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 March 31, 2008

10

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

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3171943

(I.R.S. Employer Identification Number)

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

(215) 488-9300

(Registrant's telephone number, including area code)

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

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o (Do no check if a smaller reporting company) Smaller Reporting company o

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

As of May 2, 2008, 96,688,377 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

Table of Contents

PART I - FINANCIAL INFORMATION

	<u>Page</u>
Item 1. Financial Statements	1
CONSOLIDATED BALANCE SHEETS	
As of March 31, 2008 (unaudited) and December 31, 2007	1
CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)	
For the Three Months Ended March 31, 2008 and 2007	2
CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)	
For the Three Months Ended March 31, 2008 and 2007	3
Notes to Consolidated Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	8
Item 3. Quantitative and Qualitative Disclosures about Market Risk	24
Item 4. Controls and Procedures	24
PART II - OTHER INFORMATION	
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	26
Item 3. Defaults Upon Senior Securities	26
Item 4. Submission of Matters to a Vote of Security Holders	27
Item 5. Other Information	27
Item 6. Exhibits	27
Signatures	28
ii	

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition; plans regarding the May 2008 Approvable Letter that we received from the FDA for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome in premature infants; our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; plans regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

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 our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Examples of the risks and uncertainties include, but are not limited to:

- the risk that we may not be able to timely respond to the Approvable Letter that we recently received for Surfaxin and that any response that we do file will not satisfy the FDA•
- the risk that the Food and Drug Administration (FDA) or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, including our New Drug Application (NDA) for Surfaxin, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations:
- · risks relating to the rigorous regulatory approval processes, including pre-NDA activities, required for approval of any drug or medical device products that we may develop, independently, with development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- · risks relating to our research and development activities, which involve time-consuming and expensive pre-clinical studies, multi-phase clinical trials and other studies and other efforts, and which may be subject to potentially significant delays or regulatory holds, or fail;
- the risk that we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances on a timely basis or in an amount sufficient to meet demand:
- · risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- · risks relating to the ability of our development partners and third-party suppliers of materials, drug substances and aerosolization systems and related components to timely provide us with adequate supplies and expertise to support development and manufacture of drug product and aerosolization systems for initiation and completion of our clinical studies, and, if approved, commercialization of our drug and combination drug-device products;
- the risk that we may not successfully and profitably market our products;
- · the risk that , even if approved, we may be unable, for reasons related to market conditions, the competitive landscape or otherwise, to successfully launch and market our products;
- · risks relating to our ability to develop a successful sales and marketing organization to market Surfaxin., if approved, and our other product candidates, in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products;

- · the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- the risk that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- the risk that we may not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT);
- · the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- · risks relating to reimbursement and health care reform;
- · risks that financial market conditions may change, additional financings could result in equity dilution, or we will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;
- the risk that we may be unable to maintain and protect the patents and licenses related to our SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect us;
- · the risk that we may become involved in securities, product liability and other litigation;
- · other risks and uncertainties detailed in "Risk Factors" and in the documents incorporated by reference in this report.

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

Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(in thousands, except per share data)

	March 31, 2008		2007	
ASSETS	(U	naudited)		
Current Assets:				
Cash and cash equivalents	\$	19,050	\$	36,929
Available-for-sale marketable securities	Ф	22,495	Ф	16,078
Receivable from collaborative arrangement		2,000		10,070
Prepaid expenses and other current assets		442		611
Total Current Assets	<u> </u>	43,987		53,618
		·		
Property and equipment, net		6,766		7,069
Restricted cash		600		600
Deferred financing costs and other assets		1,320		1,457
Total Assets	\$	52,673	\$	62,744
LIABILITIES & STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	1,927	\$	757
Accrued expenses		4,608		7,087
Equipment loan, current portion		2,794		2,625
Total Current Liabilities		9,329		10,469
Loan payable, including accrued interest		9,781		9,633
Equipment loan, non-current portion		2,384		2,991
Other liabilities		881		870
Total Liabilities		22,375		23,963
Caralitatilana Pranten				
Stockholders' Equity: Common stock, \$0.001 par value; 180,000 shares authorized; 97,001 and 96,953 shares issued; and 96,688 and 96,640				
shares outstanding at March 31, 2008 and December 31, 2007, respectively.		97		97
Additional paid-in capital		331,181		329,999
Accumulated deficit		(298,017)		(288,303)
Treasury stock (at cost); 313 shares		(3,054)		(3,054)
Other comprehensive income		91		42
Total Stockholders' Equity		30,298		38,781
Total Liabilities & Stockholders' Equity	\$	52,673	\$	62,744

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share data)

Three Months Ended March 31,

	 2008	 2007
Revenue from collaborative arrangement and grants	\$ 2,050	\$ _
Evpances		
Expenses:	7 222	E 422
Research and development General and administrative	7,232	5,422
	 4,505	 2,754
Total expenses	 11,737	 8,176
Operating loss	(9,687)	(8,176)
Other income / (expense):		
Interest and other income	441	306
Interest and other expense	(468)	(440)
Other income / (expense), net	(27)	(134)
Net loss	\$ (9,714)	\$ (8,310)
Net loss per common share -		
Basic and diluted	\$ (0.10)	\$ (0.12)
Weighted average number of common shares outstanding - basic and diluted	96,649	69,989
See notes to consolidated financial statements		
2		

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(Unaudited) (in thousands)

Three Months Ended March 31,

	Mar	ch 31,
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (9,714)	\$ (8,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	573	376
Stock-based compensation and 401(k) match	1,182	751
Loss on disposal of property and equipment	1	_
Changes in:		
Receivable from collaborative arrangement	(2,000)	
Prepaid expenses and other assets	144	348
Accounts payable and accrued expenses	(1,309)	(834)
Other liabilities and accrued interest on loan payable	159	179
Net cash used in operating activities	(10,964)	(7,490)
Cash flows from investing activities:		
Purchase of property and equipment	(109)	(275)
Restricted cash	_	160
Purchases of marketable securities	(17,773)	(2,000)
Proceeds from sales or maturity of marketable securities	11,405	
Net cash used in investing activities	(6,477)	(2,115)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	_	2,005
Proceeds from equipment loan	251	_
Principal payments under equipment loan obligations	(689)	(494)
Net cash (used in)/provided by financing activities	(438)	1,511
Net decrease in cash and cash equivalents	(17,879)	
Cash and cash equivalents - beginning of period	36,929	26,173
Cash and cash equivalents - end of period	\$ 19,050	\$ 18,079
Supplementary disclosure of cash flows information:		
Interest paid	\$ 157	\$ 123
Non-cash transactions:		
Unrealized gain on marketable securities	49	_
See notes to consolidated financial statements		
3		

Notes to Consolidated Financial Statements (unaudited)

Note 1 - The Company and Basis of Presentation

The Company

Discovery Laboratories, Inc. (referred to in these Notes as "we", "us" and "our") is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Our proprietary technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. We believe that our proprietary technology makes it possible, for the first time, to develop a series of SRT respiratory therapies to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. On May 1, 2008, we received from the U.S. Food and Drug Administration ("FDA") a third Approvable Letter for our initial SRT product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations." We are also developing Surfaxin for the treatment of Acute Respiratory Failure (ARF) in children up to two years of age and for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. AerosurfTM is our proprietary SRT in aerosolized form and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of SRT in respiratory medicine.

We also believe that our SRT will potentially address a variety of debilitating respiratory conditions such as Acute Lung Injury (ALI), cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and asthma, that affect other pediatric, young adult and adult patients in the ICU and other hospital settings.

We have implemented a business strategy that includes: (i) focusing primarily on our formal response to the Approvable Letter to potentially gain regulatory approval in 2008 for Surfaxin for the prevention of RDS in premature infants in the United States; (ii) continued investment in the development of Aerosurf for neonatal and pediatric conditions; (iii) preparing for the potential commercial launch of Surfaxin in the United States; (iv) seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT pipeline, including Surfaxin and Aerosurf; (v) continued investment in our quality systems and manufacturing capabilities to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT products; and (vi) seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific actions or transactions.

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. Certain prior period balances have been reclassified to conform to the current period presentation. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2007.

Note 2 - Accounting Policies and Recent Accounting Pronouncements

Accounting Policies

There have been no changes to our critical accounting policies since December 31, 2007. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2007. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

Recent Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," or SFAS 141(R), which is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree, and the goodwill acquired in the business combination. SFAS 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141(R) will be applied prospectively. We are currently evaluating the effect that the adoption of SFAS 141(R) will have on our results of operations and financial condition.

In December 2007, the FASB ratified EITF Issue No. 07-1, "Accounting for Collaborative Arrangements." EITF 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the collaborative arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact of the pending adoption of EITF 07-1 on our consolidated financial statements.

In June 2007, the FASB ratified EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities." EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. EITF Issue No. 07-3 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," which is effective for financial statements issued for fiscal years beginning after November 15, 2007. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The Statement also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. We SFAS 159 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No.157, "Fair Value Measurements" (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. The standard requires expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements.

Note 3 - Net Loss Per Share

Net loss per share is computed based on the weighted average number of common shares outstanding for the periods. Common shares issuable upon the exercise of options and warrants are not included in the calculation of the net loss per share as their effect would be anti-dilutive.

Note 4 - Comprehensive Loss

Total comprehensive loss was \$9.7 million and \$8.3 million for the three months ended March 31, 2008 and 2007, respectively. Total comprehensive loss consists of the net loss and unrealized gains and losses on marketable securities.

Note 5 - Receivable from Collaborative Arrangements

The receivable from collaborative arrangements is associated with a March 2008 restructuring of a collaboration arrangement with Philip Morris USA Inc. d/b/a Chrysalis Technologies (Chrysalis"). Under the modified collaboration, Chrysalis agreed to pay us \$4.5 million to support further development of the aerosolization technology, of which \$2.0 million was classified as a receivable as of March 31, 2008 and paid 30 days after execution of the modification agreements and \$2.5 million will be payable upon completion of a technology transfer, which is expected to be completed by June 30, 2008.

Note 6 - Working Capital

We have incurred substantial losses since inception and expect to continue to make significant investments for continued product research, development, manufacturing and commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities and the use of debt and our equipment financing facility.

We are subject to risks customarily associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

We plan to fund our research, development, manufacturing and potential commercialization activities through:

- · the issuance of equity and debt financings;
- · payments from potential strategic collaborators, including license fees and sponsored research funding;
- · sales of Surfaxin and our other SRT, if approved;
- · equipment financings; and
- · interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of our product development and, if approved, our commercialization plans. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although there can be no assurance that we will be able to obtain additional capital when needed with acceptable terms, if at all.

We have a Committed Equity Financing Facility (CEFF) that allows us to raise capital, subject to certain conditions, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions, including a share and dollar limitation (currently approximately 5.2 million not to exceed \$35.5 million) and the volume weighted average price of our common stock on each trading day must be at least \$2.00. We anticipate using the CEFF, when available, to support working capital needs in 2008. (See our most recent Annual Report on Form 10-K at "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility")

Note 7 - Stock-Based Employee Compensation

We use the Black-Scholes option pricing model to determine the fair value of stock options and amortize the stock-based compensation expense over the requisite service periods of the stock options. The fair value of the stock options is determined on the date of grant using the Black-Scholes option-pricing model. The fair value of stock options is affected by our stock price and several subjective variables, including the expected stock price volatility over the term of the option, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing formula and the assumptions noted in the following table:

	March 31, 2008	March 31, 2007
Expected volatility	77%	95%
Expected term	4 and 5 years	4 and 5 years
Risk-free rate	3.4% - 3.5%	4.6%
Expected dividends	_	_

The total employee stock-based compensation for the three months ended March 31, 2008 and 2007 was as follows:

(in thousands)	Three Months Ended				
	March 31,				
		2008		2007	
Research & Development	\$	332	\$		234
General & Administrative		723			424
Total	\$	1,055	\$		658

As of March 31 2008, there was \$7.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average vesting period of 1.91 years.

As of March 31, 2008, 55,913 restricted stock awards were issued and outstanding under our Amended and Restated 1998 Stock Incentive Plan (1998 Plan).

Note 8 - Litigation

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendants' motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by our Company. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania. On April 29, 2008, the Third Circuit Court of Appeals affirmed the District Court's dismissal of the complaint for the reasons set forth in the District Court opinion. Plaintiffs have 14 days, or until May 13, 2008, to decide whether to seek a rehearing of the Third Circuit's decision.

Actions such as this one, based upon similar allegations, or otherwise, may be filed in the future. The potential impact of such actions, which generally seek unquantified damages, attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any such proceedings would not have a potentially material adverse effect on our business, results of operations and financial condition.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the termination in 2006 of certain pre-launch commercial programs following our process validation stability failure. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, we believe the pending matters are unlikely to have a material adverse effect on our financial condition or results of operations. However, there can be no assurance that we will be successful in any proceeding to which we are or may be a party.

Note 9 - Subsequent Event

On May 1, 2008, we received from the FDA a third Approvable Letter for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. This official notification sets forth the remaining conditions that must be satisfied to gain U.S. marketing approval for Surfaxin.

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

"Management's Discussion and Analysis of Financial Condition and Results of Operations" should be read in connection with our accompanying Consolidated Financial Statements (including the notes thereto) appearing elsewhere herein.

OVERVIEW

We are a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Our proprietary technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. We believe that our proprietary technology makes it possible, for the first time, to develop a series of SRT respiratory therapies to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. On May 1, 2008, we received from the U.S. Food and Drug Administration ("FDA") a third Approvable Letter for our initial SRT product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants (see"Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations - Research and Development - SRT for Neonatal and Pediatric Indications - Surfaxin for the Prevention of RDS in Premature Infants"). We are also developing Surfaxin for the treatment of Acute Respiratory Failure (ARF) in children up to two years of age and for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. AerosurfTM is our proprietary SRT in aerosolized form and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of SRT in respiratory medicine.

We also believe that our SRT will potentially address a variety of debilitating respiratory conditions such as Acute Lung Injury (ALI), cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and asthma, that affect other pediatric, young adult and adult patients in the ICU and other hospital settings.

We have implemented a business strategy that includes:

- · focusing primarily on our formal response to the Approvable Letter to potentially gain regulatory approval in the United States in 2008 for Surfaxin for the prevention of RDS in premature infants;
- . continued investment in the development of Aerosurf for neonatal and pediatric conditions;
- preparing for the potential commercial launch of Surfaxin in the United States, including building our own commercial organization specialized in neonatal and pediatric indications to execute the launch of Surfaxin in the United States;
- seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT pipeline, including Surfaxin and Aerosurf. We continue to evaluate a variety of other potential strategic international and domestic collaborations intended to support the future growth of our SRT pipeline and enhance shareholder value;
- continued investment in our quality systems and manufacturing capabilities, including our recently-completed analytical laboratories in Warrington, Pennsylvania and our manufacturing operations in Totowa, New Jersey. We plan to manufacture sufficient drug product to meet the anticipated pre-clinical, clinical, formulation development and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT product candidates. For our aerosolized SRT, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our development and potential future commercial requirements. Our long-term manufacturing strategy includes potentially expanding our existing facilities or building or acquiring additional manufacturing capabilities for the production and development of our proprietary peptide-containing synthetic SRT drug products; and
- seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific actions or transactions.

Since our inception, we have incurred significant losses and, as of March 31, 2008, we had an accumulated deficit of \$298.0 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations."

Historically, we have funded our operations with working capital provided principally through public and private equity financings, debt arrangements and strategic collaborations. As of March 31, 2008, we had: (i) cash and marketable securities of \$41.5 million; (ii) approximately 5.2 million shares potentially available for issuance under a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, for future financings (not to exceed \$35.5 million), subject to certain conditions, including that the volume weighted average price of our common stock on each trading day must be at least \$2.00; (iii) \$9.8 million outstanding (\$8.5 million principal and \$1.3 million of accrued interest as of March 31, 2008) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp., which is due and payable, together with all accrued interest on April 30, 2010; and (iv) \$5.2 million outstanding under our equipment financing facility with General Electric Business Financial Services Inc. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

RESEARCH AND DEVELOPMENT

Research and development expenses for the three months ended March 31, 2008 and 2007 were \$7.2 million and \$5.4 million, respectively. These costs are charged to operations as incurred and are tracked by category rather than by project. Research and development costs consist primarily of expenses associated with our manufacturing operations, formulation development, development of aerosolization systems, research, clinical, regulatory and other direct preclinical and clinical projects.

These cost categories typically include the following expenses:

Manufacturing Development

Manufacturing development primarily reflects costs to: (i) maintain our manufacturing operations in Totowa, New Jersey and our quality assurance and analytical chemistry capabilities in Totowa and at our recently completed analytical and development laboratories at our headquarters in Warrington, Pennsylvania, to assure adequate production of clinical and anticipated commercial drug supply for our SRT programs, including Surfaxin, in conformance with current good manufacturing practices (cGMP). These costs include employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities and analytical services; (ii) design, develop, manufacture and assemble aerosolization systems necessary to administer Aerosurf, including the initial prototype version and the next-generation version of our aerosol generating device, disposable dose delivery packet and patient interface system, and (iii) develop new formulations of our SRT.

Development Operations (unallocated)

Development operations include (i) clinical, regulatory and biostatistics activities for the management of our clinical trial programs in accordance with current good clinical practices (cGCPs) and (ii) medical affairs capabilities, including medical science liaisons, to provide medical education and scientific support in connection with the potential commercial launch of Surfaxin and other products in our SRT pipeline. These costs include personnel, supplies, facilities, fees to consultants, other related costs of clinical trials and management, clinical quality control and regulatory compliance activities, data management and biostatistics. The 2007 costs also include activities associated with obtaining data and other information included in our Complete Response to the April 2006 Approvable Letter.

Direct Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include (i) pre-clinical activities prior to initiation of any potential human clinical trials and (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, costs of clinical drug supply and related external costs such as contract research consultant fees and expenses.

Three Months Ended

The following summarizes our research and development expenses by each of the foregoing categories for the three months ended March 31, 2008 and 2007:

(in thousands)	March 31,		
		2008	 2007
Research and Development Expenses:			
Manufacturing development	\$	4,366	\$ 2,864
Development operations (unallocated)		1,980	1,501
Direct pre-clinical and clinical program expenses		886	1,057
Total Research & Development Expenses	\$	7,232	\$ 5,422

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing of completion, and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Results from clinical trials may not be favorable and data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review or clinical or pre-clinical development. The status and anticipated completion date of each of our lead SRT programs are discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations." Successful completion of development of our SRT is contingent on numerous risks, uncertainties and other factors, some of which are described in detail in the "Risk Factors" section contained in our most recent Annual Report on Form 10-K.

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In March 2008, we agreed to restructure our December 9, 2005 Strategic Alliance Agreement (the "Original Alliance Agreement") with Philip Morris USA Inc., d/b/a Chrysalis Technologies ("Chrysalis"), which was created to unite two complementary respiratory technologies - our peptide-containing synthetic surfactant technology with Chrysalis' novel capillary aerosolization technology - to deliver therapeutics to the deep lung.

Under the Original Alliance Agreement, Chrysalis was primarily responsible for development activities related to its proprietary capillary aerosolization technology (the "Chrysalis Technology") and we were responsible for aerosolized drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination drug-device products using the Chrysalis Technology ("Licensed Products"). Under the restructuring, we entered into an Amended and Restated License Agreement dated March 28, 2008 (the "US License Agreement") with Chrysalis to amend and restate the Original Alliance Agreement in the United States. As Chrysalis has assigned to Philip Morris Products S.A. ("PMPSA") all rights in and to the Chrysalis Technology outside of the United States (the "International Rights"), effective March 28, 2008, we also entered into a License Agreement with PMPSA with respect to the International Rights (the "International License Agreement", and together with the US License Agreement, the "License Agreements") on substantially the same terms and conditions as the US License Agreement.

