn: General Counsel
2600 Kelly Road, Suite 100
Warrington, PA 18976

D. Severability. If any part of this Agreement is found to be invalid or unenforceable by any court of competent jurisdiction, or if any government or other agency having jurisdiction over either Battelle or Discovery Labs deems any part thereof to be contrary to any antitrust or competition law, then such declaration shall not affect the remainder of the Agreement, which shall remain in full force and effect. To the extent possible, the Parties shall revise such invalidated part in a manner that will render it valid without impairing the Parties' original business purpose.

E. Force Majeure. Except as otherwise provided herein, no Party shall be in breach of this Agreement, or liable to the other Party, for any loss, damages, delay or failure of performance to the extent such loss, damages, delay or failure is caused by circumstances beyond its reasonable control. Circumstances beyond the reasonable control of a Party include, but are not limited to, fire, strikes, riots, wars, terroristic acts, martial law, extreme natural disaster, or threat of terroristic acts, embargoes, shortages, delays in transportation, environmental contamination by nuclear fuel or nuclear waste, inability to obtain supplies of raw materials or requirements or regulations of any government or any other civil or military authority. In the event of a force majeure situation, the obligations of the Parties under this Agreement shall be suspended as long as the force majeure situation continues. Should the force majeure situation continue for more than four (4) weeks, then the Steering Committee will make appropriate determinations of the effect of the force majeure on the contractual relationship between the Parties.

F. Non-Waiver. The failure of a Party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not be construed as a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion.

G. Disclaimer of Agency. Battelle's relationship with Discovery Labs is that of an independent Contractor and not as an agent, representative, or employee of Discovery Labs. This Agreement shall not constitute, create or give effect to, or otherwise imply a joint venture, corporation, partnership, or any other form of business entity of any kind. Each Party to this Agreement shall act as an independent contractor with respect to the other Party. Neither Party to this Agreement shall have any authority or control over the other Party or the other Party's employees, nor shall either Party have the power to bind the other Party, nor shall this Agreement be construed as creating any actual or implied authority or any type of agency relationship.

In addition, Discovery Labs specifically acknowledges that Battelle is a service provider and contract manufacturer and not a distributor or supplier and Discovery Labs retains all final decision making authority and all responsibility for the design, manufacture, packaging, marketing, distribution and sale of the AEROSURF System, including, without limitation, product labeling, warnings, and instructions to users.

H. Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

I. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

J. Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of and enforced within the jurisdiction of the State of Delaware without regard to the principles of conflict of laws.

K. Entire Agreement; Amendment. This Agreement, the Exhibits attached hereto, and together with the Services Agreement, the CDA, and any Quality Agreement between the Parties, sets forth the terms of the agreement regarding AEROSURF System between the Parties hereto and, except for the CDA incorporated therein, the Quality Agreement and as otherwise set forth herein, supersedes and terminates all prior representations, term sheets, agreements and understandings between the Parties regarding the subject matter hereof. No alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

L. Survival. The following provisions shall survive the termination or expiration of this Agreement: 3, 4, 5, 6(A)(i), 6(A)(iii)-(v), 6(A)(viii), 6(B), 6(C), 7, and 9(J).

[Signatures appear on the next page]

In Witness Whereof, the Parties have duly executed this Collaboration Agreement as of the Effective Date.

DISCOVERY LABORATORIES, INC.	**BATTELLE MEMORIAL INSTITUTE** **Corporate Operations**
By:	By:
Name: John G. Cooper	Name:
Title: President and Chief Executive Officer	Title:

EXHIBIT A: Initial Warrant

EXHIBIT B: Second Warrant

SCHEDULE 1: PROJECT PLAN

Proposal No. [***]

Next-Generation Aerosurf®
Delivery System, Stage 1

Prepared by

Battelle
505 King Avenue
Columbus, Ohio 43201

Prepared for

Lawrence Weinstein
Vice President, Medical Device Development
Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622
October 9, 2014

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

AMENDED AND RESTATED SUPPLY AGREEMENT

AMENDED AND RESTATED SUPPLY AGREEMENT dated as of December 3, 2004, by and between DISCOVERY LABORATORIES, INC. ("Seller") and LABORATORIOS DEL DR. ESTEVE, S.A., a company organized and existing under the laws of Spain ("Buyer").

WHEREAS, Seller and Buyer are parties to a Amended and Restated Sublicense and Collaboration Agreement (the "Revised Collaboration Agreement") dated as of the date hereof pursuant to which Buyer and Seller have agreed to collaborate in a product development, commercialization and marketing effort for the Licensed Products (such term and other capitalized terms used and not otherwise defined herein having the meanings assigned to them in the Revised Collaboration Agreement); and

WHEREAS, Buyer hereby agrees to purchase one hundred percent (100%) of its requirements of Licensed Products from Seller, and Seller hereby agrees to supply one hundred percent (100%) of Buyer's requirements of Licensed Products, pursuant to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants set forth below, Seller and Buyer mutually agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

"Current Good Manufacturing Practices" or "cGMP" shall mean (i) with respect to the United States, the good manufacturing practices required by the FDA and set forth in the Federal Food, Drugs and Cosmetics Act or FDA regulations, policies or guidelines in effect at a particular time for the manufacture, testing and quality control of pharmaceutical materials and (ii) with respect to any other country of the Licensed Territory, the standards for the manufacture and testing of pharmaceutical materials that are imposed by any regulatory authority having jurisdiction.

"Cost of Goods" means the costs incurred (including, without limitation, costs incurred with respect to Unrelated Third parties) for the Manufacture of Licensed Product (including, for the avoidance of doubt, the Manufacture of any device and related apparatus for administration thereof) for the Licensed Territory, all direct costs, and a reasonable fully-absorbed allocation of indirect and overhead expenses directly attributable to the Manufacture of the Licensed Product for the Licensed Territory. Direct costs shall include, without limitation, raw materials, equipment and labor and costs of plant operations, and plant support services. Indirect and overhead expenses shall include, without limitation, indirect charges incurred by or on behalf of Seller in connection with Manufacturing process improvements, spoilage, waste, storage, manufacturing scale up, Manufacturing site qualification, RA, QA and QC (including testing), supply chain management, capital equipment, customs duties or excise taxes, costs for plant operations and support services (including utilities, maintenance, engineering, designing, redesigning, safety, human resources, finance, and plant management) and similar activities to the extent reasonably allocated to the Licensed Product in the Licensed Territory including depreciation and amortization of capitalized costs of any of the foregoing; provided, that the royalties, if any, payable by Seller to its licensor(s) shall be deemed to not be a component of Cost of Goods. All components of Cost of Goods shall be allocated on a basis consistent with United States GAAP and consistent with the cost accounting policy applied by Seller to other products that it produces and, if it does not Manufacture any other products, consistent with the industry standard. The parties will endeavor in good faith to establish a "standard cost" per unit for purposes of ongoing cost accounting and invoicing purposes, which "standard cost" shall be reviewed and updated periodically as appropriate. The parties shall reconcile the standard cost charges against the standard cost per unit actually paid by Buyer and appropriate credit or payment shall be made to effect such reconciliation as directed by the Steering Committee not less than annually.

"Facility" means an Owned Facility or a Contract Facility (in each case as defined in Section 3.1).

"First Commercial Sale" shall mean the first commercial sale by Buyer, its Affiliates or sublicensees of any Licensed Product following final EMEA or other regulatory approval required to market such Licensed Product commercially in the Licensed Territory for use in humans.

"Licensed Product Purchase Price" shall mean, on a Licensed Product-by-Licensed Product basis, the sum of (i) Cost of Goods together with any markup as set forth in Section 2.2; and (ii) appropriate insurance, freight charges and, where applicable, custom duties.

"Manufacture" or "Manufacturing" shall mean manufacturing, filling, processing, testing, engineering, designing, redesigning, packaging, storing, quality control, quality assurance, releasing, disposing, handling, shipping, and all other activities undertaken or required to be undertaken in order to manufacture and supply Licensed Product in its final packaging (including, without limitation, package inserts and components reasonably necessary for sale of the finished Licensed Product to the ultimate consumer) and related devices and apparatus for administration thereof.

"Net Sales" shall mean that sum determined by deducting from the gross amount billed for Licensed Products by the Buyer or any of its Affiliates or sublicensees in an arms length transaction to customers, that are Unrelated Third Parties of the Buyer or of any of its sublicensees;

(i) transportation charges or allowances, including freight pickup allowances, and packaging cost, if any;

(ii) trade, quantity or cash discounts, services allowances and independent broker's or agent's commissions, if any, allowed or paid;

(iii) credits or allowances for the Licensed Products, if any, given or made on account of price, adjustments, returns, bad debts, off-invoice promotional discounts, rebates, chargebacks, any and all federal, state or local, government rebates or discounts whether in existence now or enacted at any time during the term of this Agreement, volume reimbursements, the gross amount billed and collected for rejected Licensed Products or Licensed Products subject to recall or destruction (voluntarily made or requested or made by an appropriate government agency, sub-division or department); and

(iv) any tax, excise or other governmental charge upon or measured by the production, sale, transportation, delivery or use of the Licensed Product;

(v) in each case determined in accordance with generally accepted accounting practices.

"Specifications" shall mean the Licensed Product specifications contained in the registration dossier of the Licensed Product as approved by the EMEA and the other regulatory authorities having jurisdiction in the Licensed Territory, as the same may be amended from time to time in accordance with applicable regulatory procedures.

"Transfer Price" shall mean as defined in Section 2.2.

"Unrelated Third Parties" shall mean Persons other than Buyer and Seller and Affiliates and sublicensees of Buyer and Seller or any other related Persons and shall include hospital formularies and other similar critical and therapeutic care providers who typically purchase and administer products and therapies such as the Licensed Products.

ARTICLE II
PURCHASE AND SALE OF PRODUCTS

Section 2.1. Purchase and Sale; Delivery; Acceptance or Rejection.

(a) Seller agrees to sell to Buyer such quantities of Licensed Products, manufactured in conformity with cGMP and meeting the Specifications, as Buyer may order in accordance with the terms and conditions of this Agreement. Subject to the provisions of Section 7.2 hereof, so long as this Agreement shall remain in effect, Buyer agrees, for itself and its Affiliates and sublicensees, to satisfy solely through the purchase of Licensed Products from Seller under this Agreement one hundred percent (100%) of Buyer's and its Affiliates' and sublicensees' requirements for Licensed Products.

(b) Purchase orders issued by Buyer to Seller with respect to purchases of Licensed Products shall be subject to, and governed exclusively by, the terms of this Agreement. Buyer agrees not to issue to Seller any purchase order containing terms different from those set forth herein and further agrees that no shipment of Licensed Product by Seller in accordance with a nonconforming purchase order shall be deemed to be acceptance of any terms of such purchase order conflicting with the terms of this Agreement except to the extent such conflicting terms are initialed by Seller with the words "change accepted" written thereon by Seller. Except as aforesaid, this Agreement shall override all other conflicting terms of purchase and/or sale contained in any purchase and/or sale document generated by Seller or Buyer.

(c) Subject to paragraphs (d) and (e) below, all Licensed Product sold to Buyer hereunder shall be delivered FCA Seller's Facility or distribution warehouse (Incoterms 2000). Seller shall assist Buyer in arranging transportation in the manner specified by Buyer, in accordance with applicable regulatory requirements, to any destinations specified in writing from time to time by Buyer.

(d) Buyer shall bear all costs and expenses relating to transportation and delivery to Buyer's designated distribution sites in the Licensed Territory (including without limitation all freight charges, customs, duties, taxes, insurance premiums and all expenses relating to validation of temperature-controlled shipment conditions), regardless of whether Seller delivers the Licensed Products to Buyer from Seller's Facility or distribution site/ warehouse whether in Europe or the United States; provided, however, that in the event that Seller transports Licensed Products from its United States Facility and/ or its United States distribution site/ warehouse to a European distribution site/ warehouse or Facility, if any, then delivers such Licensed Products to Buyer's designated distribution sites in the Licensed Territory, the Steering Committee shall promptly meet to establish in good faith a system whereby Buyer does not bear any such costs in excess of those that would have been incurred if Seller had delivered such Licensed Products directly from its United States Facility or distribution site/ warehouse to Buyer's designated distribution sites in the Licensed Territory.

(e) Seller shall maintain a cGMP quality control program, as required by governmental regulations in the Licensed Territory, with respect to the Manufacture of Licensed Products. Seller will perform appropriate testing programs, and provide Buyer with documentation arising from such testing programs, as may be agreed to by the parties or required by any applicable regulatory authority. Finished Licensed Product testing for release in the Licensed Territory or required by the EMEA for Licensed Product received by Buyer shall be performed by Seller at its designated approved testing site and paid for by Seller for Licensed Product shipped to Buyer. Seller shall provide Buyer with each Licensed Product shipment with the corresponding certificate of analysis conducted in a country of the European Union, certifying that each delivery of Licensed Product was produced and tested in compliance with (i) the Specifications, (ii) cGMP requirements and (iii) all applicable regulatory documents. The parties will discuss in good faith the possibility that the quality control for Licensed Product in the European Union ("EU-QC") shall be conducted by Buyer for an agreed upon fee to be paid by Seller. Should, ultimately, Buyer not be the agreed upon party to conduct EU-QC, Seller shall use its best commercial efforts to provide that certain equipment acquired, as of the date hereof, by Buyer for the purposes of conducting such EU-QC shall be purchased by such agreed upon Unrelated Third Party that shall conduct the EU-QC.

(f) Buyer may reject any portion of any shipment of Licensed Product which does not conform with the Specifications. In order to reject a shipment, Buyer must (i) give notice to Seller of Buyer's intent to reject the shipment within thirty (30) days of receipt together with a detailed written indication of the reasons for such possible rejection, and (ii) as promptly as reasonably possible thereafter, but in any event within an additional thirty (30) days, provide Seller with notice of final rejection and the full basis therefor. After notice of intent to reject is given, Buyer shall cooperate with Seller in determining whether rejection is necessary or justified. If such notices of intent to reject and final rejection are not timely received, Buyer shall be deemed to have accepted such delivery of Licensed Product and to have waived all claims for non-conformity with the Specifications, damage, defect or shortage, other than claims for latent defects not capable of discovery by Buyer upon physical examination. In the event of latent defects not capable of discovery by Buyer upon physical examination, Buyer shall inform Seller within fifteen (15) days of discovering any such defect. Buyer shall be entitled to an offset of the Licensed Product Purchase Price (reduced, however, by any customs or other charges related thereto that are recoverable or avoidable by Buyer) of properly rejected Licensed Products at the time they are ultimately rejected, provided that if Seller disputes the rejection, refund shall be made, if at all, at the time the dispute is finally resolved. Seller shall notify Buyer as promptly as reasonably possible (but in any event no later than thirty (30) days after receipt of Buyer's final rejection notice) whether it accepts Buyer's basis for any rejection. In the event Seller disputes Buyer's rejection, the parties will select a mutually agreeable independent third party laboratory which shall determine whether the rejected Licensed Products meet the applicable Specifications and shall confirm or dissent from Buyer's rejection of Licensed Products. If the parties are unable to agree on a laboratory firm within thirty (30) days after receipt of Buyer's final rejection notice, the laboratory shall be appointed by computer generation of a random number, with an even number signifying Seller's right to designate the laboratory and an odd number designating Buyer's right to designate the laboratory. If the independent tester confirms Buyer's rejection, Seller will pay the fees of the tester, and if the tester dissents from Buyer's rejection, Buyer will pay the fees.

(g) Whether or not Seller accepts Buyer's basis for rejection, promptly on receipt of a notice of rejection, Seller shall use its commercially reasonable efforts, at Buyer's request, to provide replacement Licensed Product, which shall be purchased by Buyer as provided in this Agreement as soon as reasonably practicable.

(h) Unless Seller requests the return to it of a rejected batch within sixty (60) days of receipt of Buyer's final notice of rejection, Buyer shall, at Seller's cost, destroy such batch promptly and provide Seller with certification of such destruction. Buyer shall, upon receipt of Seller's request for return, promptly dispatch said batch to Seller, at Seller's cost.

(i) No change to the Specifications shall be effective unless the same shall be required or permitted by any regulatory agency having jurisdiction over (i) any country in the Licensed Territory, (ii) Buyer or (iii) the Licensed Products (and if not required, shall be agreed to in writing by Buyer and Seller). Seller shall give Buyer advance notice of any change to the Specifications required by a regulatory agency.

2.2 Transfer Pricing. Buyer shall purchase Licensed Products from Seller at a "Transfer Price" that is determined on a Licensed Product-by-Licensed Product basis and otherwise as follows:

(a) With respect to Surfaxin® for RDS and/ or BPD, the Transfer Price to be paid by Buyer to Seller will be the sum of the following:

(i) [***]% of Seller's Cost of Goods for the subject Licensed Product supplied for the Licensed Territory;

(ii) Seller's royalty obligations due with respect to the subject Licensed Product sold by Buyer in the Territory; and,

(iii) X% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

Provided, however, that the Transfer Price determined in accordance with this Section 2.2(a) shall be equal to **[***]**% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

(b) With respect to the Licensed Product for the treatment of ARDS, the Transfer Price to be paid by Buyer to Seller will be the sum of the following:

(i) [***]% of Seller's Cost of Goods for the subject Licensed Product supplied for the Licensed Territory;

(ii) [***]% of Seller's royalty obligations due with respect to the subject Licensed Product sold by Buyer in the Territory; and,

(iii) X% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

Provided, however, that the percentage to be determined pursuant to Section 2.2(b)(iii), above, shall be mutually determined in good faith by

the parties (X) within 6 months of the date of completion of a Phase 3 clinical trial for the subject Licensed Product (defined as the date when all substantive data shall be available to the parties) and (Y) based upon a methodology that is intended to ensure that both Buyer and Seller achieve reasonable profits with respect to the Licensed Product; provided, however, that in no case shall the Transfer Price be lower than **[***]**% or higher than **[***]**% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***]
HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE
COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

(c) With respect to all other Licensed Products, the Transfer Price (determined on a Licensed Product-by-Licensed Product basis) to be paid by Buyer to Seller will be the sum of the following (provided, however, that this Section 2.2(c) shall specifically exclude any New Products, as such term is defined in Section 2.5 of the Revised Collaboration Agreement):

(i) [***]% of Seller's Cost of Goods for the subject Licensed Product supplied for the Licensed Territory;

(ii) [***]% of Seller's royalty obligations due with respect to the subject Licensed Product sold by Buyer in the Territory; and,

(iii) X% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

Provided, however, that the percentage to be determined pursuant to Section 2.2(c)(iii), above, shall be mutually determined in good faith by the parties (X) within 6 months of the date of completion of a Phase 3 clinical trial for the subject Licensed Product (defined as the date when all substantive data shall be available to the parties) and (Y) based upon a methodology that is intended to ensure that both Buyer and Seller achieve reasonable profits with respect to the Licensed Product; provided, however, that the parties acknowledge that it is their mutual intent that the target Transfer Price determined pursuant to this Section 2.2(c) shall be **[***]**% and, further, that in no case shall the Transfer Price be lower than **[***]**% or higher than **[***]**% of Net Sales of the subject Licensed Product in the Territory (to be determined on a country-by-country basis).

For the avoidance of doubt, the parties hereby acknowledge and agree that the Transfer Price for each Licensed Product determined in accordance with this Section 2.2 shall be determined by the parties in good faith and shall be based upon a mutually agreeable methodology that is intended to ensure that both Buyer and Seller achieve reasonable profits with respect to sales thereof.

2.3 Reports, Reconciliation and Audit, Transfer Price Payments.

(a) Seller shall invoice Buyer on the date of each shipment of Licensed Products delivered by Seller to Buyer, its Affiliates or sublicensees at the Licensed Product Purchase Price. Buyer shall pay Seller's invoices no later than thirty (30) days following the date of the applicable invoice by electronic funds transfer in immediately available funds to such bank account(s) as Seller shall designate. Notification as to the date and amount of any such electronic funds transfer shall be provided to Seller at least two (2) Business Days prior to such transfer.

(b) Reports. Buyer, within 30 days after the first day of January, April, July, and October of each contract year, shall deliver to Seller a true and accurate report giving such particulars on a monthly basis of each of the Licensed Products: (i) shipped and invoiced by Seller to Buyer; (ii) invoiced by Buyer and its Affiliates and sublicensees to Unrelated Third Parties; (iii) the gross sales of such Licensed Products (disclosing the quantity of each of the Licensed Products) and the calculation of Net Sales thereon; (iv) the calculation, in accordance with Section 2.2 of this Agreement, of the Transfer Prices thereon, in each case during the preceding 3 months under this Agreement (each a "Contract Quarter") as are pertinent to perform an accounting of amounts due under this Agreement and (v) the difference between the Transfer Price and the Licensed Product Purchase Price invoiced by Seller in the Contract Quarter (the "Balance"). The reports referred to herein (each a "Report") shall be separately delineated not only with respect to the Licensed Products but also with respect to the different countries of the Licensed Territory and shall be in a standard format agreed by Buyer and Seller prior to the first Report delivery. Transfer Price amounts owed by Buyer to Seller shall be calculated on a product-by-product and country-by-country basis taking into account, in each instance, the average of the Euro/ U.S. Dollar exchange rate for the first and last business day of each month of the Contract Quarter as quoted in the New York version of the Wall Street Journal.

(c) Balance Payments. Balance amounts owed by Buyer to Seller under this Section 2.3 shall be paid in U.S. Dollars and shall be free of all withholdings of any nature whatsoever (including, without limitation, withholding taxes, monetary transfer fees, or similar taxes and charges), and in the event any withholding is required, Buyer shall pay the same together with such additional amount as is required so that each such payment shall be, under any circumstances and in any event, in the amount as set forth or referred to herein. Balance amounts shall be payable within five (5) Business Days of receipt by Buyer of the relevant invoice issued by Seller that shall be in accordance with the applicable Report (as set forth in Section 2.3(b)) by electronic funds transfer in immediately available funds to such bank account(s) as Seller shall designate. Notification as to the date and amount of any such electronic funds transfer shall be provided to Seller at least two (2) Business Days prior to such transfer.

(d) Reconciliation and Audit.

(i) Reconciliation. Within 15 days of Seller's receipt of a Report provided by Buyer to Seller in accordance with Section 2.3(b), Seller shall inform Buyer in writing of Seller's assent or non-assent with respect to the calculations contained therein. In the event that Seller does not agree with such calculations, it shall notify Buyer of the reasons therefor and the parties hereby agree to promptly discuss and reconcile any material differences in the calculation of Transfer Price amounts owed by Buyer to Seller and make appropriate adjustment with respect thereto.

(ii) Audit. Each party shall keep such records as are necessary to determine accurately the sums due under this Agreement. Such records shall be retained by the party (in such capacity, the "Recording Party") and, at any time during the applicable contract year and for 3 contract years thereafter, at the prior written request and expense of the other party, shall be made available for inspection, review, and audit during normal business hours, by an internationally recognized independent certified public accounting firm appointed by such other party and reasonably acceptable to the Recording Party for the sole purpose of verifying the Recording Party's accounting reports and payments made or to be made pursuant to this Agreement; provided, however, that such audits may not be performed by either party more than once per contract year. The results of each inspection, if any, shall be binding on both parties except in the event of fraud. The auditing party shall pay for such inspections, except that in the event where the adjustment shown by such inspection is greater than 10% of the amount incurred, then the Recording Party shall pay for such inspection.

ARTICLE III
PRODUCTION OF PRODUCTS

Section 3.1. Manufacturing of Licensed Products.

(a) Until such time, if any, as a Seller-owned manufacturing facility (an "Owned Facility") is qualified for the manufacture of Licensed Products sold to Buyer hereunder, Seller shall manufacture or have manufactured the Licensed Products sold to Buyer hereunder at a contract manufacturing facility (a "Contract Facility") selected by Seller and reasonably acceptable to Buyer. The parties hereby acknowledge and agree that it is the intent of the Seller that as soon as it may be practicable Seller shall maintain at least one alternate production site for Licensed Products sold to Buyer hereunder, which alternate production site, if a Contract Facility, shall also be selected by Seller and reasonably acceptable to Buyer. Seller may also satisfy its obligation for an alternate manufacturing facility through a sublicensing arrangement complying with Section 3.2.

(b) Seller shall be responsible for obtaining and maintaining all necessary licenses, registrations, authorizations and approvals (other than such licenses, registrations, authorizations and approvals that are required to be obtained or made by an owner or operator of a Contract Facility) which are necessary to manufacture, handle, store, label, package, transport and ship Licensed Products under cGMP conditions and in accordance with other regulatory requirements.

(c) Seller shall provide Buyer with copies of any correspondence sent from Seller to governmental entities relating to the manufacturing, handling, storage, labeling, packaging, transportation or shipment of Licensed Products at the time such correspondence is sent by Seller, purged of Seller proprietary and/or confidential information and trade secrets. Seller shall provide Buyer with copies of any comments, responses, notices or other correspondence received by Seller from any governmental entity relating to the foregoing matters within five (5) Business Days of receipt of such correspondence by Seller, purged of any Seller proprietary information and/or trade secrets.

(d) Seller shall furnish to Buyer (i) a summary of any report or correspondence issued by a governmental entity (or a third party authorized by a governmental entity) in connection with a visit or inquiry relating to any Owned Facility or, to the extent Seller is provided with such information, any Contract Facility, including but not limited to, any FDA Form 483 or warning letter and (ii) not later than ten (10) Business Days after the time Seller provides such to a governmental entity, summaries of any and all proposed responses or explanations relating thereto, in each case purged of trade secrets or other confidential or proprietary information of Seller. After the filing of a response with the appropriate governmental entity, Seller will notify Buyer of any further oral and/or written contacts with a governmental entity (or a third party authorized by a governmental entity) relating to the manufacturing, handling, storage, labeling, packaging, transportation or shipment of Licensed Products.

(e) If requested in writing by Buyer, Seller shall permit Buyer to inspect, once per year, during normal business hours, Seller's Facilities and manufacturing records to the extent Buyer deems it reasonably necessary to enable Buyer to verify compliance with any statutory or regulatory requirements to which Buyer is subject and which are applicable to the manufacture and/or packaging of Licensed Products. Notwithstanding the foregoing, Buyer shall have the right to inspect Seller's Facilities and manufacturing records at any time, in the event that there is a quality or regulatory problem with any Licensed Product. If, as a result of any such inspection, Buyer reasonably and in good faith concludes that Seller is not in compliance with any regulatory obligations or requirements applicable to Buyer, Buyer shall so notify Seller in writing, specifying such areas of noncompliance in reasonable detail and Seller shall remedy the problems identified.

(f) Seller agrees to use all reasonable efforts to promptly rectify or resolve any deficiencies noted by a governmental entity (or third party authorized by a governmental entity) in a report or correspondence issued to Seller with respect to an Owned Facility or a Contract Facility.

Section 3.2. Subcontracting. It is understood and agreed that Seller shall have the right in connection with its performance hereunder to contract with such third parties as Seller deems advisable to manufacture Licensed Products, provided that (i) manufacture and/or quality control by any such third party has been authorized by the competent regulatory authorities in the Licensed Territory, (ii) Seller shall provide Buyer with not less than fifteen (15) Business Days' advance notice of its intent to contract with any third party and shall identify such third party to Buyer, (iii) Buyer may audit Seller's contractor's qualifications and (iv) Seller shall remain fully liable for its performance hereunder to the same extent as if such contractor had not been engaged.

Section 3.3. Exclusivity. On a country-by country basis, for so long as the Revised Collaboration Agreement remains in effect with respect to any such country in the Licensed Territory, until such time as Buyer has a fully paid-up license in such country in accordance with the terms of the Revised Collaboration Agreement, Seller shall supply Licensed Products only to Buyer intended for distribution within such country.

Section 3.4. Allocation of Supplied Licensed Products. In the event of shortage or inability to timely supply the required Licensed Product, Seller undertakes and agrees that the amounts of Licensed Products available shall be allocated on an equitable basis according to forecasts received and that Buyer shall not be treated less favorably than Seller, its Affiliates and other distributors and/or sublicensees.

ARTICLE IV
QUANTITY FORECASTS; ORDERS

Section 4.1. Forecasts. (a) In order to assist Seller in planning its production, commencing sixty (60) days prior to the calendar month in which the First Commercial Sale of Licensed Products takes place in any country in the Licensed Territory, Buyer shall provide Seller with a twelve (12) month rolling forecast of the quantities of such Licensed Product required by Buyer, by month, for the following twelve (12) months. The first three (3) months of such projections shall constitute a binding commitment to order the quantity of such Licensed Product forecast for such period, provided that with respect to the first twelve (12) months following such First Commercial Sale of Licensed Products in any country in the Licensed Territory, only the first month's forecast with respect to such country shall be binding provided that the portion of such forecast relating to such country is separately stated and is so indicated. Projections for months four (4) through twelve (12) (or, as provided above with respect to product launches in the Licensed Territory, months two (2) through twelve (12)) shall be made in good faith and shall constitute Buyer's best estimates of future orders, but shall not be binding on Buyer. Updated twelve (12) month forecasts will be provided at the beginning of each succeeding calendar month for the twelve (12) month period commencing sixty (60) days thereafter. Buyer's forecast shall also describe anticipated regulatory modifications to any English language version of Licensed Product labeling proposed by Seller. Seller shall, no later than fifteen (15) Business Days after receipt of each such forecast, notify Buyer in writing of any prospective problems of which Seller is aware of that might prevent Seller from meeting Buyer's forecast order quantities or estimated delivery dates.

(b) Notwithstanding Buyer's obligation to provide forecasts as set forth in Section 4.1(a), Buyer hereby agrees that it shall provide Seller with its firm purchase orders for Licensed Product in accordance with the lead-times and batch size increments to be specified by Seller in writing as soon as reasonably practicable but in any event before Buyer places its first order for Licensed Products, such lead-times and batch sizes to be applicable during the term of this Agreement unless otherwise agreed in writing by the parties; provided, however, that Buyer shall have the right, up to the date of manufacture, to issue binding change orders to increase or decrease such purchase orders with the consent of Seller, which shall not be unreasonably withheld so long as Buyer agrees to compensate Seller for any damages suffered by Seller as a consequence of such change order (including damages attributable to loss of allocable overhead recoupment, but excluding loss of profit), provided that Seller shall advise Buyer before carrying out any change order of Seller's estimated increased cost of doing so. Buyer agrees to accept partial shipments of Licensed Products should, for any reason, it become necessary to ship in advance of order completion, provided that Seller shall (i) give advance written notice to Buyer of such shipment and (ii) bear any additional cost to Buyer of receiving Licensed Products in partial shipments. Seller shall make all commercially reasonable efforts to comply with any revisions to purchase order requirements consistent with the provisions of Section 4.1(a) and this Section 4.1(b). Seller, within ten (10) Business Days after the date that a purchase order is issued to it, shall acknowledge receipt of Buyer's order and confirm in writing that the order can be supplied. For purposes hereof, a purchase order will be deemed issued on the earlier of (i) the date that Seller receives the purchase order via mail and (ii) the date of receipt of the telecopied purchase order.

Section 4.2. Purchase Order Contents. (a) Each purchase order shall specify the quantity, concentration and container size of Licensed Product ordered within the Specifications, and the required delivery schedule. Seller shall use reasonable commercial efforts to deliver each shipment of Licensed Product within five (5) days of the delivery dates specified in the delivery schedule set forth in Buyer's purchase order relating thereto (provided that in no event shall any such delivery dates be less than the lead time established pursuant to Section 4.1(b), unless otherwise consented to by Seller) using carriers mutually agreeable to Buyer and Seller. Seller shall use commercially reasonable efforts to accommodate "Rush" orders from Buyer.

(b) When all appropriate validation and quality control release criteria for a particular shipment of Licensed Product have been met (the "Release Date"), Seller shall notify Buyer in writing of the expected delivery dates (including details of destination, date and time) to enable delivery and receipt to be coordinated. Title and risk of loss to Licensed Products shall pass to Buyer upon delivery of Licensed Products by Seller to the carrier.

Section 4.3. Packaging. (a) Licensed Products shall be delivered to Buyer as finished goods in final packaged and labeled form, quality controlled in accordance with Section 2.1(e) and ready for resale to the ultimate customer and in accordance with the packaging requirements set forth in the Marketing Regulatory Approvals.

(b) Buyer shall distribute all Licensed Products as packaged by Seller in accordance with Section 4.3(a). In no event shall any Licensed Products be repackaged or reconfigured by Buyer without Seller's prior written consent.

Section 4.4. Labeling. With respect to each country in the Licensed Territory, prior to distribution of a Licensed Product, Buyer shall provide Seller with evidence of the regulatory approval of labeling specifications for such Licensed Product in such country and any variations required by the applicable regulatory agency. All such materials shall be provided to Seller together with a proper English translation. Seller shall distribute Licensed Products bearing only labeling supplied or approved by Buyer and in accordance with such regulatory requirements.

ARTICLE V
CERTAIN OBLIGATIONS OF BUYER

Buyer agrees to ascertain and comply with all applicable laws and regulations and standards of industry or professional conduct in connection with the use, distribution or promotion of the Licensed Products, including without limitation, those applicable to product claims, labeling, approvals, registrations and notifications, and also to obtain Seller's prior written consent to all claims, labels, instructions, packaging or the like, which consent shall not be unreasonably withheld.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

ARTICLE VI
REGULATORY MATTERS

Section 6.1. Information Regarding Regulatory Approvals. Seller shall promptly advise Buyer in matters pertaining to U.S. regulatory requirements relating to Seller's activities hereunder. Seller shall also provide to Buyer reasonable advance notice of any regulatory submission containing information or data provided by Buyer to Seller which Seller intends to disclose to regulatory agencies under this Agreement.

Section 6.2. Quality Control Program; Additional Testing Programs. Seller shall maintain a quality control program consistent with cGMP, as required by the FDA and/or any other governmental entity in the Licensed Territory, with respect to Seller's manufacture of Licensed Products hereunder. In addition, Seller will perform such additional testing programs, and provide Buyer with documentation arising from such testing programs, as may be agreed to by Buyer and Seller or required by any applicable regulatory authority.

Section 6.3. Retention of Samples. Seller shall retain as samples such quantities of Licensed Products from each batch of Licensed Product as Buyer shall reasonably request. Retained samples shall be maintained in a suitable storage facility for one (1) year past the product's expiration date. All such samples shall be available for inspection and testing by Buyer at reasonable times and upon reasonable notice.

Section 6.4. Recalls. Buyer shall notify Seller promptly if any Licensed Product is the subject of a recall, market withdrawal or correction within the Licensed Territory (a "Recall"), and Buyer and/or its designee shall have sole responsibility for the handling and disposition of such Recall. Buyer and/or its designee shall bear the costs of all Recalls of Licensed Products except to the extent that such Recall shall have been the result of Seller's breach of any of the warranties set forth in this Agreement and/or the Revised Collaboration Agreement, in which case Seller will promptly reimburse Buyer to such extent for actual, direct costs sustained as a result of the Recall. In the event that Seller disputes Buyer's determination that the fault is due to Seller and/or to its agent, the parties will select a mutually agreeable outside consulting firm which will be instructed to review the applicable information and data and to confirm or dissent from Buyer's determination. If the consulting firm confirms Buyer's determination, Seller will pay the fees of such consulting firm. Buyer and/or its designee shall maintain records of all sales of Licensed Products and customers sufficient to adequately administer a Recall, market withdrawal or correction for a period of three (3) years after termination or expiration of this Agreement. Except as required by law, Buyer and/or its designee shall serve as the sole point of contact with the applicable governmental entity concerning any Recall within the Licensed Territory with respect to Licensed Products and Seller shall serve as the sole point of contact with the FDA with respect to any Recall. In the event that Seller is required to communicate with the FDA with respect to Recall of Licensed Products, Seller shall within one (1) Business Day notify Buyer of such communication.

ARTICLE VII
TERMINATION; RIGHTS AND OBLIGATIONS UPON TERMINATION

Section 7.1. Term. This Agreement shall commence on the date hereof and shall continue in effect with respect to each Licensed Product in each country in the Licensed Territory, unless the parties mutually agree to extend such term, for so long as the Revised Collaboration Agreement remains in effect with respect to such Licensed Product in such country(ies).

Section 7.2. Termination for Default. If either party materially defaults in the performance of any material agreement, condition or covenant of this Agreement and such default or noncompliance shall not have been remedied, or steps initiated to remedy the same to the other party's reasonable satisfaction, within ninety (90) days (or thirty (30) days in the case of non-payment) after receipt by the defaulting party of a notice thereof from the other party, the party not in default may terminate this Agreement. A material breach or default of this Agreement shall be considered as a material breach or default under the Revised Collaboration Agreement, and Section 8.2 of the Revised Collaboration Agreement shall apply.

Section 7.3 Rights and Obligations on Expiration or Termination. Except to the extent expressly provided to the contrary, the following provisions shall survive the termination of this Agreement: Sections 6.3 and 6.4 and Articles I and VIII through X. Any rights of Seller to payments accrued through termination as well as obligations of the parties under firm orders for purchase and delivery of Licensed Products at the time of such termination shall remain in effect, except that in the case of termination under Section 7.2, the terminating party may elect whether obligations under firm orders will remain in effect and except that Seller will have no obligation with respect to delivery dates more than three (3) months after termination.

ARTICLE VIII
WARRANTIES; REPLACEMENT OF PRODUCTS; INSURANCE

Section 8.1. Warranties. Seller warrants to Buyer for itself and on behalf of its subcontractors and agents who assume any of Seller's obligations hereunder that (i) when shipped to Buyer by Seller, the Licensed Products will conform to the Specifications, as then in effect, and will not be (A) adulterated or misbranded within the meaning of the Food, Drugs & Cosmetic Act or (B) be an article which may not, under the provisions of the Food, Drugs & Cosmetic Act, be introduced into interstate commerce, and (ii) any Facility used by Seller will remain in compliance with cGMP at all times during the term of this Agreement and (iii) Seller shall obtain and maintain all necessary permits, registrations and licenses necessary to carry out its obligations pursuant to this Agreement. The foregoing warranties are the only warranties made by Seller with respect to the Licensed Products delivered hereunder, and may only be modified or amended by a written instrument signed by a duly authorized officer of Seller and duly authorized officer of Buyer. THE EXPRESS WARRANTIES CONTAINED IN THIS ARTICLE 8 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTIBILITY OR FITNESS FOR A PARTICULAR USE.

Section 8.2. Replacement of Licensed Products. Any Licensed Products delivered to Buyer by Seller which do not conform to the Specifications and are properly rejected as set forth in Article 2, or which are otherwise not in compliance with the warranties made in Section 8.1, shall be replaced, or Buyer's account may be credited, at Buyer's election. The remedy of replacement or credit shall not be available if and to the extent that such nonconformance was caused by Buyer's misuse, unauthorized modification, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, transportation, use beyond any dating provided, by accident, fire or other hazard. THE EXPRESS OBLIGATIONS STATED IN THIS SECTION 8.2 AND IN SECTIONS 2.1 AND 8.3 ARE IN LIEU OF ALL OTHER LIABILITIES OR OBLIGATIONS OF SELLER FOR DAMAGES, INCLUDING BUT NOT LIMITED TO DIRECT OR CONSEQUENTIAL DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THE DELIVERY, USE OR PERFORMANCE OF THE PRODUCTS.

Section 8.3. Insurance. Buyer and Seller shall maintain during the term of this Agreement products liability insurance policies, covering their respective obligations under this Agreement, issued by reputable insurance companies under ordinary terms and conditions in the pharmaceutical industry and will prove the existence thereof to the other party if so requested.