We hold an exclusive license in the United States under the US License Agreement and an exclusive license to the International Rights under the PMPSA License Agreement in and to the Chrysalis Technology for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, the "Exclusive Field"). In addition, under the US License Agreement, we hold a license to use the Chrysalis Technology with other drugs to treat specified target indications in specified target populations. Our exclusive license under each License Agreement now includes, in addition to the rights we previously had, the right to develop and have developed Licensed Products in the Exclusive Field in the respective territory.

The US License Agreement provides that prior to June 30, 2008, Chrysalis will complete a technology transfer of the Chrysalis Technology to us in scope sufficient to permit us to practice the Chrysalis Technology. The License Agreements provide that we are solely responsible for future development of the Chrysalis Technology; however, Chrysalis has agreed to provide to us continued development support through, but in no event after, June 30, 2008. In addition, the US License Agreement provides that Chrysalis will provide to us transition assistance in the form of payments totaling \$4.5 million, with respect to which we expect to receive the last payment in the third quarter 2008.

Under the Original Alliance Agreement, we were obligated to pay Chrysalis royalties based on a multi-tiered royalty structure (that escalated upon attaining collaboration product revenues greater than \$500 million and \$1 billion). Under the License Agreements, we are now obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field in the respective territory. In connection with the exclusive undertakings of Chrysalis and PMPSA not to exploit the Chrysalis Technology in the Exclusive Field, we are obligated to pay royalties on all product sales, including sales of any aerosol devices and related components sold by us in the Exclusive Field that are based on aerosolization technology other than the Chrysalis Technology. In addition, we have agreed in the future to pay minimum royalties, but are entitled to a future reduction of royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned under the License Agreements.

Under the License Agreements, we generally own the intellectual property that we create or reduce to practice in the performance of the License Agreements or exercise of the licenses granted thereunder, except such inventions that relate primarily, in each instance, to the Chrysalis Technology (the "Chrysalis Technology Improvements"). We are obligated to assign to Chrysalis and PMPSA all such Chrysalis Technology Improvements and all such inventions are then made subject to our rights under each License Agreement. The License Agreements also contain provisions related to the calculation and payment of royalties, record-keeping and audit rights, and prosecution of patents, and include customary representations, warranties and indemnities. Each License Agreement, unless terminated earlier will expire as follows as to each Licensed Product in each country in the respective territory, on a country-by-country basis, upon the latest of: (a) the tenth anniversary of the date of the first commercial sale of the Licensed Product; (b) the date on which the sale of such Licensed Product ceases to be covered by a claim of an issued and unexpired patent in such country, or (c) the date a generic form of the product is introduced in such country. The License Agreements may be terminated, by Chrysalis or PMPSA, as appropriate, in the event that we fail to make the payment of the minimum royalties, as provided therein, or by us, in whole or in part, initially upon payment of a termination fee. In addition, either party to each License Agreement may terminate upon a material breach by the other party (subject to a specified cure period).

PLAN OF OPERATIONS

We have incurred substantial losses since inception and expect to continue to make significant investments for product research, development, manufacturing, sales and marketing and general administrative activities. We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability.

Through March 31, 2008, we had no revenues from any product sales, and had not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into collaboration and other agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through March 31, 2008, we had not generated taxable income. At December 31, 2007, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$258.7 million. The future utilization of such loss carryforward may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we had a research and development tax credit carryforward of \$6.1 million at December 31, 2007. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 through 2026.

Over the next 12 to 24 months, we plan to undertake a variety of initiatives that are discussed below.

Research and Development

We will continue to focus our research, development and regulatory activities to advance our pipeline of potential SRT for respiratory diseases. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the applicable risks discussed herein and those contained in the "Risk Factors" section in our most recent Annual Report on Form 10-K. See "Management's Discussion and Analysis – Research and Development."

Our major research and development projects include:

SRT for Neonatal and Pediatric Indications

In order to address the most prevalent respiratory disorders affecting infants in the NICU and PICU, we are conducting several therapeutic programs that target respiratory conditions that have been cited as some of the most significant unmet medical needs in the neonatal and pediatric community.

Surfaxin for the Prevention of RDS in Premature Infants

In October 2007, we submitted to the FDA our Complete Response to the April 2006 Approvable Letter. The FDA thereafter established May 1, 2008, as its target date to complete its review of our NDA.

Since the filing of our Complete Response and prior to receiving the May 1, 2008 Approvable Letter, the following important events have occurred:

- · As of March 2008, we have submitted to the FDA 12-month stability data on our Surfaxin process validation batches, which continue to demonstrate conformance to our established stability specifications.
- In March 2008, the FDA completed a pre-approval inspection (PAI) of our manufacturing operations at Totowa, New Jersey, and recently issued an Establishment Inspection Report (EIR) indicating an approval recommendation. We believe that our manufacturing operations are prepared to produce sufficient drug product to meet the commercial requirements of Surfaxin, if approved.
- · On April 30, 2008, as part of our NDA review, we completed labeling discussions with the FDA and agreed to the content of the Surfaxin package insert. Although the package insert will not be considered final until the FDA approves our NDA, we are pleased with the competitive profile of the current form of package insert.

On May 1, 2008, we received another Approvable Letter from the FDA. Importantly, this Approvable Letter contains no requirement for additional clinical trials to gain FDA approval for Surfaxin. The Approvable Letter includes, among other things, requests (i) to further tighten an acceptance criterion for our release and stability biological activity test, (ii) to further tighten acceptance criteria for lipid drug substance impurities, and (iii) to submit (for inclusion in the NDA) summary information from certain equipment-related qualification reports.

Based on our assessment of the Approvable Letter, conducted by our regulatory, manufacturing and quality management in consultation with our expert consultants, we believe that with our current dataset for Surfaxin we and the FDA can reach agreement on appropriate acceptance criteria and drug product specifications for Surfaxin. We also believe that the requested equipment qualification summary information will be acceptable to the FDA because the reports in question have been reviewed and found acceptable during the pre-approval inspection of our manufacturing operations at Totowa in March 2008. Based on our regulatory assessment and our experts' advice, we believe the meeting will qualify for priority scheduling and that the FDA may designate our formal response to this Approvable Letter as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period).

We anticipate being in a position to submit our formal response to the Approvable Letter in approximately 6 to 8 weeks, although this timeline may be shortened or extended following discussions with the FDA. If our understanding of the timeline is correct, we now anticipate the potential approval of Surfaxin in 2008.

In October 2004, we filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) for clearance to market in Europe Surfaxin for the prevention and rescue treatment of RDS in premature infants. In June 2006, following the Surfaxin process validation stability failure, we determined that we could not resolve our manufacturing issues within the regulatory time frames mandated by the EMEA procedure. Consequently, in June 2006, we voluntarily withdrew the MAA without resolving with the EMEA certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials. We have recently consulted with regulatory experts in Europe and, if we receive approval for Surfaxin in the United States, plan to have further discussions with the EMEA and potentially develop a strategy to gain approval for Surfaxin in Europe.

Surfaxin for BPD in Premature Infants

In October 2006, we announced preliminary results of our Phase 2 clinical trial for Surfaxin for the prevention and treatment of BPD, which was designed as an estimation study to evaluate the safety and potential efficacy of Surfaxin in infants at risk for BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD. We plan to seek scientific advice from the FDA and other regulatory agencies with respect to potential clinical trial designs to support the further development of Surfaxin for the prevention of BPD. At this time, we expect to pursue these discussions only after we have successfully gained FDA approval of Surfaxin for the prevention of RDS in premature infants.

Surfaxin for Acute Respiratory Failure

In June 2007, we initiated a clinical trial to determine if restoration of surfactant with Surfaxin will improve lung function and result in a shorter duration of mechanical ventilation and NICU/PICU stay for children up to two years of age suffering with ARF. The Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care masked by a sham air control. Approximately 180 children (subject to sample size adjustment per protocol) under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 35-40 sites throughout the world in both the Northern and Southern Hemispheres. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. Patient enrollment is dependent upon the strength of the viral seasons. Following conclusion of the upcoming viral season in the Southern Hemisphere in the fourth quarter 2008, we plan to assess the status of patient enrollment in this trial and determine at that time whether adjustments to our timeline are required. Currently, we believe that data from this trial will be available in the first half of 2009, although this time line may be extended as we conserver resources to focus on seeking approval of Surfaxin for the prevention of RDS in premature infants.

Aerosurf, Aerosolized SRT

Aerosurf is our first aerosolized SRT that is administered through less-invasive means and is being developed to potentially obviate the need for intubation and conventional mechanical ventilation. Aerosurf holds the promise to significantly expand the use of surfactants in respiratory medicine. We have demonstrated, through both research and feasibility studies that we can aerosolize our SRT and have completed a small Phase 2 clinical study of Aerosurf that concluded that it is feasible to administer Aerosurf through nasal continuous positive airway pressure (nCPAP) and that the treatment was generally safe and well tolerated. We are currently developing Aerosurf using the Chrysalis technology.

Under our restructured strategic alliance with Chrysalis, we have assumed full responsibility for development of the initial prototype version of the novel aerosolization system (see "Corporate Partnerships and Agreements"). Our design engineers, together with our contract manufacturers and third-party medical device experts and consultants, are optimizing the initial prototype version of this novel aerosolization system. Once development milestones have been achieved, we plan to file our regulatory package in support of our Phase 2 clinical program and manufacture aerosolization systems.

In anticipation of our planned Phase 2 clinical trials using the initial version of the novel capillary aerosolization technology, we are executing a series of supportive pre-clinical studies that will support our regulatory package. In that regard, we have also met with and received guidance from the FDA with respect to the design of our proposed Phase 2 clinical program. and we currently expect to initiate our Phase 2 clinical program utilizing this novel aerosolization technology in 2008. However, this time line may be extended as we conserver resources to focus on seeking approval of Surfaxin for the prevention of RDS in premature infants.

Based on the knowledge gained to date, we are also engaged in activities to develop the next-generation aerosolization system based on this technology for use in potential Phase 2 and Phase 3 clinical trials for Aerosurf and, if approved, future commercial activities. For this development phase, we are working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, both in the United States and other international markets. If we are successful in developing Aerosurf for patients in the NICU and PICU, we plan to use the knowledge gained from this effort to develop a program for aerosolized SRT administered as a prophylactic for adult patients in the hospital setting.

SRT for Critical Care and Hospital Indications

We are also evaluating the potential development of our proprietary synthetic peptide-containing SRT to address respiratory disorders such as CF, ALI, COPD, asthma, and other debilitating respiratory conditions.

Manufacturing

Our SRT, including Surfaxin, must be manufactured in compliance with cGMP established by the FDA and other international regulatory authorities. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications.

We plan to invest in and support our manufacturing strategy for the production of our proprietary peptide-containing synthetic SRT to meet anticipated clinical needs and, if approved, commercial needs in the United States, Europe and other markets:

Current Manufacturing Capabilities

We have owned our own manufacturing operations since December 2005. We believe that this has provided us with potentially improved control and economics for the production of clinical and potential commercial supply of our lead product, Surfaxin, and our SRT pipeline products.

In April 2006, to respond to Surfaxin process validation stability failures, we initiated a comprehensive investigation that focused on analysis of our manufacturing processes, analytical methods and method validation, and active pharmaceutical ingredient suppliers. We thereafter identified a most probable root cause and implemented a corrective action and preventative action (CAPA) plan. In February 2007, we completed manufacture of three new Surfaxin process validation batches, which as of March 2008 have successfully attained 12-months stability and continue to demonstrate conformance to established stability specifications. In March 2008, the FDA completed an inspection of this facility as part of its review of our Surfaxin NDA and, in April, issued an Establishment Inspection Report (EIR) indicating an approval recommendation for our Surfaxin NDA. See"Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations - Research and Development - SRT for Neonatal Intensive Care Unit - Surfaxin for the Prevention of RDS in Premature Infants."

Our manufacturing strategy includes investing in our analytical and quality systems. In October 2007, we completed construction of a new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters, where we have consolidated our analytical, quality and development activities previously located in Doylestown, Pennsylvania and Mountain View, California. The activities to be located in our new laboratories include release and stability testing of raw materials as well clinical and, if approved, commercial drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our SRT technology. The laboratory will expand our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our newly-consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics.

Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operations in Totowa, New Jersey, that should allow for sufficient production of drug product to supply (i) the potential worldwide commercial demand for Surfaxin for our RDS program, if approved, (ii) the preclinical and clinical and, if approved, potential worldwide commercial demand for Surfaxin for our ARF and BPD programs, and (iii) the anticipated preclinical and clinical and, if approved, potential worldwide commercial demand for Aerosurf.

Owning our own manufacturing operations in Totowa is an initial step in our manufacturing strategy to support the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our Totowa facility expires in December 2014. In addition to customary terms and conditions, the lease is subject to a right of the landlord, first after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. Currently, our manufacturing strategy includes (i) potentially renegotiating our current lease to amend the termination and other provisions, (ii) building or acquiring additional manufacturing capabilities for the production of our SRT drug products, and (iii) potentially using contract manufacturers, for the production of our SRT drug products.

Aerosol Devices and Related Componentry

To manufacture aerosolization systems for our planned Aerosurf clinical trials, we expect to utilize third-party contract manufacturers, suppliers and integrators. The manufacturing process involves assembly of key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, disposable dose delivery packets, which must be assembled in a clean room environment, and patient interface systems necessary to administer our aerosolized SRT. Under our manufacturing plan, third-party vendors will manufacture customized parts for us and assemble the key device sub-components and ship them to one central location for final assembly and integration into the aerosolization system. Once assembled, the critical drug product-contact components and patient interface systems will be packaged and sterilized. The aerosolization systems will be quality-control tested prior to release for use in our clinical trials. We have entered into a Master Services Agreement with Kloehn, Inc. to act as integrator of the prototype aerosolization system device sub-components and disposable dose delivery packets that we plan to use in our planned Phase 2 clinical trials.

See the applicable risks discussed herein and in the "Risk Factors" section contained in our most recent Annual Report on Form 10-K.

Sales and Marketing

To prepare for the potential approval of Surfaxin for the prevention of RDS in premature infants, we plan to establish our own U.S. specialty pulmonary commercial organization that will initially specialize in neonatal and pediatric indications and, as products are developed, may potentially expand to adult critical care and other hospital settings. This strategy is intended to allow us to manage our own sales and marketing activities, establish a strong presence in the NICU, and optimize the economics of our business.

We expect to rely primarily on our commercial organization to market Surfaxin in the United States, if approved. Our pre-approval preparations have included the hiring of experienced management personnel. We have also begun to invest in our medical affairs capabilities to provide for increased scientific and medical educational activities. We plan to hire our sales representatives only after we have received approval to market Surfaxin. We expect to incur significant expenses to develop a complete U.S. commercial capability. We also intend to pursue potential collaboration arrangements with international partners to co-develop and/or co-commercialize our neonatal and pediatric pipeline for Surfaxin and Aerosurf.

General and Administrative

We intend to invest in general and administrative resources in the near term, primarily to support our legal requirements, intellectual property portfolios (including building and enforcing our patent and trademark positions), our business development initiatives, financial systems and controls, management information technologies, and general management capabilities.

Potential Collaboration Agreements and Strategic Partnerships

We intend to seek investments of additional capital and potentially enter into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although there can be no assurance that we will enter into any specific actions or transactions.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, 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.

There have been no changes to our critical accounting policies since December 31, 2007. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2007. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

RESULTS OF OPERATIONS

The net loss for the three months ended March 31, 2008 and 2007 were \$9.7 million (or \$0.10 per share) and \$8.3 million (or \$0.12 per share), respectively.

Revenue from Collaborative Arrangements and Grants

The Revenue from collaborative arrangements is associated with a March 2008 modification to our collaboration arrangement with Chrysalis. Chrysalis has agreed to pay us \$4.5 million to support further development of the aerosolization technology, of which \$2.0 million was paid 30 days after execution of the modification agreements and \$2.5 million will be payable upon completion of a technology transfer, which is expected to be completed by June 30, 2008. For further discussion, see "Management's Discussion and Analysis - Corporate Partnership Arrangements."

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2008 and 2007 were \$7.2 million and \$5.4 million, respectively. For a description of expenses and research and development activities, see "Management's Discussion and Analysis - Research and Development." For a description of the clinical programs included in research and development, see "Management's Discussion and Analysis - Plan of Operations."

The increase in research and development expenses for the three months ended March 31, 2008 compared to the same period in 2007 primarily reflects:

- (i) Manufacturing development activities (included in research and development expenses) to support the production of clinical and anticipated commercial drug supply for our SRT programs, including Surfaxin, in conformance with cGMP. Expenses associated with manufacturing development activities for the three months ended March 31, 2008 and 2007 were \$4.3 million and \$2.9 million, respectively. Manufacturing development expenses primarily consist of costs to: (i) enhance and support our manufacturing operations and our quality assurance and analytical chemistry capabilities to assure adequate production of clinical and anticipated commercial drug supply for our SRT programs, in conformance with current good manufacturing practices (cGMP); (ii) design, develop, manufacture and assemble aerosolization systems necessary to administer Aerosurf, including the initial prototype version and the next-generation version of our aerosol generating device, disposable dose delivery packet and patient interface system, and (iii) develop new formulations of our SRT. Included in the expenses for the three months ended March 31, 2007 were activities associated with obtaining data and other information included in our Complete Response to the April 2006 Surfaxin Approvable Letter. The increase in the first quarter of 2008 as compared to the same period in 2007 is primarily due to: (a) investments to enhance our quality assurance and analytical chemistry capabilities to support the production of clinical and anticipated commercial drug supply for our SRT programs in accordance with cGMP; and (b) activities related to the development and optimization of the initial version of the capillary aerosolization technology system necessary to administer Aerosurf.
- (ii) Research and development operations to manage the development and advancement of our SRT pipeline. Expenses related to these activities for the three months ended March 31, 2008 and 2007 were \$2.0 million and \$1.5 million, respectively. These costs are primarily associated with scientific and clinical management, clinical quality control and regulatory compliance activities, data management and biostatistics, and medical affairs activities. The increase in the first quarter of 2008 as compared to the same period in 2007 is primarily due to investment in our medical affairs capabilities, including medical science liaisons, to provide scientific and medical educational support to the neonatal medical community regarding Surfaxin and our SRT pipeline.
- (iii) Direct pre-clinical and clinical program activities related to the advancement of our SRT pipeline. Expenses related to these activities were \$0.9 million and \$1.1 million for the months ended March 31, 2008 and 2007, respectively. These expenses in 2008 and 2007 primarily include: (i) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin for ARF in children up to two years of age; and (ii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for the prevention and treatment of RDS in premature infants. Additionally, included in these expenses for the three months ended March 31, 2007 were activities associated with obtaining data and other information included in our Complete Response to the April 2006 Surfaxin Approvable Letter.

For the three months ended March 31, 2008 and 2007, research and development expenses included charges of \$0.4 million and \$0.2 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2008 and 2007 were \$4.5 million and \$2.8 million, respectively. General and administrative costs primarily include costs associated with executive management, evaluation of various strategic business alternatives, financial and legal management, pre-launch commercialization activities and other administrative costs.

The increase in general and administrative expenses for the three months ended March 31, 2008 compared to the same period in 2007 primarily reflects:

- (i) pre-launch commercialization activities in 2008 in anticipation of the potential approval of Surfaxin related to building a United States commercial organization. Expenditures for these activities for the three months ended March 31, 2008 were \$1.3 million. We did not incur any pre-launch commercialization expenses for the three months ended March 31, 2007; and
- (ii) charges associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R) which for the three months ended March 31, 2008 and 2007 were \$0.7 million and \$0.4 million, respectively.