ARTICLE IX
MISCELLANEOUS

Section 9.1. Entire Agreement This Agreement constitutes the entire agreement and understanding between the parties as to the subject matter hereof. All prior negotiations, representations, agreements, contracts, offers and earlier understandings of whatsoever kind, whether written or oral between Seller and Buyer in respect of the subject matter of this Agreement, are superseded by, merged into, extinguished by and completely expressed by this Agreement (including, without limitation, the Supply Agreement dated March 6, 2002, and the Supply Agreement dated October 26, 1999, in each case between Buyer and Seller). No aspect, part or wording of this Agreement may be modified except by mutual agreement between the Seller and Buyer taking the form of an instrument in writing signed and dated by duly authorized representatives of both Seller and Buyer. The representation and warranties made by Licensor (i.e. Seller) and Licensee (i.e. Buyer) in the Revised Collaboration Agreement are incorporated herein by reference, provided that no breach of such representations and warranties shall be the basis for the termination of this Agreement unless the Revised Collaboration Agreement is terminated simultaneously.

Section 9.2. Notices Any notice or communication or permitted to be given by this Agreement shall be given by post-paid, first class, registered or certified mail or reputable courier service addressed to:

In the case of Seller: Discovery Laboratories, Inc.
2600 Kelly Drive
Warrington, Pennsylvania 18976
Attention: David L. Lopez, Esq., CPA
Senior Vice President and General
Counsel

With a copy to: Dickstein Shapiro Morin & Oshinsky, LLP
1177 Avenue of the Americas,
New York, NY 10036-2714
Attn: Ira L. Kotel, Esq.
Facsimile: (212) 997-9880

In the case of Buyer: Laboratorios del Dr. Esteve, S.A.
Av. Mare de Déu de Montserrat, 221
08041 Barcelona (Spain)
Attention: Development Director
Facsimile: (34) 93 433 00 72

With a copy to: JAUSAS
Av. Diagonal 407 bis, 10th Floor
08008 Barcelona (Spain)
Attention: Hector Jausas
Facsimile: (34) 93 415 20 51

Such addresses may be altered by notice so given. If no time limit is specified for a notice required or permitted to be given by this Agreement, the time limit therefor shall be ten (10) Business Days, not including the day of mailing. Notice shall be considered made as of the date of deposit with the appropriate Post Office or courier service.

Section 9.3. Governing Law. This Agreement and its effect are subject and shall be construed and enforced in accordance with the laws of the State of New York, United States (without giving effect to the principles of conflict of laws), except as to any issue which depends upon the validity, scope or enforceability of any patent within the Patent Rights, which issue shall be determined in accordance with the applicable patent laws of the country of such patent.

Section 9.4. Representations regarding Authorization; Organization; Corporate Action; No Conflicts. Each party hereto severally represents and warrants that it is a duly organized and validly existing corporation and/or partnership under the laws of its jurisdiction of incorporation, and has taken all required corporate action to authorize the execution, delivery and performance of this Agreement and the Revised Collaboration Agreement and perform all of its obligations hereunder and thereunder; the execution and delivery of this Agreement and the Revised Collaboration Agreement and the consummation of the transactions contemplated herein and therein do not violate, conflict with, or constitute a default under its charter or similar organization document, its by-laws or the terms or provisions of any material agreement or other instrument to which it is a party or by which it is bound, or any order, award, judgment or decree to which it is a party or by which it is bound; and upon execution and delivery, this Agreement and the Revised Collaboration Agreement will constitute the legal, valid and binding obligation of it. The persons signing on behalf of each of the parties hereby warrant and represent that they have the authority to execute this Agreement and the Revised Collaboration Agreement on behalf of the party for whom they have signed.

Section 9.5. Registration. Buyer shall take all reasonable and necessary steps to register this Agreement in any country where such is required to permit the transfer of funds and/or payment of amounts due to Seller hereunder or is otherwise required by the government or law of such country to effectuate or carry out this Agreement. Notwithstanding anything contained herein but subject to Section 9.4 hereof, Buyer shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, Buyer shall not be relieved of its obligation to make any payment due to Seller hereunder at Seller's address specified in Section 9.2 hereof, where such payment is blocked due to any failure to register this Agreement.

Section 9.6. Headings. As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by the context. The headings appearing at the beginning of the numbered Articles and Sections hereof have been inserted for convenience only and do not constitute a part of this Agreement.

Section 9.7. Agency. Nothing herein shall be deemed to create an agency, joint venture or partnership between the parties hereto.

Section 9.8 Dispute Resolution. (a) Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the Steering Committee, which will use its good faith efforts to resolve the Dispute within ten (10) Business Days. If the Steering Committee is unable to resolve the Dispute in such period, the Steering Committee will refer the Dispute to the Chief Executive Officers (or equivalent position) of Buyer and Seller. For all Disputes referred to the Chief Executive Officers (or equivalent position), the Chief Executive Officers (or equivalent position) shall use their good faith efforts to meet in person and to resolve the Dispute within ten (10) Business Days after such referral.

(b) Arbitration. If, pursuant to Section 9.8(a), within such ten (10) Business Days or such other period as may be agreed upon between the parties, the dispute remains unresolved, it shall be settled on application by either party by arbitration conducted in the English language, in Stockholm (Sweden) in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said rules. The parties expressly agree to abide the award rendered. This provision shall not prevent either party from addressing any competent court or tribunal in order to seek interim measures.

(c) Costs. The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute, and the costs of mediator(s) and arbitrator(s) shall be equally divided between the parties.

Section 9.9. Force Majeure. Notwithstanding any other provisions of this Agreement, neither of the parties hereto shall be liable in damages for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including but not limited to acts of God, governmental restrictions, wars, or insurrections, strikes, floods, work stoppages and/or lack of materials; provided, however, that the party suffering such delay or default shall notify the other party in writing of the reasons for the delay or default. If such reasons for delay or default continuous exist for six (6) months, this Agreement may be terminated by either party.

Section 9.10. Assignment. Except as otherwise set forth in Sections 2.1 and 2.3 of the Revised Collaboration Agreement with respect to Buyer's right to grant sublicenses and appoint co-marketers and/or co-promoters, neither party hereto may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a party may make such an assignment without the other party's consent to Affiliates or to a successor to substantially all of the business of such party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall 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 9.10 shall be null and void and of no legal effect.

Section 9.11. Successors and Assigns. Subject to Section 9.10, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Seller and Buyer respectively.

Section 9.12. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

ARTICLE X
BASIS OF BARGAIN

EACH PARTY RECOGNIZES AND AGREES THAT THE WARRANTY DISCLAIMERS AND LIABILITY AND REMEDY LIMITATIONS IN THIS AGREEMENT ARE MATERIAL, BARGAINED FOR BASES OF THIS AGREEMENT AND THAT THEY HAVE BEEN TAKEN INTO ACCOUNT AND REFLECTED IN DETERMINING THE CONSIDERATION TO BE GIVEN BY EACH PARTY UNDER THIS AGREEMENT AND IN THE DECISION BY EACH PARTY TO ENTER INTO THIS AGREEMENT.

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective as of the date first written above.

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

LABORATORIOS DEL DR. ESTEVE, S.A.

By: /s/ Antonio Esteve

Name:
Title:

Exhibit 10.3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXECUTION COPY

AMENDED AND RESTATED SUBLICENSE AND COLLABORATION AGREEMENT

between

DISCOVERY LABORATORIES, INC.

and

LABORATORIOS DEL DR. ESTEVE, S.A.

Concerning Sinapultide

December 3, 2004

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

AMENDED AND RESTATED SUBLICENSE AND COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED SUBLICENSE AND COLLABORATION AGREEMENT (this "Agreement" or "Revised Collaboration Agreement") is made as of December 3, 2004 (the "Effective Date"), between DISCOVERY LABORATORIES, INC. ("Licensor"), a Delaware corporation, and LABORATORIOS DEL DR. ESTEVE, S.A., a corporation organized and existing under the laws of Spain ("Licensee").

WHEREAS, Licensor has the exclusive worldwide right, under a license from Johnson & Johnson, Inc., to sublicense certain technology, including certain technology relating to synthetic pulmonary surfactant peptides and proteins, one of which is known as sinapultide;

WHEREAS, Licensor owns certain technology and patent rights relating to synthetic pulmonary surfactant formulations;

WHEREAS, Licensor and Licensee have entered into a Sublicense Agreement and a Supply Agreement, in each case dated March 6, 2002, for the commercialization of Licensed Products (as such term is defined therein);

WHEREAS, Licensor and Licensee desire to replace the aforementioned agreements by an Amended and Restated Sublicense and Collaboration Agreement and an Amended and Restated Supply Agreement, in order to modify the collaborative relationship between the parties and the territories where Licensee shall be entitled to commercialize the Licensed Products (as such term is hereinafter defined).

NOW, THEREFORE, in consideration of the promises and the performance of the covenants herein contained, the parties agree as follows:

ARTICLE 1
DEFINITIONS

For the purposes of this Agreement, the following terms shall have the following meanings:

"Affiliate(s)" of a Person shall mean any Person which directly or indirectly Controls, is Controlled by or is under common Control with such Person.

"Business Day" shall mean any day on which banking institutions are open or authorized to be open in the Commonwealth of Pennsylvania and in Barcelona, Spain.

"Control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of a Person having outstanding voting securities, or a fifty percent (50%) or greater interest in the income of a Person not having outstanding securities, or, in either case, the power to direct or cause the direction of the management or policies of such Person.

"Development" shall refer to all activities relating to formulation, process development, manufacturing scale-up, quality assurance/quality control, clinical studies and regulatory affairs in connection with a Licensed Product.

"EMEA" shall mean the European Medicines Evaluation Agency or any successor entity thereof.

"FDA" shall mean the United States Food and Drug Administration or any successor entity thereof.

"Initial Period" shall mean, on a country by country and Licensed Product-by-Licensed Product basis, the period beginning on the Effective Date and ending on that date that is the latest of the following dates:

(i) the expiration of the last Patent Rights containing a Valid Claim covering the subject Licensed Product in such country;

(ii) the first commercial sale of the first to appear generic formulation of the subject Licensed Product in such country; or

(iii) the tenth (10th) anniversary of the first commercial sale of the subject Licensed Product in such country.

"Licensed Know-how" shall mean all know-how, data, information or technology arising before or during the course of this Agreement which are proprietary to the Licensor and/or with respect to which Licensor has the power and right to grant the licenses provided for herein and which relate to the development or therapeutic use of Licensed Products.

"Licensed Methods" shall mean the methods for the Licensed Products arising before or during the course of this Agreement which are proprietary to the Licensor and/or with respect to which Licensor has the power and right to grant the licenses provided for herein and which relate to the development or therapeutic use of Licensed Products.

"Licensee Proprietary Information" shall mean any scientific and technical information or data developed, possessed or acquired by Licensee relating to Licensed Products, Patent Rights or Licensed Know-how which Licensee is free to disclose other than such information that is generally available to the public.

"Licensed Products" shall mean surfactant pharmaceutical compositions which are formulations of lipids and solely the polypeptide sinapultide and, in no manner whatsoever in any composition including any other pharmacological agents, that have been developed by Licensor or that may be developed by Licensor during the term of this Agreement limited to the following:

(i) In suspension for pulmonary instillation or in aerosol formulation, for the prophylaxis and/or treatment of Respiratory Distress Syndrome (RDS), Meconium Aspiration Syndrome (MAS), Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), and/or Bronchopulmonary Dysplasia (BPD), in each case in the hospital setting;

(ii) In any formulations (including, without limitation, any associated devices/ apparatus) for use in conjunction with nasal continuous positive airway pressure for neonatal pulmonary disorders solely treated in the Neonatal Intensive Care Unit (NICU) (collectively, nCPAP Licensed Product(s)); and

(iii) In any formulations which may be developed for the treatment of asthma and/or chronic obstructive pulmonary disease (COPD) diagnosed and treated in the hospital setting.

"Licensed Rights" shall mean collectively the Patent Rights, the Licensed Methods, the Trademarks and the Licensed Know-how.

"Licensed Territory" shall mean Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain.

"Marketing Regulatory Approvals" shall mean all permissions and applications for such permissions from the regulatory and/or governmental health authorities in the Licensed Territory which are necessary for the importation of the Licensed Products and their marketing, use, distribution and sale in the Licensed Territory.

"MAA" means a Marketing Authorisation Application submitted to the EMEA or with any regulatory authority of any country within the Licensed Territory.

"NDA" shall mean a New Drug Application or Product License Application filed with the United States Food and Drug Administration under 21 USC 355(b) (FDCA Section 505(b)).

"Original License" shall mean the Sublicense Agreement dated as of October 28, 1996 between the Original Licensor and Licensor.

"Original Licensor" shall mean Johnson & Johnson, Inc.

"Patent Rights" shall mean any patents and/or patent applications which contain one or more Valid Claims covering the Licensed Products whether owned by Licensor or to which Licensor may have rights during the term of this Agreement, including (i) the patents and patent applications set forth on Schedule I hereto; (ii) any other patents or patent applications covering the surfactant pharmaceutical compositions referenced in the patents and patent applications in Schedule I or their use or administration owned by Licensor or under which Licensor has the right, at any time while this Agreement is in effect, to license to Licensee; and (iii) with respect to the foregoing letters patent and patent applications, all corresponding national patents and patent applications, Patent Cooperation Treaty and European Patent Convention filings and applications and filings and applications under similar administrative international conventions, together with any divisional, continuation, continuation-in-part, substitution, reissue, extension, supplementary protection certificate or other application based thereon. Notwithstanding the foregoing, "Patent Rights" shall not include any patents or patent applications, filings, or applications under any treaty, or any divisional, continuation, continuation-in-part, substitution, reissue, extension, supplementary protection certificate or other application that do not relate in whole or in part to any of the Licensed Products.

"Person" shall mean any natural person, corporation, limited liability company, unincorporated association, partnership, joint venture or other entity.

"Phase 2" shall mean that portion of clinical trials of a candidate drug in the target patient population of a sufficient number and sufficient length of time whereby adequate safety data is provided and there is a clear indication of dosage effects with respect to efficacy as defined in the study protocol for such drug candidate.

"Phase 3 Development" means those clinical trials intended to generate safety and efficacy data to support regulatory approval in the proposed therapeutic indication.

"Pricing Approvals" shall mean approvals by the regulatory and/or governmental health authorities in the Licensed Territory granting the prices of the Licensed Products and reimbursement conditions for the sale thereof.

"Scripps Patent Rights" shall mean the Patent Rights identified in part (a) of Schedule I.

"Trademark" shall mean Surfaxin® and such other trademarks owned by Licensor that are selected by the Development Committee (as defined in Section 5.6) for use within the Licensed Territory in connection with one or more Licensed Products.

"Valid Claim" shall mean a claim of an unexpired patent within the Patent Rights which has matured into an issued patent or a claim being prosecuted in a pending application within the Patent Rights. In each case a claim shall be presumed to be valid unless and until it has been held to be invalid by a final, unappealable judgment of a court of competent jurisdiction.

ARTICLE 2
GRANT

Section 2.1. Grant of License. Licensor hereby grants to Licensee, and Licensee hereby accepts from Licensor, upon the terms and conditions herein specified, an exclusive license under the Patent Rights, the Licensed Know-how and the Trademark, and the right to practice Licensed Methods, solely in connection with the importation, promotion, distribution, use and sale of Licensed Products under the Trademark in the Licensed Territory. Licensor hereby agrees that it shall not grant any other licenses to exploit the Licensed Rights or the Licensed Products in the Licensed Territory to any third party (including, without limitation, its Affiliates) during the term of this Agreement. The license granted hereunder does not include any right or license of Licensee to make or have made Licensed Products, all such right and license being hereby retained by Licensor. The license granted under this Article 2 shall be subject to the terms and conditions of this Agreement and the following terms:

(a) The rights of the Original Licensor to use the Scripps Patent Rights for educational and research purposes;

(b) To the extent applicable, the rights of the United States Government pursuant to 35 U.S.C. 202 et seq. and 37 C.F.R. 401.1 et seq. which may have arisen or resulted from federal funding of research relating to the Scripps Patent Rights, including the non-exclusive right of the United States Government to practice the inventions covered by the Scripps Patent Rights;

(c) The reserved right of Licensor, to use the Licensed Rights for research and development purposes and, to the extent permitted by Section 7.2, for publication purposes subject to approval by Licensee, which approval shall not be unreasonable withheld; and

(d) The Standard of Diligence (as such term is set forth in Section 5.6).

Licensee shall have no right to sublicense or otherwise share its rights hereunder with any other Person other than (i) Affiliates of Licensee (provided that Licensee shall not be relieved of any of its obligations under this Agreement), as provided for in Section 15.9, and (ii) third parties pursuant to a sublicense or distribution agreement complying with Section 2.3.

Section 2.2 No Active Sales Outside Licensed Territory. Licensee shall neither directly nor indirectly carry out any active sales of or actively seek customers for the Licensed Products outside the Licensed Territory and it shall not advertise the Licensed Products or maintain branches for the distribution of the Licensed Products outside the Licensed Territory.

Section 2.3. Sublicense Agreements. Subject to prior determination by the Steering Committee (in accordance with Section 6.1) on a Licensed Product-by-Licensed Product and country-by-country basis that any sublicensing, co-marketing or co-promotion, as applicable, is consistent with maximizing the value of the subject Licensed Product, Licensee shall be entitled to (X) sublicense its rights and obligations under the Agreement in any country of the Licensed Territory, with the exception of the country of Spain or (Y) co-market or co-promote in any country of the Licensed Territory, provided that for each of (X) and (Y), above, (i) any such sublicense or co-marketing/ promotion agreement shall be under terms no less stringent than the ones contained in this Agreement including, without limitation, Licensee's performance requirements set forth in Section 5.6; (ii) any such sublicense or co-marketing/ promotion agreement shall not be an effective assignment of all of Licensee's rights and a delegation of all of its obligations under this Agreement, (iii) Licensee shall have obtained the approval of the Steering Committee (in accordance with Section 6.1) for the sublicense, co-marketing or co-promotion partner, which approval shall not be unreasonably withheld or delayed and (iv) Licensee hereby warrants and represents that any such sublicensee or co-promotion/ co-marketing partner of Licensee will comply with all applicable terms of this Agreement and, further, Licensee guarantees performance of this Agreement by any such party.

The parties hereto agree and acknowledge that the performance of the obligations hereunder shall take into account the following: (A) that solely with respect to the Licensed Product that is Surfaxin® for RDS and/or BPD, it is the prior mutual strategic determination of Licensor and Licensee that sublicensing shall be allowed for Italy and Greece, without any further approval from the Steering Committee, except as may be provided for with respect to the selection and approval of actual sublicensees in accordance with this Section 2.3, and (B) in the event of co-promotion or co-marketing of Licensed Products in Spain, Licensee shall be primarily responsible for the promotional and marketing activities for any such Licensed Products through its own marketing and sales forces.

Section 2.4. Consideration for Licensed Products. Licensee shall not accept as consideration for the sale or transfer of Licensed Products any consideration other than cash except as consented to by Licensor following agreement between Licensor and Licensee on the methodology for valuing such non-cash consideration.

Section 2.5. Right of First Negotiation on New Products. For a period of [***] years from the Effective Date ("New Product Negotiation Term"), subject, however, to prior termination as hereinafter provided in Article 8, Licensor shall grant to Licensee an exclusive right of first negotiation to a maximum of [***] future products developed by Licensor (each a "New Product"), solely to the extent to which Licensor is not legally restricted or prevented from licensing any such rights within the Licensed Territory, in accordance with the following terms and conditions:

(a) Within sixty (60) days of completion of Licensor's written clinical study report(s) for all Phase 2 clinical trials with respect to any such product opportunity, Licensor shall present in writing, including a copy of the relevant Phase II clinical study final report(s), such product opportunity to Licensee together with any additional information which, at Licensor's judgment, is reasonably necessary for Licensee to evaluate its possible interest in the New Product in a manner that is reasonably intended to provide a basis for Licensee's decision as to whether to exercise its option hereunder (a "New Product Presentation"). At Licensee's request, Licensor shall provide Licensee with any additional information solely to the extent that such additional information is reasonably necessary for Licensee to evaluate its possible interest in the New Product.

(b) Within sixty (60) days from the date of any such New Product Presentation, Licensee shall notify Licensor in writing of Licensee's intention to enter into negotiations to license the rights to any such product. Should Licensee fail to notify Licensor of Licensee's intention to license such rights or should Licensee notify Licensor of Licensee's lack of intent to license such rights, Licensor shall have the immediate right to offer the New Product opportunity to any other third party offeree(s) without any further obligation hereunder. In the

event that Licensee has notified Licensor of its intent to license any such rights, Licensee and Licensor hereby expressly agree that such license or any other similar grant of rights in respect thereto shall contain, among other customary terms and conditions, the following:

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(i) up-front cash payment(s) to be paid by Licensee to Licensor in amounts that are consistent with customary pharmaceutical industry practices and appropriate with reference to the technology value and potential product value of such New Product;

(ii) Licensor, Licensee and other sublicensees of the Licensor shall share all future clinical development work and or expenses with respect to any such New Product opportunity, in relation with Phase 3 clinical trials necessary to obtain and/or maintain the Marketing Regulatory Approvals in the Licensed Territory, on a [***] basis using the relevant IMS annual global pharmaceutical data relative to the aggregate pharmaceutical market size of the proposed licensed territory for all pharmaceutical products as the basis of determining the amount of such costs to be borne by each of the parties at the time. Licensee and its sublicensees shall be responsible for the work and costs associated with any and all clinical development activities that is conducted in the Licensed Territory for the New Product that are not necessary to obtain or maintain Marketing Regulatory Approval for any such New Product;

(iii) payment to Licensor of cash milestones in amounts that are consistent with customary pharmaceutical industry practices and are reflective of the value of such New Product created during the development process and which amounts take into account Licensee's contribution to development of any such value;

(iv) Licensee shall be responsible for customary commercialization costs associated with the New Product including, without limitation, sales, marketing, distribution, and safety and medical affairs expenses, in a manner similar to that set forth in this Agreement with respect to Licensed Products; and

(v) Licensor shall be responsible for the manufacture of any such New Product. The economic terms for the New Product, which shall duly take into account the development expenses and cash milestones paid by Licensee for any such New Product, shall ensure a reasonable profit for the parties in the light of the prevailing and expected market conditions at that time.

(c) In cases where Licensee has indicated its intention to enter into negotiations to license rights to a New Product as provided hereunder and the parties fail to enter into definitive agreements within hundred and twenty (120) days of the date of Licensee's notice, delivered to Licensor in accordance with Section 2.5(b) (hereinafter, such event being defined as an "Unrealized New Product"), Licensor shall have the right to offer the Unrealized New Product opportunity to any other third party offeree(s) at terms and conditions that are in substance no more favorable for such other third party offeree(s) than those last offered to Licensee in writing, provided, however, that Licensor shall not execute any agreement on the New Product with any such third party offeree(s) without previously offering Licensee the right to enter into an agreement on substantially similar terms than those contained in the final agreement with the relevant third party offeree.

(d) Should senior executive officers of Licensor become aware of the possible interest of any third party to enter into an agreement in relation with any New Product prior to completion of all Phase 2 clinical trials, then Licensor shall promptly notify Licensee of such possible interest of a third party. In such event, and notwithstanding Section 2.5(a) herein, Licensor and Licensee agree to initiate good faith negotiations with respect of such New Product with a view to enter into an agreement for the development and commercialization of such New Product prior to the completion of the Phase 2 development for that New Product; provided, however, that in any such event the parties agree that any negotiations hereunder shall be performed within timeframes similar to those as set forth in Section 2.5 and shall encompass terms and conditions similar to those set forth in Sections 2.5(b) and (c).

(e) Prior to the expiration of the New Product Negotiation Term, Licensee's rights hereunder to New Products shall be terminated upon the occurrence of any two of the following events, in any combination thereof: (i) a New Product license is entered into by the parties; and (ii) An Unrealized New Product event occurs.

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ARTICLE 3
GRANT BACK

In consideration for Licensor (i) making the Licensed Know-how (including any improvements thereto and solely to the extent provided for in Section 2.1) available to Licensee on a continuing basis for the duration of this Agreement and (ii) procuring, and making available to Licensee the benefit of, equivalent grants from Licensor's other licensees for the Licensed Products outside the Licensed Territory Licensee hereby grants to Licensor and such other licensees as Licensor may designate a royalty-free, nonexclusive license outside the Licensed Territory, with the right to grant sublicenses, under any and all inventions and Licensee Proprietary Information (whether patentable or not) hereafter during the term of this Agreement, developed, possessed or acquired by Licensee related to the Licensed Products, Patent Rights, Licensed Know-how or Licensed Methods; provided that Licensee is not legally restricted or prevented from granting such rights in connection with the relevant invention. Licensee shall provide Licensor with a written enabling disclosure of each invention (such as a patent application or internal docket reference) unambiguously identifying it as an invention governed by this Article 3 prior to filing a patent application or taking any other action disclosing or potentially disclosing the same to third parties.

Licensee shall promptly disclose all Licensee Proprietary Information to Licensor and, subject to the execution of confidentiality undertakings comparable to those set forth in Article 7, to Licensor's other licensees (and or Affiliates and permitted sublicensees) of Patent Rights outside the Licensed Territory on a continuing basis during the term of this Agreement. Licensee hereby grants to Licensor and such licensees a royalty-free nonexclusive license, with the right to grant sublicenses, to use the Licensee Proprietary Information outside the Licensed Territory. Licensee shall not disclose any such invention and or Licensee Proprietary Information under circumstances that would reasonably be expected to result in the loss of the protectible status of any such invention and or Licensee Proprietary Information without the prior written consent of Licensor, which consent shall not be unreasonably withheld or delayed.

ARTICLE 4
CONSIDERATION

Section 4.1. Common Stock Grant. Contemporaneously with the execution of this Agreement, Licensor shall issue 500,000 shares of Licensor's common stock, par value $.001 per share to Licensee for no additional consideration. Licensee shall be entitled to the registration rights for such shares of common stock that are provided for in the Common Stock Letter Agreement between Licensor and Licensee dated as of December 3, 2004.

Section 4.2. Supply Agreement. Concurrently with the execution of this Agreement, Licensor and Licensee shall enter into an amended and restated supply agreement for Licensed Products (the "Revised Supply Agreement").

Section 4.3 Sharing of Fees. With respect to cash amounts as provided for herein that are received by Licensor from third parties regarding any partnerships or alliances entered into in connection with the Development and/or commercialization of the Licensed Products (as such term is defined in this Revised Collaboration Agreement) anywhere in the Licensed Territory (provided, however, that solely for the purposes of this Section 4.3 that Licensed Territory shall be as defined in the Collaboration Agreement dated March 6, 2002, between the parties), Licensor and Licensee shall share in any such cash amounts according to the following ratio: Licensor [***]%; Licensee [***]% (provided, however, that the aggregate of any amounts received by Licensee pursuant to this Section 4.3 shall not exceed $20 million (USD)).

Cash amounts received by Licensor from third parties that shall be subject to sharing under this Section 4.3 shall expressly be limited to license fees, technology access fees and performance-based milestones (i.e., such milestones solely intended to reward the Licensor upon the occurrence of events characteristic of the product development process and of the process of application for and grant of regulatory approval to market the subject Licensed Products and price approval therefor) for licenses granted by Licensor and shall exclude, without limitation, amounts received by Licensor: in return for supplying or royalties and other revenues associated with the sale of Licensed Products; as funding for product development, commercialization, manufacturing, and regulatory activities; and with respect to any bona fide equity or loan transactions). Licensor shall conduct negotiations with third parties with respect to potential licenses in the greatest commercially practicable manner so as the entering into of any such relationship would provide for cash license fees, technology access fees and performance-based milestones that are appropriate with reference to the technology and potential value of the Licensed Products and the value created during the Development process.

For the purposes of this Section, upon execution of any such agreement with a third party, Licensor shall immediately notify Licensee as to the agreed upon commercial terms with such party in order to enable Licensee to assess the cash amounts to which it is entitled. Licensee may verify the information provided by Licensor by means of the audit of an external consultant, acceptable to Licensor, which, at reasonable business hours, may inspect Licensor's premises by giving prior reasonable notice. Any such inspections shall be at the sole cost of Licensee, except in the event where the adjustment shown by such inspection is greater than 10% of the amount incurred, then the Licensor shall bear such costs.

Section 4.4 Cash Payments to Licensor for Milestones. Licensee shall pay to Licensor the following cash amounts upon the attainment of the following:

1. $ [***] upon EMEA Marketing Regulatory Approval for RDS.
2. $ [***] upon EMEA Marketing Regulatory Approval for BPD.
3. $ [***] upon price approval in the Territory for ARDS provided, however, that the parties have reached a mutually satisfactory Transfer Price in accordance with the Amended and Restated Supply Agreement.

4. $ [***] upon EMEA Marketing Regulatory Approval for ALI prophylaxis.
5. $ [***] upon filing for EMEA Marketing Regulatory Approval of the nCPAP Licensed Product.
6. $ [***] upon EMEA Marketing Regulatory Approval of the nCPAP Licensed Product.
7. $ [***] upon filing for EMEA Marketing Regulatory Approval for asthma in the hospital setting.
8. $ [***] upon EMEA Marketing Regulatory Approval for asthma in the hospital setting.
9. $ [***] upon filing for EMEA Marketing Regulatory Approval for COPD in the hospital setting.
10. $ [***] upon EMEA Marketing Regulatory Approval for COPD in the hospital setting.

Section 4.5 Manner of Payment. The amounts provided for in Section 4.3 and Section 4.4 shall be paid in United States Dollars. Any and all taxes that are levied on payments accruing under this Article 4 of the Agreement in a country in which provision is made in the law or by regulation for withholding may be deducted by the payor from such amounts and paid to the proper taxing authority and evidence of such payment shall be secured and sent to the payee as promptly as possible. The parties shall do all such lawful acts and things and sign all such lawful deeds and documents as either party may reasonably request from the other party to enable Licensee or Licensor, or their respective Affiliates and/or sublicensees to take advantage of any applicable legal provision or any double taxation treaties with the object of paying the sums due to any payee hereunder without withholding any tax or as promptly as practicable recovering any such withheld tax. Amounts to be paid hereunder shall be paid: (i) with respect to amounts due to Licensee pursuant to Section 4.3, as soon as practicable following Licensor's receipt of any such shareable amounts received thereunder but in no event later than ten (10) Business Days after such receipt; and (ii) with respect to amounts due to Licensor pursuant to Section 4.4, as promptly as practicable upon Licensee's receipt of Licensor's invoice issued upon occurrence of any such event, but in no event later than ten (10) Business Days after receipt of Licensor's invoice.

ARTICLE 5
SCOPE OF THE COLLABORATION

Section 5.1. Goals of the Collaboration. Subject to Section 8.6(b) hereinbelow, the parties hereto desire to collaborate in a strategic relationship with regard to product Development and commercialization programs for the Licensed Products with the following goals and in the following manner:

(a) the Development and clinical testing of Licensed Products;

(b) Marketing Regulatory Approval of Licensed Products in the Licensed Territory; and

(c) the manufacturing by Licensor and the marketing, sale, and distribution by Licensee of Licensed Products in the Licensed Territory.

In performance of the foregoing, Licensor and Licensee agree to collaborate diligently in the overall strategic relationship and in the Development and commercialization of Licensed Products in the Licensed Territory in accordance with the terms and conditions contained in this Agreement including, without limitation, the respective roles and responsibilities of the parties as set forth in this Article 5.

Section 5.2. Roles and Responsibilities. The principal mechanism by which the parties contemplate coordinating their respective clinical Development and sales and marketing activities will be through consensus-based decision-making through: (i) a joint Development Committee (established and governed pursuant to Section 6.2 of this Agreement) and (ii) a joint Commercialization Committee (established and governed pursuant to Section 6.3 of this Agreement); in each case, under the oversight of a joint Steering Committee (established and governed pursuant to Section 6.1 of this Agreement), provided, that the parties expressly acknowledge and agree that the following shall apply:

(a) Conduct of Clinical Investigations. The Development Committee (as such term is defined in Section 6.2) shall be responsible for the Development of Licensed Products in the Licensed Territory; provided, however, that

(i) Licensor, at its cost, shall be responsible for planning and managing the research and development work related to Licensed Products that is necessary to obtain EMEA approval, regardless of where conducted, subject to Section 5.2(a)(ii), below;

(ii) Subject to Section 8.6(b) hereinbelow, Licensee shall contribute for Phase 3 Development of Licensed Products in the Licensed Territory by conducting, sponsoring, and funding the cost (up to the amounts specified below for each category of Licensed Products) of Phase 3 clinical trials that are conducted in the Licensed Territory (it being acknowledged by the parties that any such trials are intended to be a part of a global European development program for the Licensed Products), as discussed and agreed to by the Development Committee. Licensee's contribution under this Section 5.2(a)(ii) shall be solely limited to those costs that may be incurred with respect to Phase 3 Development conducted with respect to clinical sites located in the Licensed Territory and shall solely include (x) shipping costs for investigational product and other materials supplied to clinical sites; and (y) external costs and payments for the subject Phase 3 clinical trial including, without limitation, consultants, contract research organizations, payments to clinical investigators and support staff, insurance companies, clinical sites, and regulatory fees ("Phase 3 Costs"); provided, however, that with regards to each of (x) and (y), above, Licensee's obligation for contribution shall apply whether such costs are contracted for and/ or initially paid by Licensor or Licensee. The Development Committee shall (A) be responsible for developing and approving the budgets for Phase 3 Costs taking into account the nature of the Phase 3 Costs, and (B) approve the selection, without limitation, of clinical sites and specific consultants, contractors and clinical investigators to be used in the performance of Phase 3 Development. Such approval by the Development Committee shall constitute the parties' commitment to undertake the relevant Phase 3 Development and Licensee's agreement to contribute to any such Phase 3 Costs up to a maximum of the following amounts in U.S. Dollars ("Licensee's Maximum Contribution"):

1. For Licensed Products for the ARDS and/ or ALI indications, up to $[***];
2. For Licensed Products for the BPD indication, up to $[***];
3. For nCPAP Licensed Product(s), up to $[***];
4. For Licensed Products for the asthma and COPD indication in the hospital setting, up to $[***]; and
5. For Licensed Products for the COPD indication in the hospital setting, up to $[***], only if a separate Phase 3 pivotal trial is conducted for this indication (i.e. independent from the Phase 3 pivotal trial for asthma).

Provided, however, that the determination of whether separate Phase 3 Development has occurred for the purposes of this Section 5.2(a)(ii) shall not be based upon the existence of separate formulations of Licensed Product.

(iii) Promptly upon the completion of the experimental phase of the subject Phase 3 clinical trial in the Licensed Territory (i.e. when the last visit of the last patient has occurred), a reconciliation of Licensee's Phase 3 Cost contributions determined hereunder (including, without limitation, those costs previously invoiced, paid or still to be invoiced and paid) shall be made with reference to Licensee's Maximum Contribution for such trial. Both parties shall keep such records as are necessary to determine accurately the sums due under this Section 5.2(a). Such records shall be retained by each party and, at any time during the Term of the Agreement, at the prior written request and expense of the other party, shall be made available for inspection, review, and audit during normal business hours, by an internationally recognized independent certified public accounting firm selected by the auditing Party and reasonably acceptable to the other Party for the sole purpose of verifying the accounting reports and

payments made or to be made pursuant to this Section 5.2(a); provided, however, that such audits may not be performed more than once per contract year. The auditing Party shall pay for such inspections, except that in the event where the adjustment shown by such inspection is greater than 10% of the amount incurred, then the audited Party shall pay for such inspection.

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(iv) Licensee shall be the sponsor in the Licensed Territory of all Phase 3 clinical trials to which it contributes in accordance with this Section 5.2 and, subject to the prior approval of the Development Committee, Licensee shall be entitled to conduct monitoring and auditing of the sites at its own cost and expense. With respect to Licensee's sponsorship, monitoring and auditing, as applicable, Licensor, through the operation of the Development Committee or directly, shall (i) have the sole authority to approve the clinical site agreement that may be entered into by Licensee and a clinical site prior to its signature and, to the greatest extent possible with reference to then or future applicable law, be named as a co-sponsor thereto; and (ii) be entitled to oversee and audit clinical site operations including, without limitation, site interactions, site initiation, and monitoring and auditing conducted by Licensee, all at Licensor's expense.

(v) Licensor and Licensee shall keep each other fully informed on the progress of all clinical trials of Licensed Products and shall promptly provide the other with copies of all submissions to regulatory authorities in connection therewith, all significant communications received from such regulatory authorities and reasonably detailed descriptions (in English) of all meetings with and verbal communications with such regulatory authorities which are of significance.

(vi) Each of Licensor and Licensee shall use its best commercial efforts to complete all clinical trials for which it is responsible within the parameters established by (and as such parameters may be modified by) the Development Committee.

(b) Commercialization Activities. Through the governance mechanism of the Commercialization Committee (as such term is defined in Section 6.3), Licensor and Licensee shall actively participate in the strategic marketing activities for Licensed Products in the Licensed Territory. Without prejudice to Section 2.1 and 2.3, Licensee shall be responsible for activities and associated costs and expenses involved in the pre-launch, launch and post-launch marketing, sales, and distribution of Licensed Products in the Licensed Territory including, without limitation, (i) providing country-specific marketing resources including, but not limited to, personnel, marketing materials and other customary marketing tools and methods; (ii) furnishing sufficient sales personnel to adequately detail Licensed Products in the Licensed Territory and achieve insertion of Licensed Products into hospital formularies; (iii) managing and conducting order taking, storage and distribution of Licensed Product in the Licensed Territory; (iv) performing country-specific regulatory affairs activities and price and reimbursement negotiations during the Regulatory Marketing Approval process; (v) managing local medical affairs and reporting of drug safety issues to Licensor and appropriate regulatory authorities; and (vi) periodically report to the Commercialization Committee and Steering Committee on Licensee's marketing and sales activities related to pre-launch, launch and post-launch periods for all Licensed Products.

(c) Licensee, shall develop a sales and marketing plan, which shall be subject to the periodic review and approval (no less frequently than every 12 months) of the Steering Committee as provided hereunder, comprised of individual sales and marketing (pre-launch, launch and post-launch) plans for each Licensed Product on a country-by-country basis in the Licensed Territory in a form and content consistent with general pharmaceutical industry practices (the "Marketing Plan").

Section 5.3 Regulatory Approvals.

(a) Subject to the completion of requisite clinical investigations by the Licensor, Licensor shall prepare and submit to the EMEA a MAA within 6 months of the date of acceptance of filing of the applicable NDA by the FDA and shall use its diligent efforts to obtain and maintain all EMEA Marketing Regulatory Approvals for the term of this Agreement, all at the cost and expense of Licensor, except as may otherwise be provided for in Section 5.2. When filing for MAA, Licensor shall designate, as appropriate, Licensee or such Licensee's Affiliates or permitted sublicensees and/or partners designated by Licensee as its distributors or local representatives for the Licensed Products in the Licensed Territory. Licensor shall, upon the granting of each Marketing Regulatory Approval obtained by Licensor, promptly supply Licensee with a copy of such approval.

(b) Subject to receipt of MAA Marketing Regulatory Approval by Licensor, Licensee, where appropriate, shall prepare and submit to the regulatory authorities in the Licensed Territory country-specific and Licensed Product specific applications for Pricing Approvals as soon as practicable and shall use its diligent efforts to obtain and maintain all Pricing Approvals that are obtained by Licensee for the term of this Agreement, all at the cost and expense of Licensee. Licensee shall, upon the granting of each Pricing Approval obtained by Licensee, promptly supply Licensor with a copy of such approvals. The parties contemplate that country-specific applications for Marketing Regulatory Approvals shall not be necessary for any of the Licensed Products in the Licensed Territory, however, should any such country-specific applications be required, Licensee shall be responsible for all associated costs for filing and maintaining such Marketing Regulatory Approvals.

(c) Each party shall, in connection with any Marketing Regulatory Approvals and Pricing Approvals obtained by such party in the Licensed Territory, grant to the other party an irrevocable right of access and reference thereto and shall effect such notifications to regulatory authorities as shall be reasonably necessary to accomplish the foregoing. Each party shall assist the other party in maintaining any such Marketing Regulatory Approvals and Pricing Approvals including supplying to the other party any information in connection therewith.