Other Income and (Expense)

Other income and (expense) for the three months ended March 31, 2008 and 2007 were (\$27,000) and (\$134,000), respectively.

Interest and other income for the three months ended March 31, 2008 and 2007 was \$0.4 million and \$0.3 million, respectively. The increase for the three months ended March 31, 2008 as compared to the same period last year is primarily due to an increase in our average cash and marketable securities.

Interest, amortization and other expenses for the three months ended March 31, 2008 and 2007 was \$0.5 million and \$0.4 million, respectively. These expenses consist of: (i) interest related to the outstanding balance under the PharmaBio loan; (ii) interest expense related to the amortization of deferred financing costs associated with warrants issued to PharmaBio in October 2006 in consideration for renegotiating the terms on the existing \$8.5 million loan; and (iii) interest associated with our equipment loan obligations with General Electric Business Financial Services, Inc. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

We have incurred substantial losses since inception and expect to continue to make significant investments for continued product research, development, manufacturing and commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities and the use of debt and our equipment financing facility.

We are subject to risks customarily associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that our research and development projects will be successful, that products developed, including Surfaxin for the prevention of RDS in premature infants, will obtain necessary regulatory approval, or that any approved product will be commercially viable.

We plan to fund our research, development, manufacturing and potential commercialization activities through:

- the issuance of equity and debt financings;
- · payments from potential strategic collaborators, including license fees and sponsored research funding;
- sales of Surfaxin and our other SRT, if approved;
- · equipment financings; and
- · interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of the product development and commercialization plan. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability. There is no assurance that we will be able to obtain additional capital when needed with acceptable terms, if at all.

We have a CEFF that allows us to raise capital, subject to certain conditions and limitations, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions, including a share limitation (currently approximately 5.2 million shares) and the volume weighted average price of our common stock on each trading day must be at least \$2.00. We anticipate using the CEFF, when available, to support working capital needs in 2008. (See our most recent Annual Report on Form 10-K at "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility".)

We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although there can be no assurance that we will enter into any specific actions or transactions.

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2008, we had cash, cash equivalents and marketable securities of \$41.5 million, as compared to \$53.0 million as of December 31, 2007. The decrease is primarily due to \$11.5 million used in operating activities, purchases of capital expenditures and principal payments, offset by new financings under our equipment financing facility with GE Business Financial Services Inc.

Committed Equity Financing Facility (CEFF)

In April 2006, we entered into a new Committed Equity Financing Facility (CEFF) in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to \$50 million or up to 11,677,047 shares of our common stock. (See our most recent Annual Report on Form 10-K at "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility".)

As of March 31, 2008, there were approximately 5.2 million shares available for issuance under the CEFF (up to a maximum of \$35.5 million in gross proceeds) for future financings.

In 2006, in connection with the CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of \$5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant is exercisable for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.8 million. As of March 31, 2008, the Class C Investor Warrant had not been exercised.

In 2004, in connection with a previous Committed Equity Financing Facility that we entered with Kingsbridge in July 2004 (2004 CEFF), which has been terminated, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to \$12.0744 per share. The warrant, which expires in January 2010, is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds, if exercised, of approximately \$4.5 million. As of March 31, 2008, the Class B Investor Warrant had not been exercised.

October 2005 Universal Shelf Registration Statement

In October 2005, we filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering, from time to time, of up to \$100 million of our debt or equity securities. In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to us of \$20.0 million. In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors resulting in gross proceeds of \$30.2 million. In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors resulting in gross proceeds of \$25.0 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately \$24.8 million of equity or debt securities. There can be no assurance, however, that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our research and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

Debt

Loan with PharmaBio

PharmaBio, the strategic investment group of Quintiles Transnational Corp., extended to us a secured, revolving credit facility of \$8.5 to \$10.0 million in 2001. Currently, the outstanding principal amount, \$8.5 million, matures on April 30, 2010. Interest on the loan accrues at the prime rate, compounded annually, and after October 1, 2006, is payable together with the outstanding principal at maturity. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. our obligations to PharmaBio under the loan documents are secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the related Security Agreement.

In October 2006, in consideration of PharmaBio's agreement to restructure the loan, we entered into a Warrant Agreement with PharmaBio, pursuant to which PharmaBio has the right to purchase 1.5 million shares of our common stock at an exercise price equal to \$3.5813 per share. The warrants have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the PharmaBio loan agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we filed a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants. As of March 31, 2008, the warrants had not been exercised.

As of March 31, 2008, the outstanding balance under the loan was \$9.8 million (\$8.5 million of pre-restructured principal and \$1.3 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

Equipment Financing Facility with GE Business Financial Services, Inc.

On May 21, 2007, we entered into a Credit and Security Agreement (Loan Agreement) with Merrill Lynch Capital ("Merrill Lynch"), a division of Merrill Lynch Business Financial Services Inc., as Lender, pursuant to which Merrill Lynch agreed to provide us a \$12.5 million credit facility (Facility) to fund our capital programs. Previously, our capital financing arrangements had been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) under a Master Security Agreement dated December 20, 2002, as amended (GECC Agreement). We simultaneously terminated our arrangement with GECC and drew down \$4.0 million of the Facility to prepay all of our then-outstanding indebtedness under the GECC Agreement. Effective in February 2008, as a consequence of the acquisition of Merrill Lynch Capital by GECC or an affiliate of GECC, GE Business Financial Services, Inc., as successor to Merrill Lynch Capital, is now the Lender under the Loan Agreement and the provider of the Facility.

The minimum advance under the Facility is \$100,000. Interest on each advance accrues at a fixed rate per annum equal to LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances will be payable in equal installments on the first business day of each month. We may prepay advances, in whole or in part, at any time, subject to a prepayment penalty, which, depending on the period of time elapsed from the closing of the Facility, will range from 4% to 1%.

We may use the Facility to finance (a) new property and equipment and (b) up to approximately \$1.7 million "Other Equipment" and related costs, which may include leasehold improvements, intangible property such as software and software licenses, specialty equipment, a pre-payment penalty paid to GECC (with respect to the termination of our previous arrangement) and "soft costs" related to financed property and equipment (including, without limitation, taxes, shipping, installation and other similar costs). Advances to finance the acquisition of new property and equipment are amortized over a period of 36 months. The promissory note related to the GECC prepayment is amortized over a period of 27 months and Other Equipment and related costs is amortized over a period of 24 months.

The right to draw funds under the Facility will expire on May 30, 2008, subject to a best efforts undertaking by the Lender to extend the draw down period beyond the expiration date for an additional six months. We plan to approach GE Business Financial Services, Inc. to discuss the potential six-month extension of the Facility. In addition, our obligations under the Facility are secured by a security interest in (a) the financed property and equipment, including the property and equipment securing GECC under the GECC Agreement at the time of prepayment, and (b) as Supplemental Collateral, all of our intellectual property, subject to limited exceptions set forth in the Loan Agreement. Under the Loan Agreement, the Supplemental Collateral will be released on the earlier to occur of (i) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (ii) the date on which we shall have maintained over a continuous 12-month period ending on or after March 31, 2008, measured at the end of each calendar quarter, a minimum cash balance equal to our projected cash requirements for the following 12-month period.

As of March 31, 2008, approximately \$5.2 million was outstanding under the Facility (\$2.8 million classified as current liabilities and \$2.4 million as long-term liabilities) and \$4.9 million remained available for use, subject to the conditions of the Facility.

Lease Agreements

We maintain facility leases for our operations in Pennsylvania, New Jersey and California.

We maintain our headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, analytical technical services, research and development, sales and marketing, and administration. In April 2007, the lease, which originally expired in February 2010 with total aggregate payments of \$4.6 million, was extended an additional three years through February 2013 with additional payments of \$3.0 million over the extension period.

We lease 21,000 square feet of space for our manufacturing facility in Totowa, New Jersey, at an annual rent of \$150,000. This space is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements and is our only manufacturing facility. The lease expires in December 2014, subject to a right of the landlord, first exercisable after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. The total aggregate payments since inception of the lease are \$1.4 million. For a discussion of our manufacturing strategy, see "Plan of Operations – Research and Development – Manufacturing."

We lease approximately 5,600 square feet office and analytical laboratory space in Doylestown, Pennsylvania, with an annual rent of approximately \$93,800, which since August 2007 has been leased on a monthly basis. We are currently consolidating the activities at this location into our new laboratory space in Warrington, Pennsylvania and plan to terminate this lease in the third quarter of 2008.

We lease 16,800 square feet of office and laboratory space at our facility in Mountain View, California, at an annual rent of approximately \$275,000. The lease expires in June 2008, with total aggregate payments over the lease term of \$804,000. In March 2007, we subleased approximately 1,800 square feet of this facility for total aggregate receipts of \$46,000. In December 2007, we consolidated these activities into our new laboratory space in Warrington, Pennsylvania and will not renew or extend this lease.

Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our manufacturing, research and product development activities and to repay our indebtedness. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative or joint development or commercialization arrangements with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our CEFF with Kingsbridge and our equipment financing facility with GE Business Financial Services, Inc., the use of which are subject to certain conditions, we have no contractual arrangements under which we may obtain additional financing. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although there can be no assurance that we will enter into any specific actions or transactions.

If a transaction involving the issuance of additional equity and debt securities is concluded, such a transaction may result in additional dilution to our shareholders. We cannot be certain that additional funding will be available when needed or on terms acceptable to us, if at all. If we fail to receive additional funding or enter into business alliances or other similar opportunities, we may have to reduce significantly the scope of or discontinue our planned research, development and manufacturing activities, which could significantly harm our financial condition and operating results.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer. We currently do not hedge interest rate or currency exchange exposure. We classify highly liquid investments purchased with a maturity of three months or less as "cash equivalents" and commercial paper and fixed income mutual funds as "available for sale securities." Fixed income securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. 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, within the company 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 Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Changes in internal controls

There were no changes in internal controls over financial reporting or other factors that could materially affect those controls subsequent to the date of our evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendants' motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by our Company. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania. On April 29, 2008, the Third Circuit Court of Appeals affirmed the District Court's dismissal of the complaint for the reasons set forth in the District Court opinion. Plaintiffs have 14 days, or until May 13, 2008, to decide whether to seek a rehearing of the Third Circuit's decision.

Additional actions such as this one, based upon similar allegations, or otherwise, may be filed in the future. The potential impact of such actions, which generally seek unquantified damages, attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any such proceedings would not have a potentially material adverse effect on our business, results of operations and financial condition.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the termination in 2006 of certain pre-launch commercial programs following our process validation stability failure. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, we believe the pending matters are unlikely to have a material adverse effect on our financial condition or results of operations. However, there can be no assurance that we will be successful in any proceeding to which we are or may be a party.

ITEM 1A. RISK FACTORS

In addition to the risks, uncertainties and other factors set forth below and elsewhere in this Form 10-Q, see the "Risk Factors" section contained in our most recent Annual Report on Form 10-K.

Under our restructured collaboration arrangement with Chrysalis, we are responsible for future development, which will require us to build internal development capabilities or enter into future collaboration or other arrangements to gain the engineering expertise required to further develop the Chrysalis Technology.

In March 2008, we restructured our collaboration arrangement with Philip Morris USA Inc., d/b/a Chrysalis Technologies ("Chrysalis"). We now have responsibility for the development of the Chrysalis' proprietary capillary aerosolization technology (the "Chrysalis Technology") and will not have development support from Chrysalis after June 30, 2008. Our future development of the Chrysalis Technology is subject to certain risks and uncertainties, including, without limitation:

- · We may not be able to complete the development of the initial prototype aerosolization device, if at all, on a timely basis and such inability may delay or prevent initiation of our planned Phase 2 clinical trials;
- We will require sophisticated engineering expertise to continue the development of the Chrysalis Technology. Although we are building our own internal medical device engineering expertise and have recently begun working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, there is no assurance that our efforts will be successful or that we will be able to identify other potential collaborators to complete the development of the next-generation aerosolization system and enter into agreements with such collaborators on terms and conditions that are favorable to us, and, if we are unable to identify or retain design engineers and medical device experts to support our development program, this could impair our ability to commercialize or develop it's aerosolized drug products;
- PMPSA and Chrysalis are no longer affiliated entities; as such, there is a risk that, if we were to require the consent of PMPSA and Chrysalis under the License Agreements, they may not agree on the appropriate course and we may be forced to develop the Chrysalis Technology in the two territories under different circumstances. Such inconsistencies could have an adverse effect on the our ability to develop the Chrysalis Technology or to successfully commercialize the Licensed Products in one or both of the territories; and
- We have additional rights under the US License Agreement that are not provided under the International License Agreement. Although the International License Agreement provides for the potential expansion of rights with the consent of PMPSA, there can be no assurance that PMPSA would agree to any such expansion and, as a result, we may be unable to develop and commercialize Licensed Products under its expanded rights outside the United States markets.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations – Research and Development – Corporate Partnership Agreements."

Our pending NDA for Surfaxin for the prevention of RDS in premature infants may not be approved by the FDA in a timely manner or at all, which would adversely impact our ability to commercialize this product.

Receipt of the May 2008 Approvable Letter has delayed the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. Based on our assessment of the Approvable Letter, conducted by our regulatory, manufacturing and quality management in consultation with our expert consultants, we believe that with our current dataset for Surfaxin we and the FDA can reach agreement on appropriate acceptance criteria and drug product specifications for Surfaxin. Based on our regulatory assessment and our experts' advice, we believe the meeting will qualify for priority scheduling and that the FDA may designate our formal response to this Approvable Letter as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period). We anticipate being in a position to submit our formal response to the Approvable Letter in approximately 6 to 8 weeks, although this timeline may be shortened or extended following discussions with the FDA. Although the FDA has not requested additional clinical data to date, it could at any time in its review process request additional data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product and would have a material adverse effect on our business.

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

During the three months ended March 31, 2008, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options. There were no stock repurchases during the three months ended March 31, 2008.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

Date: May 8 2008

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.

Discovery Laboratories, Inc.

(Registrant)

Date: May 8 2008 By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

President and Chief Executive Officer

By: /s/ John G. Cooper

John G. Cooper

Executive Vice President and Chief Financial Officer (Principal Financial

Officer)

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Amended and Restated By-Laws of Discovery.	Incorporated by reference to Exhibit 3.2 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the SEC on March 15, 2004.
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6 , 2004.
3.4	Certificate of Amendment to the Certificate of Incorporation of Discovery, dated as of May 28, 2004.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 9, 2004.
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of Discovery, dated as of July 8, 2005.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 8, 2005.
4.1	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.3	Class B Investor Warrant dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.4	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.5	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.6	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.

Exhibit No.	Description	Method of Filing		
4.7	Registration Rights Agreement, dated as of April 17, 2006, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.		
4.8	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. (PharmaBio)	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.		
4.9	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.		
4.10	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.		
10.1	Amendment dated January 3, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert J. Capetola and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008.		
10.2	Amendment dated January 3, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between John G. Cooper and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008.		
10.3	Amendment dated January 3, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between David L. Lopez and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008.		
10.4+	Amended and Restated License Agreement by and between Discovery and Philip Morris USA Inc., d/b/a Chrysalis Technologies dated March 28, 2008.	Filed herewith.		
10.5+	License Agreement by and between Discovery Laboratories, Inc. and Philip Morris Products S.A., dated March 28, 2008.	Filed herewith.		
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.		
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.		
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.		

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

Confidential Treatment Requested

Execution Version

AMENDED AND RESTATED

LICENSE AGREEMENT

by and between

DISCOVERY LABORATORIES, INC. (a Delaware corporation)

and

PHILIP MORRIS USA INC., d/b/a CHRYSALIS TECHNOLOGIES (a Virginia corporation)

March 28, 2008

Table of Contents

ADTICLE 1	4 DEPINITIONS	Page 1
	1 DEFINITIONS	
	2 TECHNOLOGY TRANSFER	9
2.1	Technology Transfer	9
2.2	Transfer of Regulatory Files, Data and Filings	9
ARTICLE 3	3 LICENSE	10
3.1	License	10
3.2	Limitations	10
3.3	Sublicensing Rights	10
3.4	Retained Rights	10
		<u>.</u>
	4 PRODUCT DEVELOPMENT	10
4.1	Licensed Product Development	10
4.2	Notice of Development of Licensed Products	11
4.3	Development Effort	11
4.4	Costs	11
4.5	Development Support by Chrysalis	11
4.6	Design Configurations	11
4.7	Status Updates	11
ARTICLE 5	5 COMMERCIALIZATION	12
5.1	Exclusive Right to Sell the Licensed Products	12
5.2	Responsibility For Commercialization Matters	12
5.3	Commercialization	12
5.4	Status Updates	12
ARTICLE 6	6 REGULATORY MATTERS	12
6.1	Responsibility and Consultation	12
6.2	Regulatory Updates and Communications	13
6.3	Records	13
6.4	Product Liability Litigation	13
ARTICLE 7	7 FINANCIAL PROVISIONS	13
7.1	Transition Assistance Fees	13
7.2	Royalties with Respect to Licensed Products and Substitute Products	13
7.3	Minimum Royalties	14
7.4	Prohibition on Bundling	14
7.5	Fixed Consideration	14
7.6	Treatment of Partial Product Sales	15
7.7	Royalty Reports	15
7.8	Payment of Estimated and Actual Amounts	15
7.9	Pass-Through Royalties	16
7.10	Records and Audits	16
7.11	Foreign Exchange	16
7.12	Manner of Payments	17
7.13	Late Payments	17
7.14	Tax Withholding	17

ARTICLE 8	8 INTELLECTUAL PROPERTY	17
8.1	Ownership	17
8.2	Disclosure, Assignment, License and Exploitation	18
8.3	Agreement with Personnel	19
8.4	Prosecution of Patents	19
8.5	Patent Term Extensions	19
8.6	Third Party Infringement	19
8.7	Infringement of Third Party Rights	21
ARTICLE 9	9 CONFIDENTIAL INFORMATION	22
9.1	Use of Confidential Information	22
9.2	Permitted Disclosure and Use	22
9.3	Disclosure for SEC Filings	23
9.4	Publications	23
9.5	Public Announcements	24
9.6	Survival	24
ARTICLE :	10 REPRESENTATIONS, WARRANTIES AND COVENANTS	24
10.1	Mutual Representations and Warranties	24
10.2	Intellectual Property	25
10.3		26
ARTICLE :	11 ADDITIONAL COVENANTS	26
11.1	Compliance with Laws	26
11.2		27
11.3	•	27
ARTICLE :	12 DISCLAIMERS AND LIMITATION OF LIABILITY	27
12.1		27
12.2		27
ARTICLE	13 INDEMNIFICATION; INSURANCE	28
13.1		28
13.2		29
13.3		30
	** **	
ARTICLE :	14 TERM	30
INCIPOLL .		30
ARTICI E	15 TERMINATION	31
15.1		31
15.1		31
15.3		31
15.4		31
15.5		32
15.6		32
15.0	Direction Administration Selections,	32
ARTICI E	16 STANDSTILL AGREEMENT	32
16.1		32
16.1		33
16.3		33
10.3	Exception for an Acquisition Transaction	
ADTICLE	17 DICHITTE DECOLUTION	າາ
	17 DISPUTE RESOLUTION Dispute Possilution	33
17.1 17.2		33 34
1/.2	Executive (vegotiation)	34

17.3	Mediation	34
17.4	Arbitration	34
17.5	Right to Injunctive and Other Relief	35
ARTICLE 18	MISCELLANEOUS	35
18.1	Original Agreement	35
18.2	Choice of Law	35
18.3	Severability	36
18.4	Relationship of the Parties	36
18.5	Parties in Interest	36
18.6	Enforcement of Certain Agreements	36
18.7	Use of Affiliates, Subcontractors, Sublicensees and Distributors	36
18.8	Assignment	37
18.9	Further Assurances and Actions	37
18.10	Waiver	37
18.11	Section 365(n) of the Bankruptcy Code	37
18.12	Notices	38
18.13	Construction	38
18.14	Registration and Filing of this Agreement	39
8.15	Force Majeure	39
18.16	Entire Agreement	39
18.17	Third Party Beneficiaries	39
18.18	Execution in Counterparts; Facsimile Signatures	39

AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT effective as of March 28, 2008 (the "Amended and Restated Effective Date") by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Discovery"), and PHILIP MORRIS USA INC., d/b/a CHRYSALIS TECHNOLOGIES, a Virginia corporation ("Chrysalis") amends and restates the Strategic Alliance Agreement effective as of December 9, 2005 (the "Original Effective Date"), by and between Discovery and Chrysalis (the "Original Agreement"). Discovery and Chrysalis shall be referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Discovery and Chrysalis entered into the Original Agreement pursuant to which Chrysalis granted to Discovery a worldwide license under its rights in and to its capillary aerosol generation technology to develop certain combination drug-device surfactant products;

WHEREAS, Chrysalis has assigned to Philip Morris Products S.A. ("PMPSA") all rights outside of the United States in and to its capillary aerosol generation technology (the "Assigned Rights");

WHEREAS, Discovery and PMPSA are entering into a license agreement as of the Amended and Restated Effective Date pursuant to which PMPSA will grant to Discovery a license under the Assigned Rights (the "PMPSA/Discovery Agreement"); and

WHEREAS, Discovery and Chrysalis now wish to amend the Original Agreement to cease Chrysalis' active involvement in the development of such combination drug-device surfactant products, to provide a technology transfer to Discovery to permit Discovery to continue with the development of such combination drug-device surfactant products, and to account for such assignment of rights to PMPSA, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, warranties, covenants, and agreements contained herein, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1 DEFINITIONS

In addition to terms defined elsewhere in this Agreement, the following terms used in this Agreement are defined below:

"AAA" means the American Arbitration Association.