(d) In the event of termination of this Agreement pursuant to Section 8.2 (only in the event of termination by Licensor) and Sections 8.3, 8.4, and 8.6(a), Licensee shall promptly transfer to Licensor or Licensor's designee, possession, and ownership of all governmental or regulatory correspondence, conversation logs, filings, and approvals (including all country-specific Marketing Regulatory Approvals, if any, and Pricing Approvals) relating to the Licensed Products and, to the extent not already done, Licensee shall appoint Licensor as Licensee's agent for all Licensed Product-related regulatory matters in the Licensed Territory. Licensee shall execute all documents and take all such further actions as may be reasonably requested by Licensor in order to give effect to the foregoing. Licensor shall reimburse Licensee for all reasonable costs incurred in performance hereunder.

Section 5.4 Commencement of Marketing. Licensee shall consummate its first commercial sale of each Licensed Product in each country of the Licensed Territory within six (6) months after official publication of the obtaining of Pricing Approval (or if Pricing Approval is not applicable, within six (6) months of Marketing Regulatory Approval in such country); provided, however, that if Licensee has failed to meet such deadlines in any country because of reasons beyond the control of Licensee, Licensor and Licensee shall discuss in good faith a new deadline for such country. In the event Licensee does not consummate a sale within such period, Licensor may notify Licensee of a default under this Section 5.4 and, in the event such default is not cured within thirty (30) days from such notice of default, Licensor shall have the right to terminate the license granted to Licensee hereunder with respect to such Licensed Product in such country.

Section 5.5. Post-Authorization Studies. [***] shall be responsible for conducting, at its own cost and expense such post-authorization studies activities as may be useful or necessary for the better knowledge and use of the Licensed Products in the Licensed Territory provided that the protocol shall be approved in accordance with Section 5.2(a) in advance of its commencement. The Development Committee shall monitor and supervise the conduct thereof. Licensee shall purchase Licensed Product for any such clinical trials at Licensor's Cost of Goods (as set forth in the Revised Supply Agreement). Licensor shall be entitled, with reasonable prior notice and at reasonable times and intervals, to (i) audit the clinical activities of Licensee; (ii) establish a pharmacovigilance committee jointly with Licensee to monitor and assess the safety outcomes of such clinical activities; and (iii) utilize the resulting data for Licensor's own purposes, subject, however to Licensee's prior consent, which consent shall not be unreasonably withheld.

Section 5.6. Standard of Diligence. (a) Should Licensee (or any sublicensees or co-promotion/ co-marketing partners of Licensee) fail to satisfy [***]% of the annual sales targets (as such sales targets are established in the Marketing Plan in accordance with Section 5.2(c)) with respect to the subject Licensed Product in a country of the Licensed Territory for two (2) consecutive years, Licensor shall have the right to terminate the exclusivity character of the rights granted hereunder with respect to the relevant country(ies) and subject Licensed Product where such failure has occurred with a prior notice of ninety (90) days addressed to Licensee; provided, however, that such notice shall need to be sent, in order to be valid and enforceable, within sixty (60) days after Licensor becoming aware of any such failure. Should Licensee (or any sublicensees or co-promotion/ co-marketing partners of Licensee) fail to satisfy

[***]% of the annual sales targets (as such sales targets are established in the Marketing Plan in accordance with Section 5.2(c)) with respect to the subject Licensed Product in a country of the Licensed Territory for two (2) consecutive years, Licensor shall have the right to terminate this Agreement with respect to the relevant country(ies) and subject Licensed Product where such failure has occurred with a prior notice of ninety (90) days addressed to Licensee; provided, however, that such notice shall need to be sent, in order to be valid and enforceable, within sixty (60) days after Licensor becoming aware of any such failure.

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(b) Licensee shall use commercially reasonable efforts to commercialize the Licensed Products in the Licensed Territory throughout the term of this Agreement in accordance with all applicable legal and regulatory requirements, including promoting the Licensed Products by accepted promotional practices consistent with those used (i) by Licensee in connection with the promotion of its other products and (ii) in the critical care pharmaceutical industry generally.

Section 5.7. Marketing Plan. Licensee, shall submit to the Steering Committee the Marketing Plan (as such term is defined in Section 5.2(b) hereinabove) for:

(i) The Surfaxin® Licensed Product for RDS, the first action of the Commercialization Committee shall be to establish the schedule for submission of the applicable pre-launch market development plan by Licensee.
(ii) Except for as set forth in Section 5.7(i), for all Licensed Products Licensee shall submit pre-launch market development plans as directed by the Commercialization Committee.
(iii) For all Licensed Products, Licensee shall submit within ninety (90) days prior to the planned launch date for a subject Licensed Product for each country of the Licensed Territory a Marketing Plan (i.e., a launch plan).
(iv) For all marketed Licensed Products, Licensee shall submit an updated Marketing Plan for each country of the Licensed Territory before the end of each calendar year.

Section 5.8. Record-keeping. Licensor shall maintain complete and accurate records for such periods as may be required by applicable law, but in no event less than three (3) years, of all Licensed Products sold by it, including distribution data.

Section 5.9. Promotional Material. (a) Licensor shall supply free of charge to Licensee samples of all training aids and literature used by Licensor and its Affiliates and distributors and sublicensees thereof for training their sales representatives and samples of all promotional and sales material used by Licensor or its Affiliates and distributors and sublicensees thereof for the Licensed Products.

(b) Licensee shall submit to Licensor, for Licensor's prior review and written approval (which approval is intended to ensure consistency with global strategic marketing initiatives and regulatory requirements and which shall not be unreasonably withheld or delayed), all training aids, promotional and sales materials, literature, and other relevant media proposed to be used by Licensee and its Affiliates and distributors and sublicensees thereof for training sales representatives for the Licensed Products. In the event Licensor has not provided its approval to the materials submitted for its review within a term of ten (10) Business Days, such materials shall be deemed approved.

Section 5.10. Promotional Claims. All technical and scientific information and therapeutic claims referred to by Licensee in promotional advertisements, promotional literature, sales aids, training aids and literature and the like with respect to each Licensed Product shall be consistent with any Marketing Regulatory Approval and the information and claims made by Licensor with respect thereto insofar as the latter are consistent with Marketing Regulatory Approvals or permitted practices in the Licensed Territory. Licensee shall not employ any sales practice or display any advertisement which the Commercialization Committee determines is detrimental to Licensor's interests and Licensor shall be entitled to require licensee to promptly cease any such practice or withdraw any such advertisement.

Section 5.11. Samples of Licensee's Promotional Material. Licensee shall supply free of charge Licensor with samples of product labeling, packages and/or cartons and the like and of all advertisements, promotional literature, sales aids, training material for salesmen, used by Licensee in connection with the promotion and sale of the Licensed Products.

Section 5.12. Adverse Event Reporting. The parties shall establish a procedure for the handling of adverse events as soon as is practicable after the Effective Date, which procedure shall be in conformance with all applicable laws, rules and regulations; provided, however, that (i) Licensee shall be responsible at its expense for collecting local safety data on the Licensed Product in the Licensed Territory and the timely submission thereof to Licensor, and (ii) Licensor shall be responsible for maintaining a global adverse event reporting system and appropriate database at its sole cost and expense and for the timely submission of required safety reports to appropriate authorities. Each party shall advise the other, by telephone or facsimile, within twenty-four (24) hours after it becomes aware of any serious adverse event arising in connection with the use of any Licensed Products and shall include the following information: a description of the patient (which shall be made in compliance with any applicable data protection regulations), the Licensed Product, the reporting source and a description of the event and/or such other information as may be required by the relevant regulatory authorities in the Licensed Territory at the time the serious adverse event occurs. No later than five (5) days after its initial report, the party informing of a serious adverse event shall provide the other with a written report delivered by confirmed facsimile of any reported serious adverse event stating

the full facts known to it, including but not limited to such information as may be required by the relevant regulatory authorities in the Licensed Territory at the time the serious adverse event occurs. The Adverse Event Reporting to the EMEA and other regulatory agencies shall be made by Licensor at its sole cost and expense. In any event, Licensor and Licensee shall promptly provide each other with a copy of any Adverse Event notice that they may address to any regulatory agency (including, without limitation, the FDA) in connection with the Licensed Products.

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Section 5.13. Licensed Product Distribution. For the Licensed Products, Licensee shall provide customary distribution services, including, without limitation, storage, order taking, shipping, billing, accounts receivable, returns/allowances in the Licensed Territory at its cost and expense.

ARTICLE 6
GOVERNANCE AND COMMITTEE STRUCTURE

Section 6.1 Steering Committee.

(a) Licensee and Licensor shall jointly form an oversight committee (the "Steering Committee") that shall (i) manage the overall strategic relationship and the strategic marketing and sales activities for Licensed Products in the Licensed Territory, (ii) to review and approve the pre- and post-launch Marketing Plans as well as any other matters required for the sales and promotion of Licensed Products in the Licensed Territory (including, without limitation, the strategic decision-making authority to authorize sublicensing, co-promotion or co-marketing and the tactical decision to approve a recommended sublicensing, co-promotion or co-marketing partner in the Licensed Territory), except to the extent that certain matters are solely the responsibility of a single party under this Agreement; (iii) to advise, provide input and determine strategy for future clinical and/or marketing studies; (iv) have overall responsibility for the success of such matters as established by this Agreement, and (v) be charged with promptly resolving disputes of the parties, if any, subject to Section 15.4.

(b) The Steering Committee will be comprised of [***] (unless otherwise mutually agreed) that shall have the overall functional responsibility for corporate operations/business development, commercial operations and product development within their respective organizations. The Steering Committee shall be chaired [***]. The initial members of the Steering Committee shall be designated by the parties hereto not later than thirty (30) days after the Effective Date and the first Chairperson shall be a designee of Licensor. [***] The Steering Committee shall to the extent practicable seek to operate by consensus. In the event of any deadlock or other inability of the Steering Committee to reach a determination with respect to any matter within the authority of the Steering Committee, the issue shall be referred to the respective Chief Executive Officers (or equivalent position) of each party who shall use their best endeavors to agree in good faith to a resolution of the dispute within thirty (30) days of their receipt of notice as to such dispute. If they are unable to resolve the dispute within such thirty

(30)-day period, it shall be referred to the decision of an external expert suitably qualified to resolve such dispute which is mutually acceptable to both parties, whose decision shall be final. In resolving the dispute, the appointed expert shall take into account development and marketing practices and procedures common in the pharmaceutical industry and appropriate with reference to the subject Licensed Products. Either party may appoint, substitute or replace members of the Steering Committee to serve as their representatives upon notice to the other party.

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(c) The Steering Committee shall meet within 60 days after the Effective Date and thereafter at least every 6 months. The location of such meetings shall alternate between Discovery's Pennsylvania headquarters, United States and Barcelona, Spain, unless otherwise agreed to by Licensor and Licensee. The Steering Committee may also meet by means of a telephone or video conference call with the consent of each of Licensor and Licensee. Licensee and Licensor shall use reasonable efforts to cause their representatives to attend the meetings of the Steering Committee. If a representative of either of the parties hereto is unable to attend a meeting, such party may designate an alternate to attend such meeting in place of the absent representative.

Section 6.2 Development Committee.

(a) Licensee and Licensor shall jointly form a development committee (the "Development Committee") to oversee the Development of Licensed Products within the Licensed Territory. The Development Committee shall have functional responsibility for the success of the matters related to the Development of the Licensed Products in the Licensed Territory and related medical and regulatory activities as established by this Agreement, including without limitation: (i) to determine and oversee the overall strategy for all such activities for Licensed Products in the Licensed Territory; (ii) to plan and coordinate the parties' efforts hereunder related to all such activities for Licensed Products in the Licensed Territory; and (iii) to facilitate the flow of information among the parties, including coordinating all such activities with manufacturing schedules and distribution.

(b) The Development Committee will be comprised of [***] (unless otherwise mutually agreed) that shall have the overall functional responsibility for Licensed Product clinical Development and medical and regulatory operations. The Development Committee shall be chaired [***]. The initial members of the Development Committee shall be designated by the parties hereto not later than thirty (30) days after the Effective Date. Upon resignation by or removal of any member of the Development Committee, Licensee or Licensor, as appropriate, shall have the sole right to appoint a successor. [***] The Development Committee shall to the extent practicable seek to operate by consensus. In the event of any deadlock or other inability of the Development Committee to reach a determination with respect to any matter within the authority of the Development Committee, the issue shall be submitted to the Steering Committee.

(c) The Development Committee shall meet within 60 days after the Effective Date and thereafter at least every 6 months. The location of such meetings shall alternate between Discovery's Pennsylvania headquarters, United States and Barcelona, Spain, unless

otherwise agreed to by Licensor and Licensee. The Development Committee may also meet by means of a telephone or video conference call with the consent of each of Licensor and Licensee. Licensee and Licensor shall use reasonable efforts to cause their representatives to attend the meetings of the Development Committee.

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(d) The Development Committee will report to the Steering Committee semi-annually in an appropriately detailed manner and shall provide the Steering Committee annually with a written comprehensive report on the execution of the clinical development programs contemplated hereunder.

Section 6.3 Commercialization Committee.

(a) Licensee and Licensor shall jointly form a commercialization committee (the "Commercialization Committee") to oversee the commercialization of Licensed Products within the Licensed Territory. The Commercialization Committee shall have functional responsibility for the success of the matters related to commercialization of the Licensed Products in the Licensed Territory as established by this Agreement, including without limitation: (i) the overall Commercialization strategy to assure consistency with Licensor's global branding strategy; (ii) planning and coordinating commercialization activities; (iii) submitting Marketing Plans to the Steering Committee for its review and approval, (iv) facilitating the flow of appropriate commercial information among the parties, including coordinating commercialization activities with manufacturing schedules and distribution and (v) recommending to the Steering Committee sublicensees, co-promoters and/or co-marketers for the Licensed Products as set forth under Section 2.3 hereinabove.

(b) The Commercialization Committee will number [***]. The initial members of the Commercialization Committee shall be designated by the parties hereto not later than (thirty) 30 days after the Effective Date. Upon resignation by or removal of any member of the Commercialization Committee, Licensee or Licensor, as appropriate, shall have the sole right to appoint a successor. The representatives of Licensor shall collectively be entitled to one (1) vote and the representatives of Licensee shall collectively be entitled to one (1) vote. The Commercialization Committee shall to the extent practicable seek to operate by consensus. In the event of any deadlock or other inability of the Commercialization Committee to reach a determination with respect to any matter within the authority of the Commercialization Committee, the issue shall be submitted to the Steering Committee.

(c) The Commercialization Committee shall meet within 60 days after the Effective Date and thereafter at least every 6 months. The location of such meetings shall alternate between Discovery's Pennsylvania headquarters, United States and Barcelona, Spain, unless otherwise agreed to by Licensor and Licensee. The Commercialization Committee may also meet by means of a telephone or video conference call with the consent of each of Licensor and Licensee. Licensee and Licensor shall use reasonable efforts to cause their representatives to attend the meetings of the Commercialization Committee.

(d) The Commercialization Committee will report to the Steering Committee semi-annually in an appropriately detailed manner and shall provide the Steering Committee annually with a written comprehensive report on the execution of the commercialization programs contemplated hereunder.

Section 6.4 General Committee Procedures.

(a) Each party shall be responsible for all of its own expenses of participating in any committee or any working group. If a representative of either of the parties hereto is unable to attend a meeting, such party may designate an alternate to attend such meeting in place of the absent representative.

(b) Meeting Agendas and Minutes. Each Party will disclose to the other proposed agenda items along with appropriate information at least 10 Business Days in advance of each meeting of the applicable Committee; provided that under exigent circumstances requiring Committee input, a party may provide its agenda items to the other party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting. The chairperson(s) of each Committee shall be responsible for calling meetings, preparing, and circulating an agenda in advance of each meeting of such Committee and preparing and issuing minutes of each meeting within 15 days thereafter; provided that such minutes will not be finalized until both parties review and confirm the accuracy of such minutes in writing.

(c) Other employees of each party involved in the Development, manufacture, or commercialization of the Licensed Products may attend meetings of any of such Committees as nonvoting participants, and, with the consent of each party, consultants, representatives, or advisors involved in the Development, manufacture, or commercialization of Licensed Products may attend meetings of any of such Committees as nonvoting observers; provided that such third-party representatives are under obligations of confidentiality and non-use applicable to information of each party and that are at least as stringent as those set forth in Article 7.

Section 6.5. Cost Sharing of Global Marketing Activities. Each of Licensor and Licensee hereby agree that the Commercialization Committee shall discuss in good faith the possibility for the parties to share in the cost and expense of any global marketing activities which may beneficially effect Licensor's commercialization of Licensed Products. Any such agreement as to sharing of costs and expenses shall take into account the value of the Licensed Territory relative to the global value of the Licensed Product.

Section 6.6. Coordination of Committee Activities with Licensor's other Collaborators. Licensee hereby acknowledges that Licensor intends to establish collaborative arrangements substantially similar to those provided for by this Agreement with third parties for Licensed Products outside of the Licensed Territory and agrees that it shall be to the mutual benefit of each of Licensee, Licensor, and potential other collaborators of Licensor to coordinate Development and commercialization activities for Licensed Products on a global basis. Licensee acknowledges that Licensor intends to establish global committees with functional responsibilities similar to those committees outlined herein and that Licensee shall participate on any such global committee.

Section 6.7. Global Project Management. Licensor shall have overall responsibility for management of global product development and commercialization activities. Licensee hereby acknowledges and agrees that Licensor shall be entitled to maintain oversight on all development and commercialization activities conducted in connection with the Licensed Products and the Licensed Territory in order to ensure consistency of all such activities with Licensor's global product and commercialization plans.

ARTICLE 7
TRANSFER OF LICENSED KNOW-HOW; CONFIDENTIALITY; PUBLICATION

Section 7.1. Transfer of Licensed Know-How. Promptly after the Effective Date and from time to time as it becomes available during the term of this Agreement, Licensor shall provide Licensee with the Licensed Know-How, subject, however, to the terms and conditions contained herein including, without limitation, those set forth in Article 2 of this Agreement.

Section 7.2. Confidentiality. Any information disclosed by either party, its Affiliates or permitted licensees to the other party hereunder shall be safeguarded by the recipient, shall not be disclosed to third parties and shall be made available only to recipient's employees, Affiliates, licensees for the Licensed Products, independent contractors or external counsels who agree to or are bound by equivalent conditions and who have a need to know the information for the purposes specified under this Agreement. Subject to the license granted under Article 2, all confidential information shall remain the property of and shall be immediately returned to the disclosing party, upon request, after any termination of this Agreement. These mutual obligations of confidentiality shall apply during and for a period of ten (10) years after the term of this Agreement, but such obligations shall not apply to any information that can be established by competent evidence:

(a) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation under this Agreement; or

(b) was already known to the recipient as evidenced by prior written documents in its possession; or

(c) is disclosed to the recipient by a third party who is not in default of any confidentiality obligation to the disclosing party hereunder; or

(d) is developed by or on behalf of the receiving party, without reliance on confidential information received hereunder; or

(e) is provided to third parties under appropriate terms and conditions including confidentiality provisions equivalent to those in this Agreement for Development purposes including, without limitation, consulting, manufacturing Development, manufacturing, external testing and marketing trials with respect to the Licensed Products; or

(f) is used with the consent of the disclosing party (which consent shall not be unreasonably withheld) in applications for patents or copyrights under the terms of this Agreement; or

(g) has been approved in writing for publication by each of the parties; or

(h) is required to be disclosed in compliance with applicable laws or regulations in connection with the manufacture or sale of Licensed Products; or

(i) is otherwise required to be disclosed in compliance with applicable laws or regulations or order by a court or other regulatory body having competent jurisdiction; or

(j) is product-related information which is reasonably required to be disclosed in connection with marketing of Licensed Products.