"Actual Amount" has the meaning set forth in Section 7.8.2.

[***]

"<u>Aerosol Device</u>" means a device to aerosolize a pharmaceutical compound for administration to humans. It is contemplated that the Aerosol Device shall consist of (i) permanent (*e.g.*, nondisposable) components that control power and electronics (*e.g.*, control unit) and (ii) a physical mechanism (*e.g.*, pump) to provide a means for dispensing the Drug Product from the container closure system.

"Aerosol Technology." means any technology related to the aerosolization of a liquid form of a pharmaceutical compound. Aerosol Technology does not include technology that is related to the delivery of aerosols as dry powders.

"Affiliates" means with respect to any Party, any Person, directly or indirectly, controlling, controlled by or under common control with such Party. For purposes of this Section, "control" means (i) in the case of a Person that is a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) for the election of directors of such Person or (ii) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of (A) more than fifty percent (50%) of the economic or partnership interest in the income or capital of such Person or (B) the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise; and the terms "controlling," "controlled by" or "under common control" shall have the meanings correlative to the foregoing. For the purposes of this Amended and Restated License Agreement, Chrysalis and PMPSA shall not be considered Affiliates with respect to each other.

"Agreement" means this Amended and Restated License Agreement, including the Schedules attached hereto.

"Breaching Party" has the meaning set forth in Section 15.4.1.

"Business Day" means a day other than a Saturday, Sunday, or other day on which commercial banks in New York, New York are authorized or required by Law to close.

"Chrysalis" has the meaning set forth in the Preamble hereto.

"Chrysalis Intellectual Property" has the meaning set forth in Section 8.1.1.

"Chrysalis Patents" means all Patents owned by Chrysalis in the Territory or to which Chrysalis otherwise has rights in the Territory, as of June 30, 2008, that claim or are directed to the Chrysalis Technology.

"Chrysalis Technology" means (a) Chrysalis' proprietary Aerosol Technology owned or controlled by Chrysalis in the Territory as of June 30, 2008 (including without limitation the technologies, devices, processes, equipment, materials and know-how relating to the aerosolization of liquid forms of drug products and the Aerosol Devices and Disposable Dose Packs therefor) and (b) all Intellectual Property owned by or licensed to Chrysalis in the Territory as of June 30, 2008 relating to such Aerosol Technology, including, without limitation, the Chrysalis Patents.

"Chrysalis Technology Improvements" means any rights in the Territory in and to any Inventions created or reduced to practice [***] in the performance of the Agreement or exercise of the license granted pursuant to this Agreement, or [***] under the PMPSA/Discovery Agreement or exercise of the license granted pursuant to the PMPSA/Discovery Agreement, in each case which Inventions relate primarily to the Chrysalis Technology.

"Clinical Trials" means Phase I, II, III and, if required, Phase IV clinical trials and such other tests and studies in human subjects or patients that are required to obtain, maintain, or sustain Regulatory Approval in a country in the Territory.

"Confidential Information" means all information received by either Party or its Affiliates from or on behalf of the other Party or its Affiliates relating to this Agreement that the disclosing Party treats as confidential, including, without limitation: (i) copies of any nonpublic information regarding a Party's Patents; (ii) techniques, technology, practices, trade secrets, inventions (whether or not patentable), designs, methods, manufacturing processes, formulae, formulations, specifications, documents, knowledge, knowhow, skill, experience, test data, and results, (including that related to pharmacology, toxicology, preclinical testing, clinical testing, expression data, Chemistry, Manufacturing and Control (CMC) data, batch records, trials, and studies, safety and efficacy, analytical, and quality control); (iii) devices and related components, compounds, polypeptides, proteins, formulations, compositions of matter, cells, cell lines, markers, assays, and physical, biological, or chemical material; (iv) marketing information, market research data, medical/physicians advisory boards, and consultant input, including clinical studies designed to support promotional efforts; (v) the terms of this Agreement, and (vi) other proprietary business information such as business plans, financial or personnel matters, present or future products, research, process and technology development programs, sales, suppliers, customers, employees, investors, or other business information, whether in oral, written, graphic, or electronic form.

"Contract Month" means each month during any Contract Year.

"Contract Quarter" means each three (3) month period ending on March 31, June 30, September 30 and December 31 during any Contract Year.

"Contract Year" means a twelve (12) month period ending on December 31. The initial Contract Year will be deemed to begin on the Amended and Restated Effective Date and end on December 31 of that Contract Year in which it falls.

"Diligent Commercialization Efforts" means efforts and resources reasonably comparable to those commonly used in the research-based pharmaceutical industry for a medical device, pharmaceutical product or pharmaceutical compound at a similar stage in its commercialization or product life of similar market potential, taking into account safety and efficacy, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the potential profitability of the product and alternative products and other relevant factors relating to the commercialization of a Licensed Product, including, without limitation, the potential cost, risk, timing and reward, <u>provided</u>, <u>however</u>, that the fact that the Parties are required to share revenues with respect to the Licensed Products shall not be a factor taken into account in determining whether Diligent Commercialization Efforts were satisfied. Diligent Commercialization Efforts shall be determined on a market by market basis for a particular Licensed Product, and it is anticipated that the level of effort will change over time reflecting changes in the status of the Licensed Product and the market involved.

"<u>Diligent Development Efforts</u>" means efforts and resources reasonably comparable to those commonly used in the research-based pharmaceutical industry for a medical device, pharmaceutical product or pharmaceutical compound at a similar stage in its development of similar market potential, taking into account safety and efficacy, product profile, difficulty in developing the product, competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the potential profitability of the product and alternative products and other relevant factors affecting the cost, risk and timing of development and total potential reward to be obtained if a Licensed Product is commercialized, <u>provided</u>, <u>however</u>, that the fact that the Parties are required to share revenues with respect to the Licensed Products shall not be a factor taken into account in determining whether Diligent Development Efforts were satisfied.

"Discovery" has the meaning set forth in the Preamble hereto.

"Discovery Intellectual Property" has the meaning set forth in Section 8.1.2.

"Discovery Patents" means all Patents owned by Discovery or to which Discovery otherwise has rights that claim or are directed to any Discovery Intellectual Property.

"<u>Discovery Technology</u>." means (a) Discovery's proprietary Pulmonary Surfactant technology (including without limitation the technologies, formulations, processes, equipment, materials and know-how relating to the manufacture and use of Pulmonary Surfactants for treatment of respiratory conditions), and (b) all Intellectual Property owned by or licensed to Discovery relating to such Pulmonary Surfactant technology, including, without limitation, the Discovery Patents.

"<u>Discovery Technology Improvements</u>" means any Inventions created or reduced to practice [***] in the performance of the Agreement or exercise of the license granted pursuant to this Agreement, which Inventions relate primarily to Pulmonary Surfactants (alone or in combination with [***]).

"<u>Disposable Dose Packet</u>" consists of: (i) Drug Product within a container (comprising the drug formulation containing the drug substance and the container closure system in which it is packaged), (ii) aerosolization capillary (heatable capillary through which the formulation is pumped to produce an aerosol), (iii) patient interface (components through which the aerosol produced by the capillary travels in order to reach the patient), and (iv) all ancillary tubing, connectors and fittings related thereto.

"Dispute" has the meaning set forth in Section 17.1.

"Dollars" and "\$" means, unless otherwise specified, United States Dollars.

"Drug Product" means a pharmacological agent(s), including Pulmonary Surfactants, together with any excipients or inactive ingredients, formulated for use in connection with an Aerosol Device or Disposable Dose Packet.

"Estimated Amount" has the meaning set forth in Section 7.8.1.

[***]

"Exchange Act" has the meaning set forth in Section 16.1.

"Exclusive Field" means (i) the therapeutic or preventative use in humans of Aerosol Technology to deliver Pulmonary Surfactants (alone or in combination with any other pharmaceutical compound(s)) as an active ingredient for the prevention or treatment of Respiratory Indications, and (ii) the therapeutic or preventative use in humans of Aerosol Technology to deliver [***] as an active ingredient.

"FDA" shall mean the United States Food and Drug Administration, and any successor agency.

"First Commercial Sale" means the first arms-length commercial sale of a Licensed Product to a Third Party by Discovery or its Affiliates or sublicensees, as the case may be, in any country in the Territory after receipt of Marketing Authorization in such country which results in an exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.

"Force Majeure Event" means an event or occurrence that materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of due diligence have been avoided, including without limitation fire, earthquake, acts of God, acts of war, labor strikes or lockouts, riots, civil disturbances, actions or inactions of governmental authorities (except actions in response to a breach of applicable Law by such Party).

"GAAP" means generally accepted accounting principles in the United States of America.

"Hospital Setting" means a (i) hospital-setting in the delivery room, NICU, PICU, CCU, emergency department, surgical care unit and/or intermediate care unit, (ii) emergency and specialized medical treatment centers, such as birthing centers, treatment centers for chronic diseases, trauma centers and other similar facilities, and (iii) an institution setting which is used to provide long-term care for people with chronic illness or disability, including hospice settings and nursing homes.

"Indemnitee" has the meaning set forth in Section 13.2.1.

"Indemnitor" has the meaning set forth in Section 13.2.1.

"Infringement Notice" has the meaning set forth in Section 8.6.1.

"Intellectual Property" means all know how, Inventions, Patents, copyrights, trademarks, trade secrets and any other intellectual property rights in the Territory that may be secured in any place under laws now or hereafter in effect.

"Invention" means any new or improved apparatus, process, information, product, invention, discovery, idea, suggestion, material, data, equipment, design, circuit component, drawing, tooling, prototype, report, computer software, documentation or other intellectual property or know-how (whether or not patentable) discovered, produced, conceived, created or reduced to practice by either or both Parties (or their Affiliates, sublicensees, subcontractors, successors or assigns).

type of regulatory body (including common law) or securities exchange or automated quotation system.

"Law" means any applicable statute, law, ordinance, regulation, order, or rule of any federal, state, local, foreign, or other governmental agency or body or of any other

"<u>Licensed Product</u>" means a combination drug-device product using or otherwise practicing the Chrysalis Technology and delivering Pulmonary Surfactants or [***] (each alone or in combination with [***]).

"Losses" has the meaning set forth in Section 13.1.1.

"Marketing Authorization" means, with respect to each country in the Territory, the principal Regulatory Approval required to market the Licensed Product in such country (e.g., the NDA), including satisfactory pricing and reimbursement approval, when applicable.

"NDA" shall mean a new drug application, biologics license application, pre-market approval application, or a pre-market clearance under FDCA Section 510k that may be filed with the FDA in the United States or any comparable application that may be filed with any equivalent Regulatory Authority in the Territory.

"Net Sales" means, with respect to Licensed Products and Substitute Products, as applicable, sold by Discovery, its Affiliates and sublicensees in the Territory, the [***] amount [***] for Licensed Products or Substitute Products, as applicable, by Discovery, its Affiliates, and any sublicensees of Discovery in arms-length, commercial transactions in the Territory with customers that are Third Parties, less the following deductions to the extent included in such [***] amount:

[***]

Any discretionary rebates, discounts or other adjustments to the [***] amount shall be commercially reasonable and consistent with standard industry practices. Net Sales (including each applicable deduction from the [***] amount) shall be determined from the books and records of Discovery maintained in accordance with GAAP consistently applied.

"Non-Breaching Party" has the meaning set forth in Section 15.4.1.

"Original Effective Date" has the meaning set forth in the Preamble hereto.

"Party" and "Parties" have the meanings set forth in the Preamble hereto.

"<u>Patents</u>" means all patents and patent applications, and all patents issuing thereon (including utility, model and design patents and certificates of invention), together with all reissue patents, patents of addition, divisions, renewals, continuations, continuations-in-part, substitutions, additions, extensions (including supplemental protection certificates), registrations, confirmations, re-examinations, and foreign counterparts of any of the foregoing in the Territory.

"Person" means any natural person, corporation, company, partnership, limited liability company, proprietorship, trust or estate, joint venture, association, or other legal entity.

"Pulmonary Surfactant" means surface active agents designed for deposition in the lungs in order to exert a physiological or pharmacological affect to prevent or treat Respiratory Indications.

"Regulatory Approval" means any approvals (including, where necessary for the marketing, use, or other distribution of a drug, medical device, or combination drug and medical device in a regulatory jurisdiction, pricing, and reimbursement approvals), licenses, registrations, or authorizations or equivalents necessary for the manufacture, use, storage, import, export, clinical testing, transport, marketing, sale, and distribution of the Drug Product or Aerosol Device and any Licensed Product in a regulatory jurisdiction anywhere in the Territory, including Marketing Authorizations.

"Regulatory Authority" means any federal, national, multinational, state, provincial, or local regulatory agency, department, bureau, or other governmental entity with authority to regulate the marketing and sale of a pharmaceutical product, delivery system or device in the Territory, including the FDA in the United States.

"Regulatory Data" means any and all research data, pharmacology data, chemistry, manufacturing, and control data, preclinical data, clinical data and/or all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with an Investigational New Drug Application or NDA for Licensed Products (including any Drug Master Files, Device Master Files, Chemistry, Manufacturing and Control (CMC) data, or similar documentation).

"Respiratory Indications" means all respiratory dysfunctions, failures, syndromes, diseases, disorders, or conditions.

"Royalty Credit" has the meaning set forth in Section 7.8.2.

"Royalty Report" means the reports to be delivered by Discovery to Chrysalis pursuant to Section 7.7 with respect to each Contract Month and pursuant to Section 7.8 with respect to each Contract Quarter, which reports shall give such particulars of each of the Licensed Products and Substitute Products sold by Discovery and its Affiliates and sublicensees during the preceding Contract Month in the Territory in the case of Section 7.7 and during the preceding Contract Quarter in the case of Section 7.8 as are reasonably pertinent to perform an accounting of royalties under this Agreement.

"SEC" has the meaning set forth in Section 9.3.

"Substitute Product" means any Aerosol Device, Disposable Dose Packet or Drug Product (other than a Licensed Product) sold by Discovery, its Affiliates and sublicensees for use within the Exclusive Field.

"Target Indications" means the following Respiratory Indications: [***].

"Target Populations" means human patients [***] receiving forms of treatment for the applicable Respiratory Indication that are typically and principally provided [***].

"Taxes" has the meaning set forth in Section 7.14.

"Term" has the meaning set forth in Article 14.

"Territory" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, and Northern Mariana Islands.

"Third Party" means any Person other than Chrysalis or Discovery or their respective Affiliates.

"Third Party Claim" has the meaning set forth in Section 13.1.1.

"<u>Valid Claim</u>" means a claim of an issued and unexpired patent, which claim has not been held unpatentable, invalid, or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise, which claim, but for the licenses granted herein, would be infringed by the sale of a Licensed Product.

ARTICLE 2 TECHNOLOGY TRANSFER

- 2.1 <u>Technology Transfer</u>. Prior to June 30, 2008, Chrysalis shall provide Discovery with a technology transfer reasonable in scope to enable Discovery to practice the Chrysalis Technology for purposes of exercising the license rights granted to Discovery hereunder. Chrysalis shall have satisfied its obligations pursuant to this Section 2.1 in the event Chrysalis complies with the specific obligations set forth in Exhibit A.
- 2.2 <u>Transfer of Regulatory Files, Data and Filings.</u> In connection with the technology transfer contemplated pursuant to Section 2.1, Chrysalis shall provide to Discovery or its designee, a copy of all governmental or regulatory correspondence, conversation logs, filings, and approvals relating to the development, manufacture or commercialization of the Licensed Product (including study protocols, study results, analytical methodologies, validation documentation, and regulatory documentation) that are reasonably necessary for the continued development and sale of the Licensed Product, including without limitation those materials that are reasonably necessary for inclusion in a new drug application or equivalent filing with the FDA or other regulatory bodies. Chrysalis shall also provide to Discovery copies of, and permit Discovery to reference in connection with any Licensed Products, all Regulatory Data relating to Licensed Products reasonably necessary to continue the development, marketing and sale of the Licensed Products. From and after such time, all such Regulatory Data and information provided to Discovery shall remain Confidential Information of Chrysalis; provided, however, that Discovery may use all such Regulatory Data and information solely for the purposes of continuing to pursue the development and commercialization of Licensed Products. Chrysalis shall execute all documents and take all such further actions as may be reasonably requested by Discovery and required in order to give effect to the foregoing.

ARTICLE 3 LICENSE

- 3.1 <u>License</u>. Subject to the terms, conditions, and limitations of this Agreement, Chrysalis hereby grants to Discovery an exclusive right and royalty-bearing license or sublicense, as applicable, in the Territory, with the right to grant sublicenses solely as set forth in Section 3.3, under the Chrysalis Technology and Chrysalis Technology Improvements to make and have made, to use and have used, to develop and have developed, to sell and have sold, to offer for sale and have offered for sale, to import and export and have imported and exported Licensed Products in the Exclusive Field in the Territory during the Term.
- 3.2 <u>Limitations</u>. The license granted pursuant to Section 3.1 shall be exclusive only to the extent that Chrysalis has the right to grant an exclusive license with respect to the Licensed Product in question. No right or license outside of the Exclusive Field is granted and all such rights are expressly reserved by Chrysalis. No right or license is or shall be granted under this Agreement by implication. All such rights or licenses are or shall be granted only as expressly provided in this Agreement. Discovery shall not practice the Chrysalis Technology in the Territory except as expressly licensed herein. Nothing herein shall limit the ability of Chrysalis to perform any research or development work on or using the Chrysalis Technology. Notwithstanding any other provision of this Agreement, no rights with respect to any trademarks, trade names, service marks or logos of Chrysalis are granted pursuant to this Agreement.
- 3.3 <u>Sublicensing Rights</u>. The license granted to Discovery pursuant to Section 3.1 by Chrysalis shall include the right of Discovery to grant sublicenses, subject to terms and conditions set forth in Section 18.7. Discovery shall provide Chrysalis with prompt written notice of any sublicenses granted hereunder.
- 3.4 <u>Retained Rights</u>. Any rights of each Party not expressly granted to the other Party under the provisions of this Agreement shall be retained by each Party, and, subject to any applicable terms, conditions, and limitations of this Agreement, each Party shall retain the right to: (a) exploit such Party's own Intellectual Property relating to Licensed Products to develop, manufacture, and commercialize products outside the Exclusive Field; (b) exploit such Party's own Intellectual Property relating to Licensed Products for other purposes outside the Exclusive Field unrelated to the Licensed Products; and (c) perform its obligations and exercise its rights under this Agreement.