Section 7.3. Procedures for Obtaining Permission for Disclosure. In the event that either party (the "Disclosing Party") desires to publish or disclose, by written, oral or other presentation, any confidential information or other information regarding the Licensed Rights, the Disclosing Party shall notify the other party (the "Nondisclosing Party") in accordance with Section 15.2 at least sixty (60) days before any written or other publication or disclosure. The Disclosing Party shall include with such notice a description of any proposed oral presentation or, in any proposed written or other disclosure, a current draft of such proposed disclosure or abstract. The Nondisclosing Party may, no later than thirty (30) days following the receipt of such notice, notify the Disclosing Party that the Nondisclosing Party will not consent to such disclosure of confidential information. If the Disclosing Party does not receive any such objection to the proposed disclosure of confidential information or other information regarding the Licensed Rights within such 30-day period, the Disclosing Party shall be free to make such disclosure in substantially the manner and form proposed at the time notice was given to the Nondisclosing Party.

ARTICLE 8
TERMINATION

Section 8.1. Term. Unless otherwise terminated by operation of law or by acts of the parties in accordance with the provisions of this Agreement, this Agreement shall be in force from the Effective Date and shall remain in effect with respect to each Licensed Product in each country of the Licensed Territory for the duration of the Initial Period. Upon expiry of the Initial Period with respect to each country in the Licensed Territory, the license granted under Section 2.1 shall become fully paid up in such country.

In such case and in relation with each of such countries, the following shall apply:

(a) Licensee shall be entitled to continue to market the Licensed Products in the relevant country under the Trademark and the Marketing Regulatory Approval;

(b) Should Licensee decide not to purchase a Licensed Product from Licensor, Licensee shall pay a running royalty of [***] percent ([***]%) of Net Sales (as such term is defined in the Revised Supply Agreement) of such Licensed Product so purchased and sold under the Trademark in consideration of the use of the Trademark;

(c) Should Licensee decide not to purchase a Licensed Product from Licensor, Licensor shall promptly transfer free of charge the Marketing Regulatory Approval of the relevant country for such Licensed Product to Licensee or to the third party that may be indicated by Licensee, the transfer expenses being borne by Licensee; provided, however, that the EMEA Marketing Regulatory Approval shall only be transferred to Licensee upon expiry of the Initial Period in all the countries of the European Union;

(d) Should Licensee decide not to purchase the Licensed Products from Licensor, Licensor shall transfer free of charge to Licensee all such know-how that is necessary to enable Licensee to manufacture and/or have manufactured the Licensed Products, and Licensee shall pay a running royalty of [***] percent ([***]%) of Net Sales (as such term is defined in the Revised Supply Agreement) of such Licensed Product so manufactured under such know-how, it being understood that Section 7.2 hereof shall continue to apply with respect to the use of such know-how by Licensee or its subcontractors.

(e) Should Licensee decide to continue purchasing the Licensed Products from Licensor, Licensor shall maintain the Marketing Regulatory Approvals in force;

(f) Licensor shall take all appropriate steps and shall timely and diligently cooperate with Licensee so as to avoid any possible discontinuation in the commercialization of the Licensed Products in each country of the Licensed Territory upon the expiry of the Initial Period; and

(g) Should Licensee decide not to purchase the Licensed Products from Licensor, Licensee shall ensure that such purchased products conform with the Specifications (as such term is defined in the Revised Supply Agreement) and all relevant regulatory authority requirements.

Section 8.2. Termination by Breach. Upon any material breach of or default under this Agreement (including, without limitation, as provided for in Section 7.2 of the

Revised Supply Agreement) by either party, the non-infringing party may terminate this Agreement upon ninety (90) days written notice to the infringing party. Said notice shall become effective at the end of said period, unless during said period the infringing party shall cure such breach or default.

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In the event that this Agreement is terminated by Licensee pursuant to Section 8.2 of this Agreement, subsections (a) to (f) of Section 8.1 shall apply and, in addition, (i) Licensor shall transfer free of charge to Licensee all such know-how that is necessary to enable Licensee to manufacture and/or have manufactured the Licensed Products, and (ii) Licensor shall promptly return and cease to use any Licensee Proprietary Information and any other information provided by Licensee to Licensor under Article 3 hereinabove.

Section 8.3. Termination by Licensee. Licensee may terminate this Agreement hereunder as follows:

(a) Prior to the date of receipt of first Marketing Regulatory Approval, Licensee may terminate this Agreement on sixty (60) days advance written notice to Licensor for any reason, whereupon Licensee shall not be obligated to make any further payments to Licensor other than those payments accruing prior to such termination;

(b) After and including the date of receipt of first Marketing Regulatory Approval, Licensee may terminate this Agreement upon written notice to Licensor of such intention to terminate, provided that (i) Licensee hereby agrees that in any such event, in order to minimize disruption of the availability of Licensed Product in the Licensed Territory, Licensee shall negotiate with Licensor and or Licensor's designee mutually agreeable terms and conditions providing for the transfer of Licensee's rights and obligations hereunder to Licensor and or appropriate third parties and a mutually determined date of termination in accordance therewith provided, however, that failing an agreement on the date of termination, this Agreement will terminate six (6) months after the date of Licensee's termination notice sent under this Section 8.3.(b) and (ii) Licensee shall not be obligated to make any further payments to Licensor other than those payments accruing prior to such termination.

Section 8.4. Termination Upon Bankruptcy Event. If (i) Licensee files a petition in bankruptcy or for the appointment of a receiver or trustee, (ii) Licensee proposes a written agreement of composition or extension of its debts or makes an assignment for the benefit of its creditors, or (iii) an involuntary petition against Licensee is filed in any insolvency proceeding and such petition is not dismissed within sixty (60) days after filing, Licensor may immediately terminate this Agreement.

Section 8.5. No Automatic Termination upon Licensor's Bankruptcy. If (i) Licensor files a petition in bankruptcy or for the appointment of a receiver or trustee; (ii) Licensor proposes a written agreement of composition or extension of its debts or makes an assignment for the benefit of its creditors; or (iii) an involuntary petition against Licensor is filed in any insolvency proceeding and such petition is not dismissed within sixty (60) days after filing, Licensee shall have the option, as permitted by applicable law, to either:

(a) Immediately terminate this Agreement; or

(b) Continue to market the Licensed Products under the Licensed Know-How, Patent Rights, Marketing Regulatory Approvals and the Trademark, in which case the license granted hereunder to Licensee pursuant to Section 2.1 shall become a license to "make, have

made, import, use, offer to sell and sell Licensed Products", provided that such license to make or have made Licensed Products shall be nonexclusive and that Licensor shall be entitled to a royalty in an amount equal to the sum of (i) any and all royalties owed by Licensor to third parties (including without limitation, Original Licensor) with respect to Net Sales of Licensed Products and (ii) [***] percent ([***]%) of such Licensed Product Net Sales. Licensee shall be solely responsible for payment of the third party royalty obligations under such circumstances; provided, however, that any royalties to be paid under this Section 8.5 (b) shall be due only to the extent that Licensee's cost of the Licensed Product in finished, packaged and labeled form, quality controlled and ready for resale to the ultimate customer plus the royalties hereinabove established shall not exceed the applicable Transfer Price established in Section 2.2 of the Revised Supply Agreement. In addition the parties agree that in such event the intellectual property delivered to Licensee shall include all know-how necessary or useful to give Licensee the capability of manufacturing the Licensed Products and such know-how shall be delivered to Licensee in such a way as to communicate it to Licensee promptly, effectively and economically.

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COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

Section 8.6. Termination by Licensor. During the term of this Agreement, Licensor shall be entitled to terminate this Agreement as follows:

(a) With Respect to Competitive Activities. In the event Licensee acquires marketing rights in the Licensed Territory for a surfactant product suitable for use in any of the indications or applications included in the definition of Licensed Products pursuant to Article 1 (including off-label use) (a "Competitive Product"), or in the event Licensee becomes an Affiliate of a Person whose product line includes a Competitive Product (an "Affiliation"), Licensee shall notify Licensor within thirty (30) days of such acquisition or Affiliation and of its intention to either (a) divest such Competitive Product or Affiliation or (b) terminate this Agreement and the Revised Supply Agreement. Any such termination shall be effective sixty (60) days after such notice becomes effective in accordance with Section 14.2. Alternatively, Licensee may notify Licensor that it intends to retain such Competitive Product in its portfolio but does not wish to terminate this Agreement, in which event Licensor can in its sole discretion, within ninety (90) days after receipt of such notice, advise Licensee of its intent to terminate this Agreement, provided that (i) Licensee hereby agrees that in any such event, in order to minimize disruption of the availability of Licensed Product in the Licensed Territory, Licensee shall negotiate with Licensor and or Licensor's designee mutually agreeable terms and conditions providing for the transfer of Licensee's rights and obligations hereunder to Licensor and or appropriate third parties and (ii) Licensee shall not be obligated to make any further payments to

Licensor other than those payments accruing prior to such termination (including, without limitation, any payments owed by Licensee pursuant to Sections 4.4 and 5.2(a), or pursuant to Section 8.8;

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(b) Termination for Lack of Development Support. Licensee shall be entitled to choose not to provide Development support pursuant to Section 5.2(a)(ii) at any time prior to approval of Phase 3 Development for the subject Licensed Product by the Development Committee, provided, however, that in such event Licensee shall promptly provide Licensor with written notification thereof and, further, solely with respect to the subject Licensed Product, Licensee's rights under this Agreement and the Revised Supply Agreement shall immediately terminate without any compensation or indemnification being due to Licensor from Licensee with respect thereto.

(c) As provided for in Section 5.6 of this Agreement.

Section 8.7. Reversion upon certain Early Termination Cases. Upon termination of this Agreement for any reason, other than expiry of the Initial Period (which shall be governed by Section 8.1 hereinabove) or the breach of this Agreement by Licensor (which shall be governed by Section 8.2 hereinabove), all rights granted to Licensee hereunder shall revert to Licensor and Licensee undertakes:

(a) to deliver to Licensor all copies of any Licensed Know-how in its possession,

(b) not to use the Licensed Know-how as long as it has to be kept confidential under Article 7 hereof;

(c) to transfer to Licensor, at Licensor's request, a single copy of all Licensee Proprietary Information and, at Licensor's expense, all health regulatory approvals and regulatory filings relating to Licensed Products in Licensee's possession;

(d) to the extent requested by Licensor, to transfer to Licensor or its designee responsibility for and control of ongoing Licensed Products Development work, including control over contracts with third parties for such work, where permissible in accordance with such contracts, in an expeditious and orderly manner with the costs for such work to be assumed by Licensor or its designee as of the date of such transfer; and

(e) to the extent requested by Licensor, to transfer to Licensor or its designee all inventory of Licensed Products at a price equal to Licensee's fully amortized standard cost.

Section 8.8. Survival. Upon any termination of this Agreement, Articles 3, 7, 10, 11 and 12 and Sections 8.1, 8.2, 8.7 and 8.9, shall survive such termination and continue in force and effect to the extent necessary to effectuate such provisions.

Section 8.9. Disposition. Upon termination of this Agreement (other than by expiration of the Initial Period), subject to Sections 8.4 and 8.6, Licensee shall have no right under the Patent Rights to import, use or sell Licensed Products, except that Licensee shall have the right for one hundred twenty (120) days following termination to dispose of Licensed Products on hand and complete any existing contracts requiring rights under the Patent Rights which can be completed within the one hundred twenty (120) days.

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ARTICLE 9
INFRINGEMENT

Section 9.1. Notice.

(a) In the event that Licensee believes that there is an infringement of the Licensed Rights by a third party hereto selling material quantities of products in the Licensed Territory in competition with Licensee's sale of Licensed Products hereunder, Licensee shall promptly provide Licensor with written notice that such infringement is occurring. In the event that Licensee believes that such infringement is to Licensee's substantial detriment, Licensee shall provide Licensor with reasonable evidence of the infringement.

(b) Licensor shall have the right, at Licensor's sole expense (subject to Section 9.5(a)), to bring suit against the infringer for infringement of the Licensed Rights. However, if after six (6) months from the date of receipt of evidence of infringement from Licensee, Licensor has not initiated suit against the infringer, Licensee shall have the right, at Licensee's sole expense (subject to Section 9.5(b)), to bring such suit provided that the Original Licensor has consented to Licensee bringing such suit. Licensor shall make its best efforts to obtain the Original Licensor's consent in favor of Licensee.

Section 9.2. Assistance. In the event either party hereto shall initiate or carry on legal proceedings to enforce the Licensed Rights against an alleged infringer, as provided herein, the other party hereto shall render reasonable assistance to and cooperate with the party initiating or carrying on such proceedings.

Section 9.3. Legal Proceedings. In the event that either party shall institute legal proceedings to enforce the Licensed Rights, it shall have sole control of such suit and the other party shall be entitled to be represented in any such suit by counsel of its choosing, at its sole expense.

Section 9.4. Discontinuance. Neither party hereto shall discontinue or settle any such proceedings brought by it without obtaining the concurrence of the other party if such action would impose any obligations on such other party or affect the exercise of the rights granted hereunder to such other party (which concurrence shall not be unreasonably withheld).

Section 9.5. Recoveries. All damages, settlements and awards made or obtained in connection with any suit or other legal proceeding under this Article 9 shall be distributed as follows:

(a) If Licensor initiated the suit and prosecuted it to its conclusion, Licensor shall be entitled to retain the balance of any damages, settlements and awards, provided that Licensee may elect (within thirty (30) days of initiation of such suit) to fund up to [***] percent ([***]%) of Licensor's litigation costs and to share in the same proportion of net recoveries.

(b) If the Licensee initiated the suit and prosecuted it to its conclusion, Licensee shall be entitled to retain the balance of any damages, settlements and awards; provided that Licensor may elect (within thirty (30) days of initiation of such suit) to fund up to [***] percent ([***]%) of Licensee's litigation costs and to share in the same proportion of net recoveries received by Licensee.

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ARTICLE 10
NON-USE OF NAMES

Section 10.1. Non-Use. Subject to the licenses expressly granted hereunder with respect to the Trademark, nothing contained in this Agreement shall be construed as granting to Licensor or Licensee any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of the other (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of the other.

Section 10.2. Relationship. Nothing herein shall be deemed to establish a relationship of principal and agent between Licensor and Licensee, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as constituting Licensor and Licensee as partners, or as creating any other form of legal association or arrangement which would impose liability upon one party for the act or failure to act of the other party.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

Section 11.1 Representations of Licensor. Licensor represents and warrants to Licensee that:

(a) it has the right to grant the license granted and the Right of First Negotiation of New Products granted under Sections 2.1. and 2.5, respectively, of this Agreement and that it has full power and authority to execute, deliver and perform this Agreement and the Revised Supply Agreement and the obligations hereunder and thereunder.

(b) to Licensor's knowledge, there are no claims or potential claims by any third parties (other than the Original Licensor and Scripps) to an ownership interest in the Licensed Rights licensed to Licensee under this Agreement.

(c) Licensor has obtained any required third-party consents under contracts to which Licensor or any of its Affiliates is a party to Licensor's entry into this Agreement and the Revised Supply Agreement and the performance of its obligations hereunder and thereunder.

(d) To Licensor's knowledge, based solely on a review of the records of the United States Patent and Trademark Office and the corresponding offices in countries other than the United States, the patents listed on Schedule I are valid.

(e) No third party has served on Licensor or any of its Affiliates any claim, lawsuit, charge, complaint or other action alleging that the Licensed Rights are invalid or unenforceable or that the Licensed Rights infringe any patent or other proprietary or property rights of any third parties or advised Licensor or any of its Affiliates that it intends to pursue any such claim, lawsuit, charge, complaint or other action. Licensor has not, prior to the date hereof, entered into any compulsory license with a third party with respect to the Patent Rights.

(f) The rights of the Original Licensor and of any subsequent licensor (excluding the Licensor) of the Scripps Patent Rights do not prevent the grant of the license made hereunder nor do such rights permit any such person to sell (directly or indirectly) or license for sale surfactant pharmaceutical preparations based on or embodying the Patent Rights in the Licensed Territory or enable such person to demand any indemnity, royalty or compensation of whatever nature from Licensee as a result of Licensee's sales of Licensed Products in the Licensed Territory in accordance with the terms of this Agreement.

(g) Licensor is not in breach of any of its material obligations under the Original License as of the date hereof.

(h) All of Licensor's employees having access to any confidential information with respect to the Licensed Rights are subject to written confidentiality obligations with respect to the disclosure of such information.

(i) Prior to the execution of this Agreement it has disclosed to Licensee all material information pertaining to the Licensed Products and the Patent Rights reasonably relevant to Licensee in order to assess its interest in entering into this Agreement, and that no material information pertaining to the Licensed Products and the Patent Rights actually known to Licensor as of the Effective Date regarding the foregoing has been withheld from Licensee by Licensor.

Section 11.2. Mutual Representation. Each party hereby warrants that the execution, delivery and performance of this Agreement and the Revised Supply Agreement has been duly approved and authorized by all necessary corporate actions of both parties; does not require any shareholder approval which has not been obtained or the approval and consent of any trustee or the holders of any indebtedness of either party; does not contravene any law, regulation rules or order binding on either party, and does not contravene the provisions of or constitute a default under any indenture, mortgage contract or other agreement or instrument to which either party is a signatory.

Section 11.3. Validity. Subject to the foregoing provisions of this Article 11, nothing in this Agreement shall be construed as a representation or a warranty by Licensor that any process practiced or anything imported, used or sold under any license granted under this Agreement is or will be free from infringement of patents of third parties.

Section 11.4. No Consequential Damages. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE PERFORMANCE OF THIS AGREEMENT.

ARTICLE 12
INDEMNIFICATION

Section 12.1. Indemnification by Licensee. Subject to Section 11.4 and to the extent not covered by Licensor's indemnity under Section 12.2, Licensee agrees to indemnify and hold harmless Licensor and its Affiliates and their respective officers, directors, employees and agents from and against any and all claims, damages and liabilities, including reasonable attorneys fees and expenses, asserted by third parties, both government and private (collectively, "Claims"), arising from Licensee's or its Affiliates' or sublicensees' import, use, offer to sell or sale of Licensed Products pursuant to this Agreement, including without limitation any claim for breach of warranty, negligence or strict liability with respect to any Licensed Product. This Section shall apply to the Revised Supply Agreement. In the event of any contradiction between the Revised Supply Agreement and any of the terms contained in this Agreement, the terms of this Agreement shall prevail.

Section 12.2. Indemnification by Licensor. Subject to Section 11.4, Licensor agrees to indemnify and hold harmless Licensee, its Affiliates and sublicensees and their respective officers, directors, employees and agents from and against any and all Claims arising from (a) any infringement of any patent or other intellectual property interest in the Licensed Territory by any Person other than the parties to this Agreement relating to the Licensed Products; (b) any breach by Licensor of its representations and warranties set forth in this Agreement; (c) any negligent act or omission of Licensor and (d) any intrinsic or manufacturing defect of the Licensed Products existing when the Licensed Products are placed by Licensor in the custody of the carrier for transport to Licensee. This Section shall apply to the Revised Supply Agreement. In the event of any contradiction between the Revised Supply Agreement and any of the terms contained in this Agreement, the terms of this Agreement shall prevail.

Section 12.3. Insurance. Licensor and Licensee shall maintain during the term of this Agreement insurance policies covering their respective obligations under this Article 12, issued by reputable insurance companies under ordinary terms and conditions in the pharmaceutical industry and will prove the existence thereof to the other party if so requested.

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ARTICLE 13
TRADEMARK MATTERS; PATENT MARKING

Section 13.1. Trademarks Used in Connection With Licensed Products. (a) Licensed Products shall be marketed under the Trademark. Licensee admits the validity of the Trademark and agrees that it shall not challenge the same in the Licensed Territory or elsewhere.

(b) Licensor shall be responsible, at its own cost and expense, to register, maintain and renew registrations of the Trademark in the Licensed Territory, to the extent that it is necessary for the purposes of obtaining Marketing Regulatory Approval and for the marketing of the Licensed Products in the Licensed Territory. Licensee agrees not to take any actions (including without limitation effecting any trademark registrations) inconsistent with the foregoing and not to register anywhere in the world any trademark confusingly similar to Surfaxin® or any derivative thereof.

(c) Licensee agrees to take such actions as may be reasonably requested by Licensor to assist Licensor to register, maintain or renew any Trademark at the sole cost and expense of Licensor.