ARTICLE 4 PRODUCT DEVELOPMENT

4.1 <u>Licensed Product Development</u>. Discovery shall be solely responsible for the development of Licensed Products and Chrysalis shall have no obligations with respect to the development of Licensed Products unless Chrysalis agrees otherwise in writing. Chrysalis acknowledges and agrees that Discovery may partner with third parties with respect to the development of Licensed Products.

- 4.2 <u>Notice of Development of Licensed Products.</u> Discovery shall provide Chrysalis with written notification of its intention to proceed with Phase II Clinical Trials for a Licensed Product. Such written notification shall include sufficient detail for Chrysalis to understand the nature of such Licensed Product to be developed by Discovery.
- 4.3 <u>Development Effort.</u> Discovery shall use Diligent Development Efforts to develop at least one Licensed Product and to otherwise carry out its responsibilities under this Agreement relating to such Licensed Product promptly and expeditiously in accordance with all Laws. Notwithstanding the foregoing, the Parties acknowledge that the development of pharmaceutical products is inherently speculative and there is no guarantee that the Discovery will be successful in developing any commercially viable Licensed Products, or that the development of any Licensed Products will proceed as anticipated.
 - 4.4 <u>Costs.</u> Discovery shall be solely responsible for all costs incurred by Discovery in connection with the development of Licensed Products hereunder.
- 4.5 <u>Development Support by Chrysalis</u>. Chrysalis shall use commercially reasonable efforts to perform, in consultation with Discovery, the development activities mutually agreed upon by the Parties in writing on a mutually agreed upon schedule set forth in writing; provided, however, that (if the technology transfer provided for in Article 2 shall have been completed in accordance therewith) in no event shall Chrysalis have any obligation to perform any development activities or otherwise provide any support to Discovery after June 30, 2008. Discovery acknowledges and agrees that Chrysalis is transitioning out of the aerosol device business and that Chrysalis makes no commitment that Chrysalis will have or retain the personnel or resources necessary to perform any specific development activities hereunder. Chrysalis' obligation to perform the development activities set forth in this Section 4.5 is subject to Chrysalis having qualified personnel to perform such development activities. Chrysalis shall be solely responsible for all costs incurred by Chrysalis in connection with the development activities performed by Chrysalis pursuant to this Section.
- 4.6 <u>Design Configurations</u>. The Parties agree that any Aerosol Device and Disposable Dose Packet configuration developed for use outside the Exclusive Field shall be distinct in appearance from those for use with the Licensed Products and shall not be interchangeable with the Aerosol Device or Disposable Dose Packet of the Licensed Products. Without limiting the generality of the foregoing, Chrysalis shall not offer for sale or sell, nor authorize any Third Party to offer for sale or sell, any pharmaceutical product (i) in packaging similar in appearance to the Disposable Dose Packet for a Licensed Product, or (ii) in packaging that is interchangeable with the Disposable Dose Packet of a Licensed Product for purposes of use in an Aerosol Device.
- 4.7 <u>Status Updates.</u> Upon the reasonable request of Chrysalis, Discovery shall provide Chrysalis with an update on the status of the development of Licensed Products hereunder; provided that in no event shall Discovery be required to provide an update more often than once a Contract Quarter.

ARTICLE 5 COMMERCIALIZATION

- 5.1 <u>Exclusive Right to Sell the Licensed Products</u>. The Parties agree that during the Term, Discovery shall have the exclusive right to market and have marketed, sell and have sold, and offer for sale or have offered for sale any Licensed Products in the Territory.
- 5.2 Responsibility For Commercialization Matters. Discovery shall have the sole responsibility for all activities associated with the commercialization of the Licensed Products in the Territory, including, without limitation, (a) preparing, submitting and seeking Marketing Authorizations for the Licensed Products, (b) sales, advertising and marketing of the Licensed Product, (c) scientific and medical affairs, (d) customer service and distribution related services, such as order taking, shipping, billing, accounts receivable, returns, allowance activities and product support; (e) Phase IV Clinical Trials, (f) commercial manufacture of the Licensed Product; and (g) branding of the Licensed Products.
 - 5.3 Commercialization.
- 5.3.1 <u>Diligent Commercialization Efforts.</u> Discovery shall use Diligent Commercialization Efforts to bring the Licensed Products to market and to market and sell the Licensed Products in the Territory. Discovery shall promptly notify Chrysalis of the receipt of any Marketing Authorization for a Licensed Product in the Territory.
- 5.3.2 <u>Commercialization Initiation</u>. With respect to each Licensed Product, the First Commercial Sale in the Territory shall occur within [***] of receipt of the relevant Marketing Authorization for the Territory for such Licensed Product. Should Discovery materially fail to achieve any such commercialization initiation within [***] of having received written notice of such failure from Chrysalis [***].
- 5.4 <u>Status Updates.</u> Upon Chrysalis' reasonable request, Discovery shall provide Chrysalis with an update on the status of the commercialization of Licensed Products in the Territory hereunder; provided that in no event shall Discovery be required to provide an update more often than once a Contract Quarter.

ARTICLE 6 REGULATORY MATTERS

6.1 <u>Responsibility and Consultation</u>. Discovery shall be responsible for preparing, submitting, seeking and maintaining all Regulatory Approvals for the Licensed Products in the Territory, including without limitation Marketing Authorizations.

- 6.2 <u>Regulatory Updates and Communications</u>. Within thirty (30) days after the end of each Contract Quarter, Discovery shall provide Chrysalis with a written update on the status of the Regulatory Approvals for the Licensed Products in the Territory. In addition, Discovery shall provide Chrysalis with a copy of any medical device reports relating to the use of Licensed Products in the Territory and a copy (if in writing) or a description (if oral) of any significant contact or communication from any Regulatory Authority relating to a material safety issue with the Chrysalis Technology, in each case, promptly after Discovery's receipt of the same.
- 6.3 Records. Except to the extent otherwise required by law, the Parties acknowledge and agree that Chrysalis shall have no obligation to maintain any records relating to the Chrysalis Technology or the Licensed Product.
- 6.4 <u>Product Liability Litigation</u>. Discovery shall promptly inform Chrysalis of the initiation of any (i) recalls, corrections or removals of Licensed Products, and (ii) litigation or investigations in the Territory relating to the Licensed Product involving a claim of death or bodily injury (or allegations thereof) to an individual and shall provide Chrysalis with regular written updates with respect thereto. If any such recalls, corrections, removals, litigation or investigations relate to the Chrysalis Technology, then Chrysalis shall have the right to audit the books, records and facilities relating to such Licensed Products (solely to the degree that Discovery has the right to grant any such access and solely to the degree such books, records and facilities relate to such litigation and investigation), and Discovery shall reasonably cooperate with Chrysalis in connection therewith.

ARTICLE 7 FINANCIAL PROVISIONS

- 7.1 <u>Transition Assistance Fees</u>. Chrysalis shall pay to Discovery the following fixed fees in accordance with the following schedule:
 - 7.1.1 Within [***] days after the Amended and Restated Effective Date, a fixed fee of two million dollars (\$2,000,000); and
- 7.1.2 Within [***] days after the Parties mutually agree in writing that [***], a fixed fee of two million five hundred thousand dollars (\$2,500,000);

provided, however, that Chrysalis shall have no obligation to pay Discovery any amounts pursuant to this Section 7.1 if Discovery is in material breach of any material provision of this Agreement.

7.2 Royalties with Respect to Licensed Products and Substitute Products. In consideration of the significant investments made by Chrysalis in developing the Chrysalis Technology and the rights granted and payments made to Discovery herein, Discovery shall pay royalties to Chrysalis on Net Sales of Licensed Products and Substitute Products in the Territory in an amount equal to *** of the Net Sales for such Licensed Products and Substitute Products.

- 7.3 <u>Minimum Royalties</u>. Commencing [***] and continuing thereafter throughout the Term, if the royalties paid by Discovery to Chrysalis hereunder are not equal to or greater than the following for each Contract Quarter of the applicable Contract Year:
- [***] (the "Minimum Royalty."), then Chrysalis shall have the right to terminate this Agreement pursuant to Section 15.3; provided, that Discovery can cure any such royalty shortfall by paying Chrysalis [***] after the end of the applicable Contract Quarter the difference between the Minimum Royalty due for the applicable Contract Quarter and the actual royalties paid by Discovery hereunder for such Contract Quarter (the "Royalty Shortfall"). The royalty payments required to be paid in any given Contract Quarter pursuant to Section 7.2 shall be subject to an offsetting reduction by Discovery in an amount equal to the Royalty Shortfall; provided, however, that (i) no such offset shall be applied until the royalty payments for such Contract Quarter exceed the Minimum Royalties for such Contract Quarter, and (ii) such offset may be made only to the extent such Royalty Shortfall has not previously been subject to offset pursuant to this Section.
- 7.4 <u>Prohibition on Bundling</u>. Notwithstanding any other provision of this Agreement to the contrary, Discovery hereby covenants that it will not include or bundle any Licensed Products and Substitute Products or components thereof as part of a multiple product offering with any other products or services if it would result in the price of the Licensed Product or Substitute Product or any components thereof being discounted from the then-applicable sale price in such jurisdiction, nor shall Discovery permit its Affiliates or sublicensees to do so, except with the prior written consent of Chrysalis. In the event any such bundled sales occur, the Net Sales with respect to such bundled transactions shall be deemed to be the-then current average Net Sales for the Licensed Product or Substitute Product in such jurisdiction in arms length transactions or in the event there are no unbundled transactions, the fair market value of such Net Sales.
- 7.5 <u>Fixed Consideration</u>. In the event that Discovery receives any fixed payment, fee or other consideration from a Third Party (i) in consideration of any discount, credit or similar allowance granted to such Third Party in connection with the purchase of any Licensed Product(s) or Substitute Product(s) or (ii) in lieu of any royalties with respect to any Licensed Product(s) or Substitute Product(s), then Discovery shall pay to Chrysalis a royalty equal to the product of (a) such consideration multiplied by (b) the royalty rate set forth in Section 7.2. Discovery shall report on the amount of any such consideration, and the royalty payable thereon in U.S. Dollars, in the Royalty Report. For the avoidance of doubt, this Section 7.5 shall not apply with respect to any fixed payment, fee or other consideration from a Third Party in respect of development fees, milestone payments or other similar payments in transactions that incorporate a market-rate royalty structure.

7.6	Treatment of Partial Product Sales. In the event that portions of a Licensed Product or Substitute Product are sold separately, (e.g., Aerosol Device, Disposable				
Dose Packet, Drug Product) the royalties payable pursuant to this Article 7 shall be paid [***].					

- 7.7 Royalty Reports. Within [***] days after the end of each Contract Month (beginning with [***] Licensed Product or Substitute Product, as the case may be), Discovery shall deliver to Chrysalis a preliminary Royalty Report. [***] The Royalty Report shall include at least the following items, separately stated as to each of the Licensed Products and Substitute Products, as applicable:
- (i) the quantity of each of the Licensed Products and Substitute Products (delineated as Aerosol Devices and Disposable Dose Packets) invoiced by Discovery and its Affiliates and sublicensees during such Contract Month and the [***] amount therefor;
 - (ii) the allowable deductions therefrom and an itemization of each specific deduction [***];
- (iii) the calculation of royalties, if any, thereon in a manner consistent with the amounts set forth in the Royalty Report prepared in accordance with this Section 7.7.
 - 7.8 Payment of Estimated and Actual Amounts.
- 7.8.1 <u>Payment of Estimated Amounts</u>. Simultaneous with the issuance of the preliminary Royalty Report, Discovery shall make payment of estimated amounts due to Chrysalis hereunder with respect to such Contract Month (the "<u>Estimated Amount</u>").
- 7.8.2 Quarterly Reconciliation and True-Up. Within [***] days following each Contract Quarter, Discovery shall calculate the actual amount due to Chrysalis hereunder with respect to the immediately preceding Contract Quarter (the "Actual Amount") and provide to Chrysalis a true and accurate Royalty Report for such Contract Quarter, setting forth the corrected calculations for such Contract Quarter. If the Estimated Amounts paid to Chrysalis pursuant to Section 7.8.1 for the three Contract Months comprising the immediately preceding Contract Quarter exceeds the Actual Amount for such Contract Quarter, Discovery shall notify Chrysalis and such excess amount (the "Royalty Credit") shall, at the discretion of Discovery, be available to offset future royalties payable to Chrysalis by Discovery. If such Actual Amount exceeds such Estimated Amount, Discovery shall promptly pay such excess amount to Chrysalis. [***]

- 7.9 Pass-Through Royalties. Each Party shall be solely responsible for paying any royalties which may be due to Third Parties with respect to such Party's Intellectual Property.
 - 7.10 Records and Audits.
- 7.10.1 Records. Discovery shall keep, and shall require its Affiliates and sublicensees to keep, such records as are necessary to determine accurately the sums due to each other under this Agreement. Such records shall be retained by Discovery for the Term and for three (3) years thereafter.
- 7.10.2 Audit. At the written request of Chrysalis, with reasonable advance notice, Discovery shall make available for inspection, review, and audit, by an internationally recognized independent certified public accounting firm appointed by Chrysalis and reasonably acceptable to Discovery, such records of Discovery as may be reasonably necessary to verify Discovery's accounting reports and payments made or to be made pursuant to this Agreement; provided, however, that such audits may not be performed by Chrysalis more than once per Contract Year in the absence of a reasonable basis for concern regarding compliance with the Agreement or any applicable Laws. If such accountants identify a discrepancy, then the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date of receiving such accountant's written report, or as otherwise agreed upon by the Parties, plus, in the event of any underpayment, interest calculated in accordance with Section 7.13.
- 7.10.3 Audit Confidentiality. Chrysalis shall cause any accountants selected by it to enter into a confidentiality agreement acceptable to Discovery obligating such accountants to retain all such information in confidence pursuant to such confidentiality agreement. Such accountants shall not reveal to Chrysalis the details of its review, except for such information as is required to be disclosed under this Agreement, and such details shall be treated as Confidential Information. Each Party agrees to hold in strict confidence all information concerning payments and reports, and all information learned in the course of any audit or inspection (and not to make copies of such reports and information), except to the extent necessary for such Party to reveal such information in order to enforce its rights under this Agreement or if disclosure is required by Law, regulation or judicial order.
- 7.10.4 Costs of Audits. Chrysalis shall pay for such inspections, except that in the event the adjustment shown by such inspection is greater than [***] percent ([***]%) of the original royalty amounts in question, Discovery shall pay for such inspection.
- 7.11 Foreign Exchange. For the purpose of computing the Net Sales for Licensed Products and Substitute Products sold in a currency other than Dollars, such amounts shall be converted into Dollars each Contract Month in the then standard manner used by Discovery in the preparation of its audited financial statements, consistently applied. Such method of currency conversion used by Discovery shall be a commercially reasonable method consistent with industry standards, and Discovery shall disclose to Chrysalis [***] prior to First Commercial Sale of a Licensed Product or Substitute Product in a country such method of currency conversion. Notwithstanding anything herein to the contrary, at Chrysalis' option, with respect to any particular country in the Territory, Discovery shall pay royalties for Licensed Products and Substitute Products sold in such country in such country's local currency. Discovery shall not change such method of currency conversion disclosed to Chrysalis pursuant to this Section 7.11 without obtaining Chrysalis' prior written consent, such consent not to be unreasonably withheld.

7.12	Manner of Payments. All sums due to Chrysalis under this Agreement shall be payable by electronic funds transfer in immediately available funds to such banl
account(s) as Chr	ysalis shall designate at least two (2) Business Days in advance.

- 7.13 <u>Late Payments.</u> Any amounts not paid when due under this Agreement shall be subject to interest from and including the date payment is due through and including the date upon which Chrysalis has collected immediately available funds in an account designated by Chrysalis at an annual rate equal to the sum of [***] percent ([***]%) plus the annual prime rate of interest quoted in the Money Rates section of the East Coast edition of the *Wall Street Journal* calculated daily on the basis of a 365-day year, or similar reputable data source, or, if lower, the highest rate permitted under applicable law. Notwithstanding the foregoing, any payment of amounts by Discovery representing the excess of Actual Amount over Estimated Amount, calculated in accordance with Section 7.8, shall not be subject to this Section 7.13.
- 7.14 Tax Withholding. Any taxes, levies, or other duties ("Taxes") paid or required to be withheld under the appropriate local tax Laws by Discovery on account of monies payable to Chrysalis under this Agreement shall be deducted from the amount of monies otherwise payable to Chrysalis under this Agreement and paid by Discovery to the proper taxing authority. Discovery shall secure and send to Chrysalis within a reasonable period of time proof of any such Taxes paid or required to be withheld by Discovery for the benefit of Chrysalis. The Parties shall cooperate reasonably with each other to (i) ensure that any amounts required to be withheld by Discovery are reduced in amount to the fullest extent permitted by Law and (ii) to resolve such other Party's taxation concerns.

ARTICLE 8 INTELLECTUAL PROPERTY

8.1 Ownership.

8.1.1 <u>Chrysalis Intellectual Property.</u> Chrysalis shall own (i) all Intellectual Property owned or controlled by Chrysalis relating to the Chrysalis Technology or Licensed Products that was existing or conceived prior to the Amended and Restated Effective Date, (ii) all Intellectual Property relating to the Chrysalis Technology or the Licensed Products developed by Chrysalis outside of the performance of this Agreement or to which Chrysalis otherwise obtains rights from a Third Party; (iii) all Inventions conceived, created and reduced to practice solely by or on behalf of Chrysalis in the course of the performance of this Agreement, except Discovery Technology Improvements; and (iv) all Chrysalis Technology Improvements (collectively, "<u>Chrysalis Intellectual Property</u>").

- 8.1.2 <u>Discovery Intellectual Property.</u> Discovery shall own (i) all Intellectual Property owned or controlled by Discovery relating to Discovery Technology or the Licensed Products that was existing or conceived prior to the Amended and Restated Effective Date or is developed by Discovery outside of the performance of this Agreement, (ii) all Intellectual Property relating to Discovery Technology or the Licensed Products developed by Discovery outside of the performance of this Agreement or exercise of the license granted hereunder or to which Discovery otherwise obtains rights from a Third Party, and (iii) all Inventions conceived, created and reduced to practice solely by or on behalf of Discovery in the course of the performance of this Agreement or exercise of the license granted hereunder, except Chrysalis Technology Improvements; (iv) all Inventions conceived, created and reduced to practice jointly by or on behalf of the Parties in the course of the performance of this Agreement or exercise of the license granted hereunder, except Chrysalis Technology Improvements; and (v) all Discovery Technology Improvements (collectively "Discovery Intellectual Property.").
 - 8.2 Disclosure, Assignment, License and Exploitation.
- 8.2.1 <u>Disclosure</u>. Each Party shall cause all personnel conducting work or exercising rights on its behalf under the Agreement to, promptly disclose to the other Party all Intellectual Property in which the other Party has an ownership interest pursuant to Section 8.1, and to assign any and all right, title and interest in all such Inventions and Intellectual Property in accordance with this Agreement. Each Party shall maintain records in sufficient detail and in good scientific manner appropriate for patent prosecution purposes to properly reflect all work done and results achieved in conducting its work hereunder, and shall respond to reasonable requests of the other Party for information regarding Intellectual Property in which the other Party has an ownership interest.
- 8.2.2 Assignment and License. In the event Chrysalis conceives, creates or reduces to practice any Discovery Technology Improvements, Chrysalis shall promptly notify Discovery and Chrysalis shall assign all right, title and interest in and to such Discovery Technology Improvements to Discovery. In the event Discovery conceives, creates or reduces to practice any Chrysalis Technology Improvements, Discovery shall promptly notify Chrysalis and Discovery shall assign all right, title and interest in and to such Chrysalis Technology Improvements to Chrysalis, however, such Chrysalis Technology Improvements are included in the Intellectual Property licensed to Discovery pursuant to Section 3.1.
- 8.2.3 Exploitation of Intellectual Property. To the extent permitted by Law, Chrysalis agrees not to exploit the Chrysalis Intellectual Property in the Exclusive Field in any country in the world; provided, however, that in the event Discovery terminates this Agreement pursuant to Article 15 with respect to [***], this Section 8.2.3 shall no longer apply to Chrysalis with respect to such [***] and Chrysalis shall have the right to exploit the Chrysalis Intellectual Property in the Exclusive Field in the Territory with respect to such [***].

- 8.3 <u>Agreement with Personnel</u>. Each Party shall have valid and enforceable written agreements with all personnel conducting work on its behalf under the Agreement containing a nondisclosure obligation comparable in scope to Article 9 and giving the other Party all rights and authority necessary to effectuate the provisions of this Article 8. Each Party shall provide copies of these agreements to the other Party upon the other Party's request as allowed by each Party's internal personnel policies.
 - 8.4 Prosecution of Patents.
- 8.4.1 <u>Discovery and Chrysalis Patent Filings.</u> Discovery and Chrysalis each shall use commercially reasonable efforts to diligently prosecute and maintain their respective Chrysalis Patents and Discovery Patents in the Territory; provided that solely for the purposes of this Section 8.4.1 Discovery Patents shall mean those Discovery Patents that claim or are directed to Discovery Technology. Within forty-five (45) days of a Party's receipt of an allowance or grant of a Patent, the Party prosecuting the Patent shall inform the other Party of such allowance or grant, and provide the other Party with a copy of the allowed or granted Patent claims thereof.
- 8.4.2 <u>Patent Prosecution Costs</u>. Each Party shall bear its own costs to file, prosecute and maintain its Patents in the Territory (including, without limitation, patent term extension).
- 8.4.3 <u>Abandonment of Prosecution or Maintenance</u>. Each Party shall notify the other Party in the event it is unable for any reason to meet its obligations under this Article 8 with respect to any Patents that are subject to Section 8.4.1. Such notification shall be given within a reasonable period prior to the date on which such Patents will lapse or become abandoned. The Party receiving any notification hereunder shall then have the option, exercisable upon written notification to the Party that delivered such notification, to assume full responsibility, at its discretion and its sole cost and expense, for prosecution or maintenance of the affected Patents in such country or countries in the Territory.
- 8.5 <u>Patent Term Extensions</u>. Each Party shall have the right to request that the other Party file all applications and take all actions necessary to obtain patent extension pursuant to 35 U.S.C. § 156 or like foreign statutes for the respective Parties' Patents in the Territory. If the filing Party declines to pursue such patent term extensions, then as permitted by law, the other Party shall have the right (at its cost and expense) on behalf of the filing Party to file, or direct the filing of, all such applications and take all such actions necessary to obtain such patent term extensions. Each Party agrees to sign such further documents and take such further actions as may be requested by the other Party in this regard.
 - 8.6 Third Party Infringement.

- 8.6.1 Suits for Infringement. If Discovery or Chrysalis becomes aware of infringement of any Patent included in the Discovery Patents or the Chrysalis Patents by a Third Party in the Territory, such Party shall promptly notify the other Party in writing to that effect and provide a summary of the relevant facts and circumstances known to such Party relating to such infringement ("Infringement Notice"). Each Party shall have the right, at its sole discretion and expense, on its own behalf, to institute, prosecute, and control any action or proceeding to restrain infringement of any of its Patents. A Party instituting suit shall have control of such suit and all negotiations for its settlement or compromise; provided however, that the instituting Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof which would materially adversely affect the Intellectual Property rights with respect to a Licensed Product without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- 8.6.2 <u>Step-in Right</u>. If, prior to the expiration of three (3) months from said Infringement Notice, the Party whose Patents are alleged to be infringed has not obtained a discontinuance of an alleged infringement by a Third Party or brought an infringement action or proceeding or otherwise taken appropriate action to abate such infringement, such Party shall notify the other Party at any time prior thereto of its intention not to bring suit against an alleged infringer. Upon such notice and if such infringement is reasonably likely to materially adversely affect a Licensed Product in the Territory, then, and in those events only, the other Party shall have the right, but not the obligation, at its sole expense to institute, prosecute, and control any action or proceeding to restrain such infringement. Each Party agrees to be joined as a party if necessary to prosecute the action or proceeding and shall provide all reasonable cooperation, including any necessary use of its name, required to prosecute such litigation. The other Party shall have control of any such suit and all negotiations for its settlement or compromise; provided, however, that the other Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the patentee Party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- 8.6.3 <u>Allocation of Recovery.</u> All damages, settlements and rewards made or obtained in connection with any suit or other legal proceeding under this Section 8.6 shall be shared among the parties as follows:
 - (i) [***]
 - (ii) **[*****
- 8.6.4 <u>Declaratory Actions and Counterclaims</u>. In the event that an action alleging invalidity or non-infringement of any of the Discovery Patents or Chrysalis Patents is brought against Discovery or Chrysalis in the Territory, the Party defending such action or counterclaim, at its sole discretion, shall have the right, within thirty (30) days after the commencement of such action, to take or regain control of the action at its own expense. If the defending Party determines not to exercise this right, the other Party may take over or remain as lead counsel for the action at that Party's sole discretion. Any recovery obtained from such litigation, proceeding or settlement shall be shared in accordance with Section 8.6.3.

8.7 Infringement of Third Party Rights.

- 8.7.1 Infringement Claims. With respect to any and all claims instituted by Third Parties for patent infringement involving the manufacture, use, offer for sale, or sale of a Licensed Product in the Territory during the Term, the Party named as defendant shall promptly notify the other Party of such claim, and the defending Party shall have the right, at its sole discretion and expense, to defend and control any action or proceeding with respect to such claim. The other Party agrees to be joined as a Party if necessary to defend the action or proceeding and shall provide reasonable cooperation, including any necessary use of its name, required to defend such litigation. The defending Party shall have sole control of any such suit and all negotiations for its settlement or compromise; provided, however, that the defending Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the other Party if such settlement would materially adversely affect the other Party's rights or impose any obligation on the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- 8.7.2 <u>Step-in Right</u>. If, prior to the expiration of three (3) months from said claim being brought, or such sooner period as may be necessary to appropriately respond to said claim, the defending Party has not elected to defend such action or proceeding, or if the defending Party shall notify the other Party at any time prior thereto of its intention not to defend such action or proceeding, then, and in those events only, the other Party shall have the right, but not be obligated, at its own expense to defend and control any action or proceeding. Such other Party shall have sole control of any such suit and all negotiations for its settlement or compromise; provided, however, that the other Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the original defending Party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- 8.7.3 Notice of Certification. Discovery and Chrysalis each shall immediately give notice to the other of any certification filed under the U.S. "Drug Price Competition and Patent Term Restoration Act of 1984" claiming that Discovery Patents or Chrysalis Patents are invalid or that any infringement will not arise from the manufacture, use, or sale of any Licensed Product by a Third Party. If a Party decides not to bring infringement proceedings against the entity making such a certification, that Party shall give notice to the other Party of its decision not to bring suit within twenty-one (21) days after receipt of notice of such certification. The other Party may then, but is not required to, bring suit against the party that filed the certification. Any suit by Discovery or Chrysalis shall either be in the name of Discovery or in the name of Chrysalis, or jointly in the name of Discovery and Chrysalis, as may be required by Law. For this purpose, the Party not bringing suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

ARTICLE 9 CONFIDENTIAL INFORMATION

- 9.1 <u>Use of Confidential Information</u>. A Party receiving Confidential Information (the "<u>Receiving Party</u>") from the other Party (the "<u>Disclosing Party</u>") shall keep all such Confidential Information with the same degree of care it maintains the confidentiality of its own confidential information, but in no event less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement, and shall not disclose the same to any Person other than to its Affiliates and such of its and their employees or agents who have a need to know such Confidential Information to implement the terms of this Agreement, and who are subject to a nondisclosure obligation comparable in scope to this Article 9. Each Party shall advise any employee or agent who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and such Party shall ensure that all such employees and agents comply with such obligations as if they had been a Party hereto. Upon termination of this Agreement, each Party shall use commercially reasonable efforts to return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remains in such Party's or its agents' or employees' possession, except that each Party may keep one (1) copy of the Confidential Information solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 9. Notwithstanding anything to the contrary in this Agreement, Confidential Information shall not include any information or materials that the Receiving Party can demonstrate by documentary evidence:
 - (i) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party;
 - (ii) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;
- (iv) were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or
- (v) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party.
- Permitted Disclosure and Use. Notwithstanding anything to the contrary in this Agreement, in the event that the Receiving Party or any of its directors, officers, employees, agents and advisors and their representatives deems it necessary or are requested or required (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative demand or other legal process by a court or other governmental authority, or by any Regulatory Authority to obtain Regulatory Approval of a Licensed Product) to disclose all or any part of any Confidential Information, the Receiving Party will provide the Disclosing Party with prompt notice of such request or requirement (which notice shall be reasonably in advance of such requested or required disclosure), as well as notice of the terms and circumstances surrounding such request or requirement, so that the Disclosing Party may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the Receiving Party shall consult with the Disclosing Party with respect to the advisability of pursuing any such order or other legal action or available steps to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Receiving Party is, in the opinion of counsel satisfactory to the Disclosing Party and its counsel, legally compelled to disclose any Confidential Information, the Receiving Party may disclose that portion of the Confidential Information which its counsel advises the Receiving Party that the Receiving Party is legally compelled to disclose. In any event, the Receiving Party will use reasonable efforts to obtain and will not oppose action by the Disclosing Party to obtain, an appropriate protective order or other reliable assurance that confidential treatment will be afforded the disclosure of such Confidential Information. The Receiving Party may disclose Confidential Information belonging to a Disclosing Party

- 9.3 <u>Disclosure for SEC Filings</u>. Notwithstanding anything to the contrary in this Agreement, the Parties expressly acknowledge that Discovery may file a copy of this Agreement with the Securities and Exchange Commission (the "<u>SEC</u>") in any of its SEC reports and filings, as well as incorporate them by reference into other SEC filings. Discovery shall request confidential treatment of sensitive terms hereof to the extent such confidential treatment is reasonably available to Discovery under the prevailing circumstances. Discovery shall coordinate in advance with Chrysalis with regard to the terms of this Agreement, for which Discovery shall seek to be redacted in any such SEC filings, and Discovery shall use reasonable efforts to seek confidential treatment for such mutually agreed terms and terms reasonably requested by Chrysalis; provided, however, that each Party shall retain ultimate control and responsibility for their respective disclosures to the SEC and the public generally. To the extent permitted by Law, Discovery shall use reasonable efforts to provide Chrysalis reasonable advance notice of any SEC filing related to this Agreement which differs materially from prior filings.
- 9.4 <u>Publications</u>. Subject to any Third Party rights existing as of the Original Effective Date, each Party shall submit to the other Party for review and approval all proposed academic, scientific and medical publications and public presentations relating to a Licensed Product or any research or development activities conducted as part of the Agreement for review in connection with preservation of Patents, and trade secrets and/or to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation. Written copies of such proposed publications and presentations shall be submitted to the non-publishing Party no later than sixty (60) days before submission for publication or presentation and the non-publishing Party shall provide its comments with respect to such publications and presentations within ten (10) Business Days of its receipt of such written copy. The review period may be extended for an additional thirty (30) days if the non-publishing Party can demonstrate a reasonable need for such extension including the preparation and filing of patent applications. By written agreement, this period may be further extended. The Parties will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other Persons in any publications relating to a Licensed Product or any research or development activities under this Agreement.

- Public Announcements. Subject to Section 9.2 and Section 9.3, (i) neither Party will make any public announcement of any information regarding this Agreement, the Licensed Products or any research or development activities under this Agreement without the prior written approval of the other Party, and (ii) Discovery shall not make any public statements regarding its activities with Chrysalis (including without limitation any other division of Philip Morris USA Inc.), its relationship with Chrysalis (including without limitation any other division of Philip Morris USA Inc.) or any other public statements regarding Chrysalis (including without limitation any other division of Philip Morris USA Inc.) without the prior written approval of Chrysalis, provided however that each Party may disclose (a) the general stage of development, commercialization and manufacturing at any given time during the course of the Agreement, except to the extent that any such information constitutes Confidential Information, (b) any information required by Law, and (c) any other information that has been previously approved for disclosure by the other Party, without further approval from the other Party hereunder. The Parties agree and acknowledge that Discovery may, at its sole discretion, subject to its compliance with this Article 9, file a Current Report on Form 8-K with the SEC to announce the filing of the press release and file it as an exhibit thereto, as well as to incorporate it by reference into other SEC filings. Without limiting the generality of the foregoing and without any inference with respect to any other requirement of this Section 9.5, the Parties hereby acknowledge and agree that any breach of this Section 9.5 in the form of any public statement related to this Amended and Restated License Agreement or the Original Agreement (including without limitation, the performance or non-performance of any obligation by Chrysalis under the Amended and Restated License Agreement or Original Agreement and Chrysalis ceasing active involvement in the development of Licensed Products under the Amended and Restated License Agreement and the Original Agreement) that disparages Chrysalis (including without limitation any other division of Philip Morris USA Inc.) (x) by an officer or executive of Discovery or any other individual holding a senior level management position at Discovery, or (y) any other personnel or agent of Discovery, but, in the case of this Section 9.5(y), only if Discovery does not take immediate action to publicly repudiate such statement, in the case of both (x) and (y) shall constitute a material breach of a material provision of this Agreement.
 - 9.6 <u>Survival</u>. The obligations and prohibitions contained in this Article 9 shall survive the expiration or termination of this Agreement.

Date:

ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents, warrants and covenants to the other Party that as of the Amended and Restated Effective

- 10.1.1 <u>Organization; Authority.</u> It is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has full right, corporate power and authority to enter into this Agreement, to perform its obligations under this Agreement, to grant the licenses granted by such Party pursuant to this Agreement and to carry out the provisions hereof.
- 10.1.2 <u>Consents</u>. Except for any Regulatory Approvals necessary for the development, manufacture, or commercialization of a Licensed Product, all necessary consents, approvals, orders, permits and authorizations of all government authorities and Regulatory Authorities and other Persons or Third Parties required to be obtained by it as of the Amended and Restated Effective Date in connection with the execution, delivery, and performance of this Agreement have been obtained.
- No Conflict. The execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder, and the rights, licenses and sublicenses to be granted by such Party pursuant to this Agreement, (i) do not conflict with, violate or constitute a breach or default under any requirement of Laws or regulations existing as of the Amended and Restated Effective Date and applicable to such Party or under any instrument, judgment, order, writ, decree, contract of such Party or any of its Affiliates existing as of the Amended and Restated Effective Date; (ii) do not give rise to any event that results in the creation of any lien, charge or encumbrance upon any assets of such Party or the suspension, revocation, impairment, forfeiture or non-renewal of any material permit, license, authorization or approval that applies to such Party, its business or operations or any of its assets or properties; or (iii) conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party.
- 10.1.4 <u>Enforceability.</u> This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to and limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (ii) judicial discretion in the availability of equitable relief.
- 10.1.5 <u>Regulatory.</u> There are no investigations, inquiries, actions or other proceedings pending before or, to such Party's knowledge, threatened, by any Regulatory Authority or other government agency with respect to any Licensed Products (or components thereof) or any facility where such Licensed Products (or components thereof) are manufactured, and such Party has not received written notice threatening any such investigation.
- 10.2 <u>Intellectual Property.</u> Discovery represents, warrants, and covenants to Chrysalis that as of the Amended and Restated Effective Date with respect to the Discovery Intellectual Property and, except with regard to Chrysalis' intellectual property rights in the name "Aria," Chrysalis represents, warrants, and covenants to Discovery that as of the Amended and Restated Effective Date with respect to the Chrysalis Intellectual Property:
- (i) It (a) holds good title to and is the legal and beneficial owner of, or (b) is the licensee of, such Intellectual Property in the Territory free and clear of any lien, mortgage, security interest, license, right, pledge, restriction on transferability, defect of title or other claim, charge, or encumbrance of any nature whatsoever on or affecting any property or property interest and no Third Party has any right, title, or interest in or to such Intellectual Property in the Territory.

	(ii)	To its knowledge, the Patents included in such Intellectual Property are valid and enforceable in the Territory and there have been no, and such Party	
has no reason to believe that there will be any, inventorship challenges with respect to any of such Patents in the Territory.			

- (iii) There are no infringement proceedings, actions, suits or complaints pending against nor any outstanding injunctions, judgments, orders, decrees, rulings or other charges against such Party relating to such Intellectual Property in the Territory.
- (iv) It has not received any form of notice from a third party of infringement of Third Party Patent rights that may affect the making, using or selling of Licensed Products in the Territory; and to its knowledge (a) the manufacture, development and commercialization of the Licensed Products in the Territory will not infringe the Patents of any Third Party in the Territory and (b) there are no Third Party patent applications in the Territory pending which, if issued, would materially adversely affect the ability to make, use or sell the Licensed Products in the Territory.
- (v) It has not granted any third party any license, covenant not to sue, options, or other right with respect to such Intellectual Property in the Territory that would impact its ability to enforce such Intellectual Property in the Territory. There are no existing agreements, options, commitments, or rights with, of, or to any Person to acquire or obtain any rights with respect to the Intellectual Property in the Territory that are inconsistent with the rights granted herein.
- (vi) Each agreement pursuant to which a Third Party has granted, assigned or otherwise transferred rights with respect to such Intellectual Property in the Territory are in full force and effect, and no Party to such agreements is in breach or default thereunder, and the execution and performance of this Agreement will not result in a breach or default thereunder. It has provided a true and complete copy of each such Third Party agreement to which it is a party to the other Party.
- 10.3 No Adverse Effects. Discovery represents, warrants and covenants to Chrysalis that as of the Amended and Restated Effective Date, the studies of Pulmonary Surfactants conducted by Discovery prior to the Amended and Restated Effective Date have not shown any adverse effects or toxicity of the Pulmonary Surfactant in humans that could reasonably be anticipated to frustrate the purposes of this Agreement, and as of the Amended and Restated Effective Date, Discovery has not been informed of any such adverse effects or toxicity.

ARTICLE 11 ADDITIONAL COVENANTS

11.1 Compliance with Laws. Each Party shall perform its responsibilities in a good scientific manner in accordance with the terms of this Agreement and in compliance in all material respects with the requirements of Laws.

- 11.2 <u>Cooperation</u>. The Parties agree that maintaining effective and open communication between the Parties on matters relating to the Agreement is important to the success of the Agreement.
- 11.3 <u>Sharing of Information</u>. Subject to applicable Law and privileges and obligations of confidentiality, the Parties agree to provide the other Party, upon such other Party's reasonable request, copies or access to all data, documentation and work products, including Clinical Trials, relating to any Licensed Product.