Section 13.2. Patent Marking. Licensee shall mark all Licensed Products made, used, or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws.

ARTICLE 14
PATENT PROSECUTION AND MAINTENANCE

Section 14.1. Maintenance of Patent Rights. Licensor has obtained certain commitments from the Original Licensor of the Scripps Patent Rights and the patent rights listed in Section (b) of Schedule I (collectively, the "Third Party Patent Rights") that the Original Licensor will maintain the Third Party Patent Rights or, in the event that the Original Licensor does not do so, that Licensor shall be given the right to do so. Licensor undertakes to enforce its rights with respect to maintenance of the Third Party Patent Rights against the Original Licensor and, to the extent Licensor succeeds to the maintenance of the Third Party Patent Rights, to use all commercially reasonable efforts to do so. Licensor further undertakes to maintain the Patent Rights owned by Licensor as well as to carry out any and all necessary steps in order to enable such Patent Rights be enforced and applicable in each country of the Licensed Territory. Licensor shall provide Licensee with copies of all written materials received by Licensor from the Original Licensor, the Original Licensor's or Licensor's counsel, or any governmental agency or instrumentality relating to prosecution and/or maintenance of Patent Rights and shall afford Licensee the opportunity to review and comment upon any filings to be made with respect to the Patent Rights (in the case of the Third Party Patent Rights, to the same extent Licensor is entitled to do so).

Section 14.2. Cooperation By Parties. Licensor and Licensee agree to cooperate in order to avoid loss of any rights which may be available to Licensor or the Original Licensor under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the European Community and other similar measures in any country. Without limiting the foregoing, Licensee agrees to timely supply Licensor with all information reasonably requested by Licensor to file or have filed (or to permit the Original Licensor to file or have filed) an application for patent term extension within the 60-day period following U.S. NDA approval. The same shall apply with respect to the approval by health regulatory authorities in any country in the Licensed Territory.

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ARTICLE 15
GENERAL

Section 15.1. Entire Agreement. This Agreement, including the Schedules, Annexes and Exhibits hereto, constitutes the entire agreement and understanding between the parties as to the subject matter hereof. All prior negotiations, representations, agreements, contracts, offers and earlier understandings of whatsoever kind, whether written or oral between Licensor and Licensee in respect of the subject matter of this Agreement including, without limitation, the Sublicense and Collaboration Agreement dated March 6, 2002, and the Sublicense and Collaboration Agreement dated October 26, 1999, in each case between Licensee and Licensor, are superseded by, merged into, extinguished by and completely expressed by this Agreement. No aspect, part or wording of this Agreement may be modified except by mutual agreement between the Licensor and Licensee taking the form of an instrument in writing signed and dated by duly authorized representatives of both Licensor and Licensee.

Section 15.2. Notices. Any notice or communication or permitted to be given by this Agreement shall be given by post-paid, first class, registered or certified mail or by reputable courier service addressed to:

In the case of Licensor:	Discovery Laboratories, Inc. 2600 Kelly Road Warrington, Pennsylvania 18976 Attention: Robert J. Capetola, Ph.D, Chief Executive Officer
With a copy to:	Dickstein Shapiro Morin & Oshinsky 1177 Avenue of the Americas, 41st Floor New York, NY 10036-2714 Attn: Ira L. Kotel Facsimile: (212) 997-9880

In the case of Licensee: Laboratorios del Dr. Esteve, S.A.
Av. Mare de Déu de Montserrat, 221
08041 Barcelona (Spain)
Attention: Development Director
Facsimile: (34) 93 433 00 72

With a copy to: JAUSAS
Av. Diagonal 407 bis, 10th Floor
08008 Barcelona (Spain)
Attention: Hector Jausas
Facsimile: (34) 93 415 20 51

Such addresses may be altered by notice so given. If no time limit is specified for a notice required or permitted to be given by this Agreement, the time limit therefor shall be ten (10) Business Days, not including the day of mailing. Notice shall be considered made as of the date of deposit with the appropriate post office or courier service.

Section 15.3. Governing Law. This Agreement and its effect are subject and shall be construed and enforced in accordance with the laws of the State of New York, United States (without giving effect to the principles of conflict of laws), except as to any issue which depends upon the validity, scope or enforceability of any patent within the Patent Rights, which issue shall be determined in accordance with the applicable patent laws of the country of such patent.

Section 15.4 Dispute Resolution.

(a) Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the Chief Executive Officers (or equivalent position) of Licensee and Licensor. For all Disputes referred to the Chief Executive Officers (or equivalent position), the Chief Executive Officers (or equivalent position) shall use their good faith efforts to meet in person and to resolve the Dispute within two weeks after such referral.

(b) Arbitration. If, pursuant to Section 15.4(a), within two weeks or such other period as may be agreed upon between the parties following such reference, the dispute remains unresolved, it shall be settled on application by either party by arbitration conducted in the English language, in Stockholm (Sweden) in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said rules. The parties expressly agree to abide the award rendered. This provision shall not prevent either party from addressing any competent court or tribunal in order to seek for interim measures.

(c) Costs. The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute, and the costs of mediator(s) and arbitrator(s) shall be equally divided between the parties.

Section 15.5. Conflicts. Nothing in this Agreement shall be construed so as to require the commission of any act contrary to law, and whenever there is any conflict between any provision of this Agreement or concerning the legal right of the parties to contract and any statute, law, ordinance or treaty, the latter shall prevail, but in such event the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements.

Section 15.6. Registration. Licensee shall take all reasonable and necessary steps to register this Agreement in any country where such is required to permit the transfer of funds and/or payment of royalties to Licensor hereunder or is otherwise required by the government or law of such country to effectuate or carry out this Agreement. Notwithstanding anything contained herein, 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 at Licensor's address specified in Article 15.2 hereof, where such payment is blocked due to any failure to register this Agreement.

Section 15.7. Headings. As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by the context. The headings appearing at the beginning of the numbered Articles and Sections hereof have been inserted for convenience only and do not constitute a part of this Agreement.

Section 15.8. Force Majeure. Notwithstanding any other provisions of this Agreement, neither of the parties hereto shall be liable in damages for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including but not limited to acts of God, governmental restrictions, wars, or insurrections, strikes, floods, work stoppages and/or lack of materials; provided, however, that the party suffering such delay or default shall notify the other party in writing of the reasons for the delay or default. If such reasons for delay or default continuously exist for six (6) months and the parties are unable to reasonably agree upon alternatives, this Agreement may be terminated by either party.

Section 15.9. Assignment. Except as otherwise set forth in Sections 2.1 and 2.3 of this Agreement with respect to Licensee's right to grant sublicenses and appoint co-marketers and/or co-promoters, neither party hereto may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a party may make such an assignment without the other party's consent to Affiliates or to a successor to substantially all of the business of such party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall 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 15.9 shall be null and void and of no legal effect.

Section 15.10. Successors and Assigns. Subject to Section 15.9, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Licensor and Licensee respectively.

Section 15.11. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Section 15.12. Announcements. Neither party shall make any public announcement or press release regarding the content or signature of this Agreement without the other party's prior written consent other than as may be required by law or any stock exchange rules. If such public announcement or press release is required by law or any stock exchange rules the parties shall use their reasonable endeavors to agree to the text and content thereof prior to making such public announcement or press release.

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IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and duly executed this Agreement on the date(s) indicated below, to be effective the day and year first above written.

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

LABORATORIOS DEL DR. ESTEVE, S.A.

By: /s/ Antonio Esteve

Name:
Title:

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PROJECT FINANCING AGREEMENT

THIS PROJECT FINANCING AGREEMENT (this "**Agreement**") is made and entered into effective as of August 12, 2020 (the "**Effective Date**"), by and between **LEE'S PHARMACEUTICAL (HK) LTD.**, a Hong Kong company organized and existing under the laws of Hong Kong with its principal offices at 1/F, Building 20E, Phase 3, Hong Kong Science Park, Shatin, N.T., Hong Kong, ("**LP**"), and **WINDTREE THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976, USA ("**WINT**"). WINT and LP may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

RECITALS

WHEREAS, WINT owns or otherwise controls certain intellectual property rights and regulatory filings in and to the Products;

WHEREAS, LP possesses resources and expertise in the development, manufacture, marketing and commercialization of pharmaceutical products and is a licensee of WINT;

WHEREAS, LP desires to contribute to the funding of the development of AEROSURF in exchange for the right to receive future payments based on the commercialization of the Products; and

WHEREAS, WINT would like to obtain such funding from LP for such development activities, and make such future payments to LP, as set forth below in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the Parties hereby agree as follows.

ARTICLE 1

DEFINITIONS

The following terms, whether used in the singular or the plural, will have the meaning set forth below.

1.1 "**Accounting Standards**" means generally accepted accounting principles or international financial reporting standards, consistently applied by WINT, in each case as such accounting principles may be, from time to time, in force and effect, and applicable as of the date in which such accounting principles are to be applied or on which any calculation or determination is required to be made.

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

1.3 "**Affiliate**" means, with respect to a Person, any other Person that (directly or indirectly) is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means:

(a) direct or indirect ownership of fifty percent (50%) or more of the voting interest in the Person, or fifty percent (50%) or more interest in the income of the Person ; *provided, however,* that, if local law requires a minimum percentage of local ownership, control will be established by direct or indirect beneficial ownership of one hundred percent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests; or

(b) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the Person (whether through ownership of securities or other ownership interests, by contract, or otherwise).

1.4 "**Applicable Law**" means all laws, statutes, ordinances, codes, rules, and regulations that have been enacted by a Governmental Authority and are in force as of the Effective Date or come into force during the Term, in each case to the extent that the same are applicable to the performance by a Party of its obligations, and/or exercise of its rights, under this Agreement.

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

1.6 "**Breaching Party**" has the meaning set forth in Section 6.2.1.

1.7 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; *provided, however,* that (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term will end on the effective date of expiration or termination of this Agreement.

1.8 "**Calendar Year**" means (a) for the first Calendar Year of the Term, the period beginning on the Effective Date and ending on December 31, 2020, (b) for each Calendar Year of the Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last Calendar Year of the Term, the period beginning on January 1 of the Calendar Year in which this Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement.

1.9 "**Change of Control**" means, with respect to a Party: (a) the sale or exclusive license of all or substantially all of such Party's assets or business relating to this Agreement to a Third Party; (b) a merger, reorganization or consolidation involving the Party and a Third Party in which the voting securities of the Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a transaction (which may include a tender offer for such Party's stock or the issuance, sale or exchange of stock of such Party) with a Third Party or Third Parties in which the stockholders of such Party immediately prior to the transaction do not, immediately after consummation of such transaction, (i) own, directly or indirectly through one or more intermediaries, stock or other securities of such Party that possess a majority of the voting power of all of such Party's outstanding stock and other securities or (ii) possess the power to elect a majority of the members of such Party's board of directors;.

1.10 "**Commercially Reasonable Efforts**" means, as to WINT and a Product, the level of effort, expertise, and resources required to Develop and Commercialize a Product consistent with the reasonable efforts that would be typically exerted by a biotechnology or pharmaceutical company of comparable size and capabilities as WINT in pursuing the development and commercialization of a similar product with similar product characteristics at a similar stage in its development or product life, including, without limitation, with respect to commercial potential, the proprietary position of the Product, the regulatory status and approval process and other relevant technical, scientific, medical or legal factors.

1.11 "**Commercialization**," with a correlative meaning for "**Commercialize**" and "**Commercializing**," means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale and distribution of a Product in the Territory; *provided*, *however*, "**Commercialization**" excludes any activities relating to Development or manufacture of a Product.

1.12 "**Commercialization Net Revenue**" means (a) any Net Proceeds *minus* (b) any payments, such as royalties and milestone payments, owed and paid by WINT in respect to any Third Party intellectual property rights related to the Product and not previously funded by LP.

1.13 "**Confidential Information**" means any and all technical, business or other information or materials that are deemed confidential or proprietary to or by a Party and are disclosed or provided by such Party to the other Party under or in connection with this Agreement, whether disclosed or provided in oral, written, graphic, or electronic form, which may include without limitation trade secrets, processes, formulae, data, Know-How, improvements, inventions, chemical or biological materials, chemical structures, techniques, clinical, sublicensing and marketing and other Development and/or Commercialization plans, strategies, customer lists, financial data, intellectual property information, tangible or intangible proprietary information or materials or other information in whatever form.

1.14 "**Development**" means non-clinical, pre-clinical and clinical drug discovery, research, and/or development activities, including, without limitation, quality assurance and quality control development, and any other activities reasonably related to or leading to the development and submission of information to a Regulatory Authority. When used as a verb, "**Develop**" means to engage in Development.

1.15 "**Development Budget**" has the meaning set forth in Section 2.2.

1.16 "**Development Plan**" has the meaning set forth in Section 2.2.

1.17 "**Disclosing Party**" has the meaning set forth in Section 5.1.

1.18 "**Dispute**" has the meaning set forth in Section 5.1.

1.19 "**Dollars**" or "**US$**" means the lawful currency of the United States.

1.20 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.21 "**Governmental Authority**" will mean any supranational, federal, national, multinational, regional, provincial, county, city, state, or local government, court, governmental agency, authority, board, bureau, instrumentality, regulatory body, or other political subdivision, domestic or foreign.

1.22 "**JAMS Rules**" has the meaning set forth in Section 9.2.

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

1.24 "**Know-How**" means technical information and materials, including, without limitation, technology, software, instrumentation, devices, data, biological materials, assays, constructs, compounds, inventions (patentable or otherwise), practices, methods, algorithms, models, knowledge, know-how, trade secrets, skill and experience (including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, assay and related know-how and trade secrets, and all manufacturing data, manufacturing processes, specifications, assays, quality control and testing procedures, regulatory submissions and related know-how and trade secrets).

1.25 "**License Agreement**" means that certain License, Development and Commercialization Agreement by and between LP and WINT, dated as of June 12, 2017, as amended.

1.26 "**NDA**" means a New Drug Application filed with the FDA that is required for approval for the applicable Product in the United States, or its foreign equivalent in the Territory.

1.27 "**Net Proceeds**" means (a) the gross amounts received by WINT and its Affiliates for arm's length sale, divesture, license or other Development or Commercialization of the Products including without limitation, upfront and milestone payments, distributions of net profit, license maintenance fees, royalties and sublicense income, but *excluding* (i) payments made by a Third Party licensee for bona fide research and development conducted by WINT, (ii) reimbursements paid to WINT of patent expenses related to any Product, and (iii) all amounts received by WINT under the License Agreement *minus* (b) the following deductions solely to the extent incurred or allowed with respect to such sales, and solely to the extent such deductions are in accordance with Accounting Standards, and which are not already reflected as a deduction from the invoiced price: (i) discounts (to the extent not previously applied to such amounts received), charge-back payments, and rebates; (ii) credits or allowances for damaged goods, rejections, recalls or returns of such Product; (iii) freight, insurance, postage, and shipping charges for delivery of such Product, to the extent separately billed on the invoice; (iv) taxes, customs, or duties levied on, absorbed, or otherwise imposed on the sale of such Product, as adjusted for rebates and refunds, to the extent not paid by the Third Party and only to the extent such taxes, customs, or duties are not reimbursed to the paying party, but excluding all income taxes; and (iv) that portion of the annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and any other fees imposed by any Applicable Law and allocable to the Products. Net Proceeds will be determined in accordance with the Accounting Standards.

Net Proceeds shall be determined in Dollars. With respect to Net Proceeds received in a currency other than Dollars, Net Proceeds shall be determined by converting the currencies at which the sales are made into Dollars, at rates of exchange determined in a manner consistent with WINT's methods for calculating rates of exchange in the preparation of WINT's annual financial statements in accordance with the Accounting Standards.

1.28 "**Non-Breaching Party**" has the meaning set forth in Section 6.2.1.

1.29 "**Person**" means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, business trust, unincorporated organization, Governmental Authority or any other legal entity, including, without limitation, public bodies, whether acting in an individual, fiduciary or other capacity

1.30 "**Product/s**" means AEROSURF, Surfaxin, Surfaxin LS and any KL4 Surfactant-containing product as a mono-substance or combination with any other active ingredient(s).

1.31 "**Project Expenses**" means the aggregate amounts actually paid by LP to WINT under Sections 4.1 and 4.2.

1.32 "**Receiving Party**" has the meaning set forth in Section 5.1.

1.33 "**Regulatory Approval**" means approval of an NDA by the FDA for the applicable Product in the United States, or approval by the applicable Regulatory Authority of a regulatory approval application that is equivalent to an NDA in a country other than the United States, and any approvals, licenses, registrations, or authorizations necessary for the manufacture, marketing, and sale of Product in such country and, where relevant, including, without limitation, any reimbursement or pricing approvals. For the sake of clarity, except as otherwise expressly provided herein, "Regulatory Approval" will not be achieved for a Product in a country or, where applicable, a multinational jurisdiction until any approvals relating to pricing and reimbursement from the relevant Regulatory Authorities, if and to the extent such approvals are applicable and necessary before the Product's Commercialization, have been obtained in such country or such jurisdiction.

1.34 "**Regulatory Authority**" means any national or supranational Governmental Authority, including, without limitation, FDA, that has responsibility for granting any licenses or approvals or granting pricing and/or reimbursement approvals necessary for the development, marketing, and sale of a Product in any country.

1.35 "**Regulatory Filings**" means any and all regulatory applications, filings, modifications, amendments, supplements, revisions, reports, submissions, authorizations, and Regulatory Approvals, and associated correspondence required to Develop and Commercialize Products in the Territory, including, without limitation, any reports or amendments necessary to maintain Regulatory Approvals.

1.36 "**Securities Act**" means the Securities Act of 1933, as amended.

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

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

1.39 "**Term**" has the meaning set forth in Section 6.1.

1.40 "**Territory**" has the meaning set forth in the License Agreement.

1.41 "**Third Party**" means any Person other than WINT, LP, and their respective Affiliates.

1.42 "**United States**" or "**U.S.**" means the United States of America and all of its territories and possessions.

ARTICLE 2

WINT RESPONSIBILITIES; LICENSING; REPORTING

2.1 **Responsibilities**. WINT will have the sole right, as between the Parties, to Develop and Commercialize Products outside the Territory, including, without limitation, determining the marketing and regulatory strategies for seeking (if and when appropriate) Regulatory Approvals for Products outside the Territory, filing for such Regulatory Approvals, preparing, submitting, and maintaining any and all Regulatory Filings and Regulatory Approvals for Products outside the Territory, and seeking any necessary Regulatory Approvals of Regulatory Authorities for Product labeling and promotional materials to be used in the applicable jurisdiction(s) in connection with Commercializing Products outside the Territory. As between the Parties, WINT will be responsible for all costs and expenses incurred by WINT in connection with the foregoing activities, subject to LP paying WINT the Project Expenses as set forth in this Agreement. If a WINT Affiliate or a WINT appointed licensee meets or fulfills any or all of the obligations of WINT under this Agreement, and/or observes any of the terms or conditions hereof, then WINT will be deemed to have met or fulfilled such obligations or observed such terms or conditions, as the case may be.

2.2 **Development Plan and Development Budget**. WINT will use its Commercially Reasonable Efforts to conduct the activities set forth in the Development plan set forth on Appendix A (as updated pursuant to Section 2.3, the "**Development Plan**") in accordance with the Development budget set forth on Appendix B (as updated pursuant to Section 2.3, the "**Development Budget**"). WINT must obtain LP's prior consent before amending or modifying the Development Plan and Development Budget.

2.3 **Updates to Development Plan and Development Budget**. No later than September 1, 2020 and each successive six months later, the Parties shall negotiate in good faith and agree to updates to the Development Plan and Development Budget for the following six month period, which updates will reflect the Parties agreement as to the global Development and Commercialization strategy for the Products, the operating plan in respect thereof and LP funding one hundred percent (100%) of the costs of the updated Development Plan via its payment of the Project Expenses. Parties agree to negotiate in good faith a potential long-term agreement for AEROSURF focused on addressing security for LP such as [***].

2.4 **Right to License**. WINT shall retain the right to perform its activities under this Agreement through licensees. WINT will provide LP with notice of the entering into of each license within a reasonable period following the execution of such license.