ARTICLE 12 DISCLAIMERS AND LIMITATION OF LIABILITY

12.1 <u>Disclaimer of Warranties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, CONCERNING THE DEVELOPMENT, COMMERCIALIZATION, MARKETING, OR SALE OF ANY PRODUCT INCLUDING THE SUCCESS OR POTENTIAL SUCCESS THEREOF. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS, WARRANTIES AND AGREEMENTS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

THE PARTIES UNDERSTAND THAT THE LICENSED PRODUCTS ARE THE SUBJECT OF ONGOING CLINICAL RESEARCH AND DEVELOPMENT AND THAT NEITHER PARTY CAN ASSURE THE SAFETY OR USEFULNESS OF LICENSED PRODUCTS. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY EXCEPT AS SET FORTH IN THIS ARTICLE 12 CONCERNING ITS PATENT RIGHTS OR KNOW-HOW, INCLUDING THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT THE MANUFACTURE, USE OR SALE OF ANY LICENSED PRODUCT WILL NOT INFRINGE THE PATENT RIGHTS OF THIRD PARTIES.

12.2 <u>Limitation of Liability.</u> IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS PERSONNEL FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, LOST PROFITS, BUSINESS, OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES AND THEIR RESPECTIVE PERSONNEL IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT EXCEPT WHERE ATTRIBUTABLE TO A WILLFUL OR INTENTIONAL BREACH OF THIS AGREEMENT. NOTHING IN THIS SECTION 12.2 IS INTENDED TO, NOR SHALL, LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER THIS ARTICLE 12, OR ANY REMEDIES OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9.

ARTICLE 13 INDEMNIFICATION; INSURANCE

13.1 Indemnification.

- 13.1.1 <u>Obligations of the Parties</u>. Each of the Parties shall defend, indemnify and hold harmless the other Party, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents (collectively, the "<u>Indemnified Parties</u>") from and against any and all losses, costs, damages, fees, liabilities, or expenses (including reasonable attorneys' fees and expenses) (collectively, "<u>Losses</u>") incurred in connection with any Third Party claim, action or proceeding (a "<u>Third Party Claim</u>") arising out of or related to:
 - (i) any material breach by the indemnifying Party of any of its representations, warranties, covenants or obligations pursuant to this Agreement;

and

- (ii) any negligence, recklessness, willful misconduct or wrongful intentional acts or omissions of the indemnifying Party, its Affiliates, or their officers, directors, employees, contractors, consultants, agents, representatives, or sublicensees in the exercise of any of the indemnifying Party's rights or the performance of any of the indemnifying Party's obligations under this Agreement.
- 13.1.2 Additional Indemnification by Chrysalis. In addition to the indemnity set forth in Section 13.1.1 above, Chrysalis shall defend, indemnify and hold harmless Discovery, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claim that the Chrysalis Technology infringes or misappropriates such Third Party intellectual property in the Territory to the extent such Losses are directly attributable to actual infringement or misappropriation of such Third Party's intellectual property by the Chrysalis Technology, except to the extent such infringement and misappropriation is attributable to further development, modifications or enhancements of the Chrysalis Technology by Discovery or due to the combination by Discovery (directly or indirectly) of the Chrysalis Technology with any other technology and provided that Discovery uses all reasonable efforts to minimize any such Losses.
- 13.1.3 Additional Indemnification by Discovery. In addition to the indemnity set forth in Section 13.1.1 above, Discovery shall defend, indemnify and hold harmless Chrysalis, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claim arising out of or related to any intellectual property infringement and trade secret misappropriation liability relating to the development, manufacture, or commercialization of any Licensed Product, except to the extent such Losses are due to matters for which Chrysalis is required to provide indemnification pursuant to Section 13.1.2.
- 13.1.4 <u>Certain Product Liability Claims</u>. Notwithstanding Sections 13.1.1, 13.1.2, and 13.1.3, Discovery shall defend, indemnify and hold harmless Chrysalis, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claims arising out of or relating to the commercialization, marketing, sale, use, handling, manufacture and/or storage of any Licensed Product, including any claims that involve death or bodily injury (or allegations thereof) to any individual.

- 13.1.5 <u>Complete Indemnification</u>. As the Parties intend complete indemnification, all direct out of pocket costs and expenses reasonably incurred by an Indemnitee in connection with enforcement of Section 13.1 shall also be reimbursed by the Indemnitor.
 - 13.2 Indemnification Procedures.
- 13.2.1 Notification. In the case of a Third Party Claim as to which a Party may be obligated to provide indemnification pursuant to this Agreement (the "Indemnitor"), such Indemnified Party seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually prejudiced as a result of such failure.
- Assumption of Defense. If a Third Party Claim is made against an Indemnitee, the Indemnitor will be entitled, within one hundred twenty (120) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee, for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of a Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, however, that if in the opinion of counsel, such counsel and opinion being satisfactory to Indemnitor and its counsel, a conflict of interest exists between the Indemnitor and an Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel (which shall be reasonably satisfactory to the Indemnitor) to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event, the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one (1) separate counsel for such Indemnitee. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnitee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnitee (including providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control of the defense of any Third Party Claim, within the one hundred twenty (120) day period set forth above, or if such good faith and diligent defense is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, after three (3) Business Days notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

- 13.2.3 Settlements. The Indemnitee may agree to any settlement, compromise, or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all liability in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise, or discharge (including the consent to entry of any judgment), and the Indemnitee may refuse in good faith to agree to any such settlement, compromise, or discharge, that provides for injunctive or other nonmonetary relief affecting the Indemnitee. The Indemnitee shall not (unless required by Law) admit any liability with respect to, or settle, compromise, or discharge, such Third Party Claim without the Indemnitor's prior written consent (which consent shall not be unreasonably withheld, conditioned, or delayed).
- 13.3 <u>Insurance</u>. Discovery agrees to obtain and maintain commercial general liability insurance and/or self-insurance, including prior to the date a Licensed Product is first administered in humans, commercial general liability insurance and/or self-insurance for Clinical Trials and products liability, with reputable and financially secure insurance carriers, in such amounts and subject to such deductibles as are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities. Discovery shall maintain such insurance for so long as Licensed Products in the Territory continue to be developed, manufactured, or commercialized and thereafter for so long as is necessary to cover any and all Third Party Claims required to be indemnified by Discovery which Third Party Claims may arise from the development, manufacture, and/or commercialization of a Licensed Product in the Territory. Upon reasonable request by Chrysalis, Discovery shall produce evidence that such insurance policies are valid, kept up to date, and in full force and effect. The insurance obligations set forth in this Section 13.3 may be satisfied by commercially reasonable self-insurance or a commercially reasonable combination of insurance and self-insurance.

ARTICLE 14 TERM

This Agreement shall become effective on the Amended and Restated Effective Date, and unless terminated earlier in accordance with the provisions of Article 15 shall expire as follows as to each Licensed Product in each country in the Territory, on a country-by-country basis, upon the latest of: (a) the 10th anniversary of the date of the First Commercial Sale of the Licensed Product; (b) the date on which the sale of such Licensed Product ceases to be covered by a Valid Claim in such country, or (c) in consideration of the performance by Chrysalis of development services without charge, the date a generic form of the product is introduced in such country (the "Term").

ARTICLE 15 TERMINATION

- 15.1 <u>Termination by Discovery On or Before</u> [***]. At any time on or before [***] from the Amended and Restated Effective Date, Discovery may terminate this Agreement in its entirety upon written notice to Chrysalis, provided that Discovery pays Chrysalis [***]. Upon Chrysalis' receipt of such notice and such payment, this Agreement shall terminate.
- 15.2 <u>Termination by Discovery After [***]</u>. After [***] from the Amended and Restated Effective Date, Discovery may terminate this Agreement for any reason, in its entirety, [***], upon [***] days written notice to Chrysalis.
- 15.3 <u>Termination Due to Failure to Meet Minimum Royalties</u>. Chrysalis may terminate this Agreement upon [***] days' prior written notice to Discovery, if commencing [***] and continuing [***], Discovery does not pay Chrysalis each Contract Quarter the Minimum Royalties due pursuant to Section 7.3, and Discovery does not cure such shortfall as provided for in Section 7.3; provided, however, that Chrysalis shall not have a right to terminate the Agreement pursuant to this Section 15.3 for any time period in which Discovery is disputing in good faith amounts due under this Agreement.
 - 15.4 Termination for Material Breach.
- 15.4.1 Right to Terminate Agreement. If a Party (the "Breaching Party") commits a material breach of this Agreement and fails to cure such breach within the applicable Cure Period (as provided in 15.4.2 below), the other Party (the "Non-Breaching Party") may, by written notice of termination within thirty (30) days after the expiration of the applicable Cure Period, elect to terminate the Agreement. Without limiting the generality of the foregoing, and notwithstanding the Cure Period set forth in Section 15.4.2, the practice by Discovery of the Chrysalis Technology outside the scope of the licenses and sublicenses granted herein, which practice does not cease within thirty (30) days after the receipt of written notice of such breach from Chrysalis, shall constitute a material breach.
- 15.4.2 <u>Applicable Cure Periods</u>. Upon receipt of written notice of a material breach pursuant to Section 15.4.1, and except as otherwise provided for in Section 15.4.1, the allegedly Breaching Party shall have sixty (60) days to cure such material breach (the "<u>Cure Period</u>"), provided, however, that in the case of any material breach that cannot be reasonably cured within the sixty (60) day cure period, should the Breaching Party deliver to the Non-Breaching Party a plan for curing such material breach which is reasonably sufficient to effect a cure and uses commercially reasonable efforts to pursue such plan and effect a cure, the Cure Period shall be extended for an additional sixty (60) days.

- 15.5 <u>Termination Due to Certain Events</u>. Without prejudice to any other remedies available to it at Law or in equity, either Party may, subject to the provisions set forth herein, terminate this Agreement immediately upon written notice to the other Party if, at any time, the other Party shall (i) file in any court pursuant to any statute a petition for bankruptcy or insolvency, or for reorganization in bankruptcy, or for an arrangement or for the appointment of a receiver, trustee or administrator of such Party or of its assets, (ii) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, (iii) propose or be a party to any dissolution, (iv) make an assignment for the benefit of its creditors; or (v) ceases to do business in the ordinary course.
 - 15.6 Effects of Termination Generally.
- Accrued Obligations; Survival. Upon expiration or termination of this Agreement, all of the Parties' rights and obligations under this Agreement including the exclusive license in Section 3.1, shall terminate immediately except: (a) any rights that shall have accrued to the benefit of any Party prior to such termination or expiration, including the right of Chrysalis to receive royalties as provided in Article 7; and (b) any rights and obligations of the Parties which are expressly indicated to survive termination or expiration of this Agreement. All of the Parties' rights and obligations under, and the provisions contained in [***] shall survive termination or expiration of this Agreement. [***]
- 15.6.2 <u>Outstanding Payments</u>. All payments of amounts owing to either Party under this Agreement as of its expiration or termination shall be due and payable within the later of (i) to the extent such amounts can be calculated and a fixed sum determined at the time of expiration or termination of this Agreement, sixty (60) days after the date of such expiration or termination, and (ii) ten (10) days after the date in which such amounts can be calculated and a fixed sum determined.

ARTICLE 16 STANDSTILL AGREEMENT

[***] period beginning on the date of termination of this Agreement for any reason, neither Chrysalis nor any of its Affiliates will (nor assist or encourage others to), directly or indirectly, without the written consent of Discovery: (i) acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift, or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or interest in any securities or direct or indirect rights, warrants, or options to acquire, or securities convertible into or exchangeable for, any securities of Discovery; (ii) directly or indirectly effect or seek, initiate, offer, or propose or participate in any (A) tender or exchange offer, merger, consolidation, or other business combination involving Discovery, or (B) any recapitalization, restructuring, liquidation, dissolution, sale of all or substantially all the assets, or other extraordinary transaction with respect to Discovery; (iii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the SEC promulgated pursuant to Section 14 of the Exchange Act); (iv) form or become a member of a "group" (as defined under the Exchange Act) with respect to any voting securities of Discovery (including by depositing any securities of Discovery in a voting trust or by subjecting any securities of Discovery to any other arrangement or agreement with respect to the voting of such securities); or (v) enter into any agreements, discussions, or arrangements with any Third Party with respect to any of the foregoing.

- 16.2 <u>Certain Exceptions</u>. Nothing in this Article 16 shall prohibit Chrysalis' or its Affiliates' employees from purchasing securities of Discovery pursuant to (i) a pension plan established for the benefit of Chrysalis' or its Affiliates' employees, (ii) any employee benefit plan of Chrysalis or its Affiliates, (iii) any stock portfolios not controlled by Chrysalis or any of its Affiliates that invest in Discovery among other companies, or (iv) *de minimis* passive investments not to exceed five percent (5%) of Discovery's outstanding voting securities.
- 16.3 Exception for an Acquisition Transaction. This Article 16 shall terminate (subject to revival as provided below) and Chrysalis and its Affiliates shall have the right to acquire any securities of Discovery without regard to the limitations set forth in this Article 16 in the event that Discovery publicly announces a transaction, an intention or desire to effect any transaction, or the receipt of any offer, which would result in (a) the sale of all or substantially all of the assets of Discovery within the meaning of Section 271 of the Delaware General Corporation Law, or (b) Discovery common shareholders immediately prior to such transaction owning less than fifty percent (50%) of the outstanding common stock of the acquiring entity or, in the case of a merger transaction, the surviving corporation (an "Acquisition Transaction"). If the proposed Acquisition Transaction has not been consummated within six (6) months following Discovery's public announcement in respect thereof, the provisions of this Article 16 shall be revived and have full force and effect until such time as Discovery makes a subsequent public announcement regarding an Acquisition Transaction, at which time the provisions of this Article 16 shall once again apply.

ARTICLE 17 DISPUTE RESOLUTION

17.1 <u>Dispute Resolution</u>. Except as expressly otherwise provided in this Agreement, any material dispute, difference, claim, action, demand, request, investigation, controversy, threat or other question arising out of or relating to the interpretation of any provisions of this Agreement or the failure of any Party to perform or comply with any obligations or conditions applicable to such Party pursuant to this Agreement (a "<u>Dispute</u>") shall be settled in accordance with the provisions of this Article 17. If a Party intends to initiate executive negotiation, mediation or arbitration (as set forth below) to resolve a Dispute, such Party shall provide written notice to the other Party informing such other Party of such intention and the issues to be resolved.

- 17.2 <u>Executive Negotiation</u>. Promptly upon a Party's receipt of a notice by the other Party as provided in Section 17.1 with respect to a Dispute, and in any event within thirty (30) days of such receipt, the senior executives of each Party shall meet for attempted resolution of such Dispute by good faith negotiations.
- 17.3 <u>Mediation</u>. If the senior executives referenced in Section 17.2 are unable to resolve any such Dispute within ten (10) Business Days, either Party may, upon written notice to the other Party, refer such Dispute to mediation. Upon such written notice, the Parties shall mutually agree on a mediator to assist in the negotiations. If the Parties fail to mutually agree on a mediator within one week of the written notice, a mediator shall be appointed by the AAA. The Party responsible for referring the Dispute to mediation shall bear the costs of such mediation. Any settlement reached by mediation shall be resolved in writing, signed by the Parties, and shall be binding on them.

17.4 Arbitration.

- 17.4.1 <u>Referral to Arbitration</u>. In the event that a Dispute is not resolved during mediation within thirty (30) days of the selection of a mediator, either Party may refer such Dispute to final and binding arbitration by sending written notice of such election to the other Party clearly marked "Arbitration Demand," whereupon such Dispute shall be arbitrated in accordance with this Section 17.4.
- Rules and Procedures. Except as expressly otherwise provided in this Agreement, any Dispute shall be finally settled by arbitration under the thencurrent expedited procedures applicable to the then-current Commercial Arbitration Rules of the AAA in accordance with the terms set forth in this Section 17.4. The arbitration of any Dispute shall be kept confidential and shall be filed with the office of the AAA located in Washington, D.C. or such other AAA office as the Parties may agree. Such arbitration shall be conducted by three arbitrators, one appointed by each of Chrysalis and Discovery and the third selected by the first two appointed arbitrators. Each arbitrator shall be a person with relevant experience in the pharmaceutical industry. Chrysalis and Discovery must make their respective arbitrator appointments within ten (10) Business Days of notice being given to a Party by the other Party of its intention to resolve such Dispute through arbitration. Such appointed arbitrators shall select the third arbitrator within ten (10) Business Days of the last to occur of their respective appointments. Chrysalis and Discovery shall instruct such arbitrators to render a determination of any such Dispute within sixty (60) days after the appointment of the third arbitrator. All Disputes shall be resolved by submission of documents unless the arbitration panel determines that an oral hearing is necessary.
- Awards. The decision of the arbitrators with respect to any Dispute shall be in writing and state the findings, facts and conclusions of law upon which the decision is based. Any such decision and award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party submits itself to the jurisdiction of any such court for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder. The arbitrators shall have the power to grant all legal and equitable remedies except specific performance and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No Party shall seek punitive damages or specific performance in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum, provided however, that the foregoing does not preclude suits or limit damages associated with infringement.

- 17.4.4 <u>Costs</u>. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrators shall be equally shared between Chrysalis and Discovery unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party or Parties (including reasonable attorneys' fees) against the other Party or Parties, as the case may be.
- 17.4.5 No Other Forum. Except as provided in Section 17.5, the provisions of this Section 17.4 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising under this Agreement. Any Party commencing a lawsuit in violation of this Section 17.4 shall pay the costs of the other Party, including, without limitation, reasonable attorney's fees and defense costs.
- 17.5 Right to Injunctive and Other Relief. Nothing in this Agreement, shall prohibit either Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by the other Party which would cause irreparable harm to the first Party. Nothing in this Agreement shall prevent a Party from seeking any remedies available at law or in equity in any court of competent jurisdiction in the event of the practice of such Party's Intellectual Property outside the scope of the rights granted herein.

ARTICLE 18 MISCELLANEOUS

- 18.1 <u>Original Agreement</u>. The rights and obligations of the Parties prior to the Amended and Restated Effective Date are governed by the Original Agreement. As of the Amended and Restated Effective Date, the Original Agreement is terminated and the rights and obligations of the Parties are as set forth herein.
- 18.2 <u>Choice of Law</u>. This Agreement shall be governed by and interpreted under, and any action or proceeding shall apply, the Laws of the State of New York excluding (i) its conflicts of Laws principles, other than Section 5-1401 of the New York General Obligations Law (ii), the United Nations Conventions on Contracts for the International Sale of Goods and (iii) the 1974 Convention on the Limitation Period in the International Sale of Goods and any Protocols thereto, done at Vienna, April 11, 1980.