2.5 **Subcontracting**. WINT may utilize the services of Third Parties, including, without limitation, Third Party contract research organizations, contract manufacturing organizations, suppliers and service providers to perform its Development and Commercialization activities; *provided* that WINT will remain at all times fully liable for its responsibilities under this Agreement.

ARTICLE 3

REGULATORY

3.1 **Regulatory Filings**. WINT or its Affiliates or appointed licensees will solely own and control any and all Regulatory Approvals and any and all other Regulatory Filings submitted in connection with seeking and maintaining Regulatory Approvals for Products outside the Territory.

3.2 **Regulatory Communications**. WINT will be the sole contact, as between the Parties, with the applicable Regulatory Authorities and will be solely responsible, using Commercially Reasonable Efforts, for all communications with such Regulatory Authorities that relate to any Regulatory Approvals or other Regulatory Filings prior to and after any Regulatory Approval with respect to the Products outside the Territory.

Except as may be required by Applicable Law, LP will not communicate regarding Products with any Governmental Authority having jurisdiction outside the Territory unless explicitly requested or permitted in writing to do so by WINT, or unless so ordered by such Governmental Authority having jurisdiction outside the Territory, in which case LP will provide to WINT notice of such order as soon as practicable, but in no event later than five (5) Business Days after receipt of such order. If LP is required to respond to any requests from or by any and all Regulatory Authorities with respect to any Product outside the Territory, WINT will have an opportunity to comment on the response to the extent such response may materially impact the Product outside the Territory before LP submits such response and LP will provide a copy of the final response to WINT.

ARTICLE 4

PAYMENTS

4.1 **Initial Project Expenses**. In partial consideration for the right to receive the payments of Commercialization Net Revenue as set forth in Section 4.2, LP shall pay WINT the amount set forth in the table below under the heading “Payment Amount” by wire of immediately available funds on or before the date set forth in the table below under the heading “Payment Dates”. LP shall make each payment due under this Section 4.1 to an account designated by WINT.

Payment Dates	Payment
April 1, 2020	US$1,000,000*
August 12, 2020 (US time)	US$1,400,000
September 15, 2020	US$400,000

* WINT hereby confirms and acknowledges that such initial payment of US$1,000,000 has been paid by LP and was duly received by WINT on April 3, 2020.

4.2 **Additional Project Expenses**. In partial consideration for the right to receive the payments of Commercialization Net Revenue as set forth in Section 4.3, LP shall pay WINT the additional amounts set forth in each updated Development Budget in accordance with the payment schedule agreed by the Parties in writing concurrently with agreeing to each updated Development Plan and Development Budget.

4.3 **Payment of Commercialization Net Revenues**. In consideration for LP's payment of the Project Expenses to WINT, WINT agrees to pay to LP fifty percent (50%) of any Commercialization Net Revenue up to a total amount equal to one hundred and twenty-five percent (125%) of the Project Expenses. For the avoidance of doubt, at such time as WINT has paid LP Commercialization Net Revenue in an amount equal to one hundred and twenty-five percent (125%) of Project Expenses pursuant to this Section 4.3, LP shall no longer be entitled to receive any further payments from WINT with respect to any Product pursuant to this Agreement, and WINT shall retain one hundred percent (100%) of all Net Proceeds and Commercialization Net Revenue thereafter.

4.4 **Reports and Payments**. During the Term, within forty-five (45) days after the end of each of the first three (3) Calendar Quarters of each Calendar Year and within sixty (60) days after the end of the last Calendar Quarter of each Calendar Year, WINT will pay to LP any amounts of Commercialization Net Revenue due to LP and will deliver to LP a report showing:

4.4.1 the gross amount of Net Proceeds and the specific deductions applied in the calculation of Net Proceeds;

4.4.2 the Commercialization Net Revenue (in Dollars) due to LP for such Calendar Quarter and specific deductions applied in the calculation of Commercialization Net Revenues;

4.4.3 withholding taxes, if any, required by Applicable Law to be deducted with respect to such Commercialization Net Revenue due to LP; and

4.4.4 the rate of exchange used by WINT in determining the amount of Dollars due hereunder.

If no Commercialization Net Revenue is due for any Calendar Quarter hereunder, WINT will so report. WINT will keep complete and accurate records in sufficient detail to properly calculate the Net Proceeds and Commercialization Net Revenue due hereunder to be determined for a period of at least three (3) Calendar Years.

4.5 **Audits**. Upon the written request of LP and not more than once in each Calendar Year, WINT will permit an independent certified public accounting firm selected by LP and reasonably acceptable to WINT, at LP expense, to have access during normal business hours to such records of WINT as may be necessary or reasonably useful to verify the accuracy of the payment reports made and the amounts owed to LP under this Agreement for any Calendar Year period ending not more than thirty-six (36) months prior to the date of such request. Such rights with respect to any Calendar Year will terminate upon the earlier to occur of (a) the completion of an audit pursuant to this Section 4.5 with respect to such Calendar Year and (b) three (3) years after the end of any such Calendar Year. LP will provide WINT with a copy of such accounting firm's written report within thirty (30) days after completion of such report. If such accounting firm concludes that an overpayment or underpayment was made, then the owing Party will pay the amount due within thirty (30) days after the date LP delivers to WINT such accounting firm's written report so concluding, and any accrued interest as determined in accordance with Section 4.8 from the date such overpayment was paid or such underpayment was originally due, as applicable, until payment thereof. LP will bear the full cost of such audit unless such audit discloses that the additional payment payable by WINT for the audited period is more than five percent (5%) of the amount of the payments due for that audited period, in which case WINT will pay the reasonable documented fees and expenses charged by the accounting firm. If the Parties dispute any such accounting firm's conclusion, they will resolve such issue pursuant to Section 9.2. LP will treat all information subject to review under this Section 4.5 in accordance with the confidentiality provisions of this Agreement.

4.6 **Currency of Payments**. All payments under this Agreement will be made in Dollars by wire transfer of immediately available funds into an account designated by LP. Net Proceeds and Commercialization Net Revenues outside of the U.S. will be first determined in the currency in which they are earned and will then be converted into an amount in Dollars using WINT's customary and usual conversion procedures used in preparing its financial statements pursuant to the Accounting Standards for the applicable reporting period.

4.7 **Blocked Currency**. In each country outside the Territory where the local currency is blocked and cannot be removed from the country, at the election of LP, Commercialization Net Revenue in such country will be paid to LP in local currency by deposit in a local bank in such country designated by LP.

4.8 **Taxes**. Each Party will be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of payments made by WINT to LP under this Agreement. To the extent WINT is required under the Internal Revenue Code of 1986, as amended (the "**Code**"), or any other tax laws to deduct and withhold taxes on any payment to LP, and WINT pays the amounts of such taxes to the proper Governmental Authority in a timely manner, then the sum payable by WINT will be increased to the extent necessary to ensure that LP receives a sum equal to the sum which it would have received if no such increased tax deduction or withholding had been required.

ARTICLE 5

NONDISCLOSURE OF CONFIDENTIAL INFORMATION

5.1 **Nondisclosure**. Each Party agrees that, during the Term and for a period of ten (10) years thereafter (or, for any trade secret, for so long as the Disclosing Party maintains such trade secret as a trade secret), a Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") will (a) maintain in confidence such Confidential Information, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in this Article 5, and (c) not use such Confidential Information for any purpose except those expressly permitted by this Agreement.

5.2 **Exceptions**. The obligations under Section 5.1 will not apply with respect to any portion of Confidential Information of a Disclosing Party that the Receiving Party can show by competent evidence:

5.2.1 at the time of disclosure to Receiving Party is in the public domain;

5.2.2 after disclosure, becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Receiving Party or anyone to whom the Receiving Party disclosed Confidential Information;

5.2.3 was (a) in the Receiving Party's possession at the time of disclosure without any obligation to keep it confidential or any restriction on its use or (b) subsequently and independently developed by the Receiving Party's employees who had no knowledge of and who did not use, rely on or refer to any of Disclosing Party's Confidential Information, in each case as shown by Receiving Party's contemporaneous records; or

5.2.4 is received by the Receiving Party from a Third Party who has the lawful right to disclose such Confidential Information and who has not obtained such Confidential Information either directly or indirectly from the Disclosing Party.

5.3 **Authorized Disclosure**. To the extent (and only to the extent) that it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party in the following instances:

5.3.1 prosecuting or defending litigation;

5.3.2 subject to Section 5.4, required by Applicable Laws (including, without limitation, the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange) and with judicial process; and

5.3.3 to Affiliates in connection with the performance of this Agreement and to potential or actual collaborators (including, without limitation, actual and potential licensees), who prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 5, or employees, independent contractors (including, without limitation, contract research organizations, contract manufacturing organizations, consultants and clinical investigators) or agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and nonuse no less restrictive than the obligations set forth in this Article 5; *provided, however,* that the Receiving Party will remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 5.3.3 to treat such Confidential Information as required under this Article 5.

5.4 **Required Disclosure**. A Receiving Party may disclose Confidential Information of the Disclosing Party to the extent such disclosure is required pursuant to interrogatories, judicial requests for information or documents, subpoena, civil investigative demand issued by a court or Governmental Authority having valid jurisdiction or as otherwise required by Applicable Law; *provided, however,* that the Receiving Party, to the extent legally permitted, will notify the Disclosing Party promptly in writing upon receipt thereof, giving (where practicable) the Disclosing Party sufficient advance notice to permit it to oppose, limit or seek a protective order or confidential treatment for such disclosure; and *provided, further,* that the Receiving Party will furnish only that portion of the Confidential Information that it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by the Disclosing Party.

ARTICLE 6

TERM AND TERMINATION

6.1 **Term and Expiration**. The term of this Agreement will commence on the Effective Date, and will continue for as long as payments are due or payable under this Agreement, or until such date as this Agreement is sooner terminated in accordance with Section 6.2 or by mutual written consent of the Parties (the "**Term**").

6.2 **Termination for Material Breach**.

6.2.1 If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") is in material breach of this Agreement, then the Non-Breaching Party may deliver notice of such breach to the Breaching Party. In such notice, the Non-Breaching Party will identify with reasonable specificity the alleged breach and the actions or conduct that it wishes the Breaching Party to take for an acceptable and prompt cure of such breach; *provided* that such identified actions will not be binding upon the Breaching Party with respect to the actions that it may need to take to cure such breach. The Breaching Party shall have ninety (90) days to cure such breach. If the Breaching Party fails to cure such breach within such cure period, the Non-Breaching Party may, subject to Section 6.2.2, terminate this Agreement immediately by providing the Breaching Party a written notice after the end of such cure period. Notwithstanding the foregoing, if WINT is the Breaching Party and it fails to cure such breach within such cure period, but within such cure period WINT can reasonably prove, to the Lee's reasonable satisfaction, that it is using Commercially Reasonable Efforts to cure such breach, then Lee's may not terminate this Agreement for so long as WINT is using Commercially Reasonable Efforts to cure such breach.

6.2.2 Notwithstanding the foregoing, if the Breaching Party disputes in good faith the existence or materiality of such breach and provides notice to the Non-Breaching Party of such dispute within such cure period, the Non-Breaching Party will not have the right to terminate this Agreement in accordance with this Section 6.2 unless and until it has been determined in accordance with Section 9.2 that this Agreement was materially breached by the Breaching Party and the Breaching Party failed to cure such breach within the applicable cure period in accordance with Section 6.2.1. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

6.3 **Continuing Obligations**. Upon expiration or termination of this Agreement: (a) neither Party will be relieved of any obligation that accrued prior to the effective date of such termination and (b) all amounts due or payable to LP pursuant to Section 4.3 that were accrued prior to the effective date of termination will remain due and payable.

6.4 **Retention of Payments**. Upon expiration or termination of this Agreement, each Party will have the right to retain all amounts previously paid to it by the other Party.

6.5 **Survival**. Expiration or termination of this Agreement for any reason will not (a) release any Party from any obligation that has accrued prior to the effective date of such expiration or termination, (b) preclude any Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (c) terminate any right to obtain performance of any obligation provided for in this Agreement that will survive expiration or termination. Without limiting the foregoing, upon expiration or termination of this Agreement, the rights and obligations of the Parties under Sections 6.3, 6.4, and this Section 6.5 and Article 1, Article 5 (for the term set forth in Section 5.1), Article 7, Article 8, and Article 9 will survive such expiration or termination.

ARTICLE 7

REPRESENTATIONS, WARRANTIES, AND COVENANTS

7.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that:

7.1.1 it has the requisite corporate power and authority to enter into and perform its obligations under this Agreement;

7.1.2 it has full legal power to extend the rights granted to the other under this Agreement;

7.1.3 it is not aware of any impediment that would inhibit its ability to perform the terms and conditions imposed on it by this Agreement; and

7.1.4 it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement.

ARTICLE 8

DISCLAIMER; LIMITATION OF LIABILITY

8.1 **DISCLAIMER**. EXCEPT AS PROVIDED UNDER ARTICLE 7, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

8.2 **LIMITATION OF LIABILITY**.

8.2.1 NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE, OR MULTIPLE DAMAGES ARISING IN CONNECTION WITH THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, OR FOR LOST PROFITS OR LOSS OF USE ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES,

8.2.2 NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, SECTION 8.2.1 WILL NOT LIMIT OR RESTRICT (A) DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 5, (B) THE INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 7, OR (C) THE OBLIGATIONS TO MAKE PAYMENTS TO WINT UNDER SECTIONS 4.1 AND 4.2 AND PAYMENTS OF COMMERCIALIZATION NET REVENUE TO LP UNDER SECTION 4.3.

8.3 **No Assumed Obligations**. Notwithstanding any provision in this Agreement, LP is not assuming any liability or obligation of WINT or any of WINT's Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter. All such liabilities and obligations shall be retained by and remain liabilities and obligations of WINT or its Affiliates, as the case may be.

ARTICLE 9

MISCELLANEOUS

9.1 **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.

9.2 **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 (1) 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 9.2. 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 WINT, the second arbitrator will be selected by LP, 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.

9.3 **Assignment**. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed, or conditioned; *provided, however,* that either Party may, without such consent, assign this Agreement together with all of its rights and obligations hereunder to its Affiliates, or to a successor in interest in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of a Change of Control, subject to the assignee agreeing to be bound by the terms of this Agreement. Any purported assignment in violation of the preceding sentences will be void. Any permitted assignee or successor will assume and be bound by all obligations of its assignor or predecessor under this Agreement.

9.4 **Severability**. If any provision of this Agreement is held to be invalid or unenforceable, all other provisions will continue in full force and effect, and the Parties will substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

9.5 **Notices**. Any notice or other communication to a Party pursuant to this Agreement will be sufficiently made or given on the date it was sent; *provided* that such notice or other communication is sent by first class certified or registered mail, postage prepaid, or is sent by next day express delivery service, addressed to it at its address in this Section 9.5, below, or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

If to LP:

Lee's Pharmaceutical (HK) Ltd.
1/F, Building 20E, Phase 3, Hong Kong Science Park
Shatin, N.T., Hong Kong
Attention: CEO

If to WINT, to:

Windtree Therapeutics, Inc.
2600 Kelly Rd., Suite 100
Warrington, PA 18976
Attention: CEO

With a copy to (*which alone will not constitute notice*):

Troutman Pepper Hamilton Sanders LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312
Attention: Timothy C. Atkins

9.6 **Expenses**. Except as expressly set forth in this Agreement or as may be specifically agreed to in writing between WINT and LP, each Party will be responsible for all costs and expenses it incurs in connection with this Agreement.

9.7 **Headings**. The headings of Articles and Sections of this Agreement are for ease of reference only and will not affect the meaning or interpretation of this Agreement in any way.

9.8 **Waiver**. The failure of either Party in any instance to insist upon the strict performance of the terms of this Agreement will not be construed to be waiver or relinquishment of any of the terms of this Agreement, either at the time of the Party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect.

9.9 **Counterparts; Electronic Delivery**. This Agreement and any amendment may be executed in one or more counterparts (including, without limitation, by way of PDF or electronic transmission), each of which will be deemed an original, but all of which together will constitute one and the same instrument. When executed by the Parties, this Agreement will constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, PDF signatures will be treated as original signatures.

9.10 **Independent Contractors**. Nothing contained in this Agreement will be deemed to constitute a joint venture, partnership, or employer-employee relationship between LP and WINT, or to constitute one as the agent of the other. Neither Party will be entitled to any benefits applicable to employees of the other Party. Both Parties will act solely as independent contractors, and nothing in this Agreement will be construed to make one Party an agent, employee, or legal representative of the other Party for any purpose or to give either Party the power or authority to act for, bind, or commit the other Party.

9.11 **Entire Agreement**. This Agreement, together with the Appendices attached hereto, constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous proposals, oral or written, confidentiality agreements, and all other communications between the Parties with respect to such subject matter.

9.12 **Modifications**. The terms and conditions of this Agreement may not be amended or modified, except in writing signed by both Parties.

9.13 **Exports**. The Parties acknowledge that the export of technical data, materials, or products is subject to the exporting Party receiving any necessary export licenses and that the Parties cannot be responsible for any delays attributable to export controls which are beyond the reasonable control of either Party. WINT and LP agree not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples, or equipment received or generated under this Agreement in violation of any applicable export control laws.

9.14 **Further Assurances**. Each Party agrees to do and perform all such further reasonable acts and things and will execute and deliver such other agreements, certificates, instruments, and documents necessary to carry out the intent and accomplish the purposes of this Agreement.

9.15 **Interpretation**.

9.15.1 This Agreement was prepared in the English language, which language will govern the interpretation of, and any dispute regarding, the terms of this Agreement.

9.15.2 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including, without limitation, the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

9.15.3 The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine, and neuter forms. The word “any” will mean “any and all” unless otherwise clearly indicated by context.

9.15.4 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument, or other document herein 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), (b) any reference to any Applicable Laws herein will be construed as referring to such Applicable Laws as from time to time enacted, repealed, or amended, (c) any reference herein to any Person will be construed to mean the Person’s successors and assigns (after any such succession or assignment), (d) 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, and (e) all references herein to Articles, Sections, or Appendices, unless otherwise specifically provided, will be construed to refer to Articles, Sections, and Appendices of this Agreement.

9.15.5 References to sections of the Code of Federal Regulations and to the United States Code will mean the cited sections, as these may be amended from time to time.

9.16 **Force Majeure Event**. Except for the payment of money, neither Party will be in breach or default, nor will either Party be liable or responsible to the other Party for losses or damages, nor will either Party have the right to terminate this Agreement, for any breach, default or delay by the other Party that is attributable to an event beyond their reasonable control, including, without limitation, acts of God, acts of government (including, without limitation, injunctions), fire, flood, earthquake, epidemic or global pandemic outbreak, strike, lockout, labor dispute, breakdown of plant, shortage of equipment or supplies, loss or unavailability of manufacturing facilities or materials, casualty or accident, stoppage or interruption of transportation or utilities, civil commotion, acts of public enemies, acts of terrorism or threat of terrorist acts, blockage or embargo and the like (each, a "**Force Majeure Event**")**;** *provided*, *however*, that such Party will use Commercially Reasonable Efforts to avoid and/or minimize the impact of such occurrence, and give prompt written notice of any Force Majeure Event to the other Party.

[*Signature Page Follows*]

IN WITNESS WHEREOF, each of the Parties has caused its duly authorized officer to execute and deliver this Project Financing Agreement as of the Effective Date.

LEE'S PHARMACEUTICAL (HK) LTD.

By: /s/ Dr. Li Xiaoyi

Name: Dr. Li Xiaoyi

Title: CEO

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig Fraser

Name: Craig Fraser

Title: CEO

[Signature Page to Project Finance Agreement]

Appendix A

Development Plan

[***]

Appendix B

Development Budget

[***]

Exhibit 31.1

CERTIFICATION

I, Craig 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 officer 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, 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 officer(s) 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 functions):

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

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

Date: November 16, 2020

/s/ Craig Fraser
Craig 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 officer 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, 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 officer(s) 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 functions):

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

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

Date: November 16, 2020

/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, 2020, 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 Section 13(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 16, 2020

/s/ Craig Fraser
Craig 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.