- 18.3 <u>Severability.</u> If, under Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement, this Agreement shall endure except for such provision. The Parties shall consult one another and use their best efforts to agree upon a valid and enforceable provision that is a reasonable substitute for such invalid or unenforceable provision in view of the intent of this Agreement.
- Relationship of the Parties. Each Party shall bear its own fees, expenses, and disbursements, including the fees and expenses of their respective counsel, accountants, bankers, and other experts, in connection with the subject matter of this Agreement and costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the Parties' legal relationship under this Agreement shall be that of independent contractors. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a partnership, joint venture, agency, or employer-employee relationship between the Parties.
- 18.5 <u>Parties in Interest</u>. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective legal representatives, successors, and permitted assigns of the Parties hereto. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the Parties hereto, or their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement.
- 18.6 Enforcement of Certain Agreements. Each Party shall use commercially reasonable efforts at its expense to enforce the provisions of any confidentiality agreements and agreements with respect to noncompetition existing as of the Original Effective Date and the Amended and Restated Effective Date with any of its present or former employees, agents, consultants or independent contractors of Discovery that relate to any Licensed Product; provided, however, that the obligation with respect to any agreement related to this Section 18.6 shall terminate as of the date on which such agreement and the obligations regarding noncompetition have terminated or expired in accordance with its terms.
- 18.7 <u>Use of Affiliates, Subcontractors, Sublicensees and Distributors.</u> Each Party shall have the right to use Affiliates, subcontractors, sublicensees and distributors in exercising its rights and carrying out its obligations under this Agreement, provided, however, that (i) such entities agree in writing to be bound by the provisions of Article 9, (ii) the use of such entities does not in any way materially diminish the other Party's rights or otherwise modify the other Party's rights or obligations hereunder without such other Party's prior written consent, (iii) Discovery may not delegate, sublicense, assign, or otherwise transfer any of its rights or obligations hereunder to any entity (including any Affiliate) that competes with any tobacco product of Chrysalis or its Affiliates without Chrysalis' prior written consent, (iv) Chrysalis may not delegate, assign or otherwise transfer any of its rights or obligations hereunder to a company engaged in pulmonary critical care medicine, without Discovery's prior written consent and (v) except with respect to rights, benefits and obligations assigned as permitted pursuant to Section 18.8, each Party shall be liable for any actions or omissions of its Affiliates, subcontractors, sublicensees and distributors in connection with this Agreement and the Intellectual Property and Confidential Information of the other Party to the same extent as if such actions or omissions were conducted by the Party itself.

- 18.8 Assignment. Chrysalis may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any Affiliate of Chrysalis without the prior written consent of Discovery subject only to the limitations set forth in Section 18.7 (iv) above. Discovery may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any Affiliate of Discovery without the prior written consent of Chrysalis, subject only to the limitations set forth in Section 18.7 (iii) above, provided, however, notwithstanding such an assignment, Discovery shall remain responsible for the performance of the indemnification obligations set forth herein. No Party may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any other Person other than an Affiliate without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed; except that, subject to the limitations set forth in Section 18.7 (iii) and (iv) above, either Party may assign or otherwise transfer any or all of its rights and interests hereunder in connection with the sale of all or substantially all of its assets or business to which this Agreement relates, whether by way of merger, sale of stock, sale of assets or other similar transaction, provided that the assignee or transferee expressly agrees to assume all of the obligations hereunder.
- 18.9 <u>Further Assurances and Actions</u>. From time to time after the Original Effective Date, Discovery and Chrysalis shall execute, acknowledge and deliver to each other any further documents, assurances, and other matters, and will take any other action consistent with the terms and conditions of this Agreement, that may reasonably be requested by a Party and necessary or desirable to carry out the purpose and intent of this Agreement. Chrysalis and Discovery shall cooperate and use all reasonable efforts to make all other registrations, filings, and applications, to give all notices, and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications, authorizations, permits, and waivers, if any, and to do all other things necessary or desirable for the consummation of this Agreement.
- 18.10 <u>Waiver</u>. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.
- 18.11 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Reform Act of 1978, 11 U.S.C. §§ 101 et seq., as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under Section 365(n) of the Bankruptcy Code.

18.12 <u>Notices</u>. All notices that are required or permitted hereunder shall be in writing and shall be sufficient if personally delivered or sent by mail or Federal Express or other delivery service. Any notices shall be deemed given upon the earlier of the date when received at, or the third day after the date when sent by registered or certified mail or the day after the date when sent by Federal Express to, the address set forth below, unless such address is changed by notice to the other Parties hereto:

If to Chrysalis:

Chrysalis Technologies 615 Maury Street Richmond, VA 23224 Attention: Timothy Beane

If to Discovery:

Discovery Laboratories, Inc. 2600 Kelly Road, Suite 100 Warrington, PA 18976 Attention: David L. Lopez, Esq., CPA

with a copy to:

Dickstein Shapiro LLP 1177 Avenue of the Americas New York, NY 10036 Attention: Ira L. Kotel, Esq.

18.13 Construction. Unless the context of this Agreement clearly requires otherwise, (i) references to any gender include all genders, (ii) "or" has the inclusive meaning frequently identified with the phrase "and/or," (iii) "including" has the inclusive meaning frequently identified with the phrase "including but not limited to" or "including without limitation", and (iv) references to "hereunder" or "herein" relate to this Agreement and (v) all terms defined in the singular shall have the same meaning in the plural and vice versa. The section and other headings contained in this Agreement are for reference purposes only and shall not control or affect the construction of this Agreement or the interpretation thereof in any respect. Section, subsection, Schedule and Exhibit references are to this Agreement unless otherwise specified. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP.

- Registration and Filing of this Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Regulatory Authority, including the SEC or the U.S. Federal Trade Commission, in accordance with Law, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.
- 18.15 Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to Force Majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, Force Majeure is defined as causes beyond the control of the Party, including, without limitation, acts of God; acts, regulations, or laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event Discovery or Chrysalis, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled and the thirty (30) days thereafter. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any Force Majeure.
- 18.16 <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Discovery and Chrysalis.
- 18.17 <u>Third Party Beneficiaries</u>. Except for any Third Party Indemnities under Article 13, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party hereto, and no such Third Party (except for such Indemnities, as such) shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.
- 18.18 <u>Execution in Counterparts; Facsimile Signatures</u>. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and both of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto as of the day and year first written above.

PHILIP MORRIS USA INC., d/b/a CHRYSALIS TECHNOLOGIES

By: /s/ Dr. Ken Podrecz

Name: Dr. Ken Podrecz

Title: VP RD & E Administration & Compliance

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola, Ph.D.

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

[***]

Confidential Treatment Requested

Execution Version

LICENSE AGREEMENT

by and between

DISCOVERY LABORATORIES, INC. (a Delaware corporation)

and

PHILIP MORRIS PRODUCTS S.A. (a Switzerland corporation)

March 28, 2008

TABLE OF CONTENTS

		<u>Page</u>
ARTICLE 1	DEFINITIONS	1
1 DET CT E 0	. Vonvon	
ARTICLE 2		2
2.1	License	8
2.2	Limitations	9
2.3 2.4	Sublicensing Rights	9
2.4	Retained Rights	10
ADTICIE 2	PRODUCT DEVELOPMENT	10
		10
3.1	Licensed Product Development and No PMPSA Obligations With Respect to the	
2.2	Development of Licensed Products	10
3.2	Notice of Development of Licensed Products	10
3.3	Development Effort	10
3.4	Costs	10
3.5 3.6	Design Configurations Status Updates	10 11
3.0	Status Opudies	- 11
ADTICLE A	COMMEDICIALIZATION	11
4.1	COMMERCIALIZATION Exclusive Right to Sell the Licensed Products	11 11
4.1	Responsibility For Commercialization Matters	11
4.2	Commercialization	11
4.4	Status Updates	11
7.7	Status Opuates	11
ΔRTICI E 5	REGULATORY MATTERS	12
5.1	Responsibility and Consultation	12
5.2	Regulatory Updates and Communications	12
5.3	Records	12
5.4	Product Liability Litigation	12
511	Treate Substitution Substitutio	
ARTICLE 6	FINANCIAL PROVISIONS	12
6.1	Royalties with Respect to Licensed Products and Substitute Products	12
6.2	Minimum Royalties	13
6.3	Prohibition on Bundling	13
6.4	Fixed Consideration	13
6.5	Treatment of Partial Product Sales	14
6.6	Royalty Reports	14
6.7	Payment of Estimated and Actual Amounts	14
6.8	Pass-Through Royalties	14
6.9	Records and Audits	14
6.10	Foreign Exchange	15
6.11	Manner of Payments	16
6.12	Late Payments	16
6.13	Tax Withholding	16
	INTELLECTUAL PROPERTY	16
7.1	Ownership	16
7.2	Disclosure, Assignment, License and Exploitation	17
7.3	Agreement with Personnel	17
7.4	Prosecution of Patents	18

i

7.5	Patent Term Extensions	18
7.6	Third Party Infringement	18
7.7	Infringement of Third Party Rights	19
	CONFIDENTIAL INFORMATION	20
8.1	Use of Confidential Information	20
8.2	Permitted Disclosure and Use	21
8.3	Disclosure for SEC Filings	22
8.4	Publications	22
8.5	Public Announcements	22
8.6	Survival	23
ARTICLE 9	REPRESENTATIONS, WARRANTIES AND COVENANTS	23
9.1	Mutual Representations and Warranties	23
9.2	Intellectual Property	23
9.3	No Adverse Effects	24
ARTICLE 1	0 ADDITIONAL COVENANTS	25
10.1	Compliance with Laws	25
10.2	Cooperation	25
10.3	Sharing of Information	25
ARTICLE 1	1 DISCLAIMERS AND LIMITATION OF LIABILITY	26
11.1	Disclaimer of Warranties	26
11.2	Limitation of Liability	26
ARTICLE 1	2 INDEMNIFICATION; INSURANCE	27
12.1	Indemnification	27
12.2	Indemnification Procedures	28
12.3	Insurance	29
ARTICLE 1	3 TERM	30
ARTICLE 1	4 TERMINATION	30
14.1	Termination by Discovery	30
14.2	Termination Due to Failure to Meet Minimum Royalties	30
14.3	Termination for Material Breach	30
14.4	Termination Due to Certain Events	31
14.5	Effects of Termination Generally	31
	•	
ARTICLE 1	5 STANDSTILL AGREEMENT	31
15.1	General Standstill	31
15.2	Certain Exceptions	32
15.3	Exception for an Acquisition Transaction	32
	·	
ARTICLE 1	6 DISPUTE RESOLUTION	32
16.1	Dispute Resolution	32
16.2	Executive Negotiation	33
16.3	Mediation	33
16.4	Arbitration	33
16.5	Right to Injunctive and Other Relief	34
ARTICLE 1	.7 MISCELLANEOUS	34
17.1	Choice of Law	34
17.2	Severability	34

17.3	Relationship of the Parties	35
17.4	Parties in Interest	35
17.5	Enforcement of Certain Agreements	35
17.6	Use of Affiliates, Subcontractors, Sublicensees and Distributors	35
17.7	Assignment	36
17.8	Further Assurances and Actions	36
17.9	Waiver	36
17.10	Section 365(n) of the Bankruptcy Code	36
17.11	Notices	37
17.12	Construction	37
17.13	Registration and Filing of this Agreement	37
17.14	Force Majeure	38
17.15	Entire Agreement	38
17.16	Third Party Beneficiaries	38
17.17	Execution in Counterparts; Facsimile Signatures	38

LICENSE AGREEMENT

THIS LICENSE AGREEMENT effective as of March 28, 2008 (the "Effective Date") by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Discovery"), and Philip Morris Products S.A., a Switzerland corporation ("PMPSA"). Discovery and PMPSA shall be referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Discovery and Philip Morris USA Inc., Chrysalis Technologies Division, ("<u>Chrysalis</u>") entered into a Strategic Alliance Agreement effective December 9, 2005 (the "<u>Original Agreement</u>") pursuant to which Chrysalis granted to Discovery a worldwide license under its rights in and to its capillary aerosol generation technology to develop certain combination drug-device pulmonary surfactant products;

WHEREAS, Chrysalis has assigned to PMPSA all rights outside of the United States in and to its capillary aerosol generation technology (the "Assigned Rights"); and

WHEREAS, Chrysalis and Discovery are amending and restating the Original Agreement as of the Effective Date to reflect such assignment of rights to PMPSA and to cease Chrysalis' active involvement in the development of such combination drug-device pulmonary surfactant products (the "Amended and Restated Chrysalis/Discovery Agreement"); and

WHEREAS, PMPSA and Discovery desire to enter into a license agreement pursuant to which PMPSA will grant to Discovery a license under the Assigned Rights;

NOW, THEREFORE, in consideration of the foregoing premises and the representations, warranties, covenants, and agreements contained herein, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1 DEFINITIONS

In addition to terms defined elsewhere in this Agreement, the following terms used in this Agreement are defined below:

"AAA" means the American Arbitration Association.

"Actual Amount" has the meaning set forth in Section 6.7.2.

[***]

"Aerosol Device" means a device to aerosolize a pharmaceutical compound for administration to humans. It is contemplated that the Aerosol Device shall consist of (i) permanent (*e.g.*, nondisposable) components that control power and electronics (*e.g.*, control unit) and (ii) a physical mechanism (*e.g.*, pump) to provide a means for dispensing the Drug Product from the container closure system.

"Aerosol Technology" means any technology related to the aerosolization of a liquid form of a pharmaceutical compound. Aerosol Technology does not include technology that is related to the delivery of aerosols as dry powders.

"Affiliates" means with respect to any Party, any Person, directly or indirectly, controlling, controlled by or under common control with such Party. For purposes of this Section, "control" means (i) in the case of a Person that is a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) for the election of directors of such Person or (ii) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of (A) more than fifty percent (50%) of the economic or partnership interest in the income or capital of such Person or (B) the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise; and the terms "controlling," "controlled by" or "under common control" shall have the meanings correlative to the foregoing. For the purposes of this Amended and Restated License Agreement, Chrysalis and PMPSA shall not be considered Affiliates with respect to each other.

- "Agreement" means this License Agreement, including the Schedules attached hereto.
- "Breaching Party" has the meaning set forth in Section 14.3.1.
- "Business Day" means a day other than a Saturday, Sunday, or other day on which commercial banks in New York, New York are authorized or required by Law to close.
- "Clinical Trials" means Phase I, II, III and, if required, Phase IV clinical trials and such other tests and studies in human subjects or patients that are required to obtain, maintain, or sustain Regulatory Approval in a country in the Territory.

"Confidential Information" means all information received by either Party or its Affiliates from or on behalf of the other Party or its Affiliates relating to this Agreement that the disclosing Party treats as confidential, including, without limitation: (i) copies of any nonpublic information regarding a Party's Patents; (ii) techniques, technology, practices, trade secrets, inventions (whether or not patentable), designs, methods, manufacturing processes, formulae, formulations, specifications, documents, knowledge, knowhow, skill, experience, test data, and results, (including that related to pharmacology, toxicology, preclinical testing, clinical testing, expression data, Chemistry, Manufacturing and Control (CMC) data, batch records, trials, and studies, safety and efficacy, analytical, and quality control); (iii) devices and related components, compounds, polypeptides, proteins, formulations, compositions of matter, cells, cell lines, markers, assays, and physical, biological, or chemical material; (iv) marketing information, market research data, medical/physicians advisory boards, and consultant input, including clinical studies designed to support promotional efforts; (v) the terms of this Agreement, and (vi) other proprietary business information such as business plans, financial or personnel matters, present or future products, research, process and technology development programs, sales, suppliers, customers, employees, investors, or other business information, whether in oral, written, graphic, or electronic form.

"Contract Month" means each month during any Contract Year. The initial Contract Month will be deemed to begin on the Effective Date and end on the expiration of that Contract Month in which the Effective Date falls.

"Contract Quarter" means each three (3) month period ending on March 31, June 30, September 30 and December 31 during any Contract Year. The initial Contract Quarter will be deemed to begin on the Effective Date and end on the expiration of that Contract Quarter in which the Effective Date falls.

"Contract Year" means a twelve (12) month period ending on December 31. The initial Contract Year will be deemed to begin on the Effective Date and end on December 31 of that Contract Year in which it falls.

"Diligent Commercialization Efforts" means efforts and resources reasonably comparable to those commonly used in the research-based pharmaceutical industry for a medical device, pharmaceutical product or pharmaceutical compound at a similar stage in its commercialization or product life of similar market potential, taking into account safety and efficacy, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the potential profitability of the product and alternative products and other relevant factors relating to the commercialization of a Licensed Product, including, without limitation, the potential cost, risk, timing and reward, <u>provided</u>, <u>however</u>, that the fact that the Parties are required to share revenues with respect to the Licensed Products shall not be a factor taken into account in determining whether Diligent Commercialization Efforts were satisfied. Diligent Commercialization Efforts shall be determined on a market by market basis for a particular Licensed Product, and it is anticipated that the level of effort will change over time reflecting changes in the status of the Licensed Product and the market involved.

"<u>Diligent Development Efforts</u>" means efforts and resources reasonably comparable to those commonly used in the research-based pharmaceutical industry for a medical device, pharmaceutical product or pharmaceutical compound at a similar stage in its development of similar market potential, taking into account safety and efficacy, product profile, difficulty in developing the product, competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the potential profitability of the product and alternative products and other relevant factors affecting the cost, risk and timing of development and total potential reward to be obtained if a Licensed Product is commercialized, <u>provided</u>, <u>however</u>, that the fact that the Parties are required to share revenues with respect to the Licensed Products shall not be a factor taken into account in determining whether Diligent Development Efforts were satisfied.

"Discovery" has the meaning set forth in the Preamble hereto.

"Discovery Intellectual Property" has the meaning set forth in Section 7.1.2.

- "Discovery Patents" means all Patents owned by Discovery or to which Discovery otherwise has rights that claim or are directed to any Discovery Intellectual Property.
- "<u>Discovery Technology</u>" means (a) Discovery's proprietary Pulmonary Surfactant technology (including without limitation the technologies, formulations, processes, equipment, materials and know-how relating to the manufacture and use of Pulmonary Surfactants for treatment of respiratory conditions), and (b) all Intellectual Property owned by or licensed to Discovery relating to such Pulmonary Surfactant technology, including, without limitation, the Discovery Patents.
- "<u>Discovery Technology Improvements</u>" means any Inventions created or reduced to practice [***] in the performance of the Agreement or exercise of the license granted pursuant to this Agreement, which Inventions relate primarily to Pulmonary Surfactants (alone or in combination with [***]).
- "Disposable Dose Packet" consists of: (i) Drug Product within a container (comprising the drug formulation containing the drug substance and the container closure system in which it is packaged), (ii) aerosolization capillary (heatable capillary through which the formulation is pumped to produce an aerosol), (iii) patient interface (components through which the aerosol produced by the capillary travels in order to reach the patient), and (iv) all ancillary tubing, connectors and fittings related thereto.
 - "Dispute" has the meaning set forth in Section 16.1.
 - "Dollars" and "\$" means, unless otherwise specified, United States Dollars.
- "Drug Product" means a pharmacological agent(s), including Pulmonary Surfactants, together with any excipients or inactive ingredients, formulated for use in connection with an Aerosol Device or Disposable Dose Packet.
 - "Effective Date" has the meaning set forth in the Preamble hereto.
 - "Estimated Amount" has the meaning set forth in Section 6.7.1.

[***]

"Exchange Act" has the meaning set forth in Section 15.1.

"Exclusive Field" means the therapeutic or preventative use in humans of Aerosol Technology to deliver Pulmonary Surfactants (alone or in combination with [***] as an active ingredient for the prevention or treatment of Respiratory Indications.

"FDA" shall mean the United States Food and Drug Administration, and any successor agency.

"<u>First Commercial Sale</u>" means the first arms-length commercial sale of a Licensed Product to a Third Party by Discovery or its Affiliates or sublicensees, as the case may be, in any country in the Territory after receipt of Marketing Authorization in such country which results in an exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.

"Force Majeure Event" means an event or occurrence that materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of due diligence have been avoided, including without limitation fire, earthquake, acts of God, acts of war, labor strikes or lockouts, riots, civil disturbances, actions or inactions of governmental authorities (except actions in response to a breach of applicable Law by such Party).

"GAAP" means generally accepted accounting principles in the United States of America.

"Hospital Setting" means a (i) hospital-setting in the delivery room, NICU, PICU, CCU, emergency department, surgical care unit and/or intermediate care unit, (ii) emergency and specialized medical treatment centers, such as birthing centers, treatment centers for chronic diseases, trauma centers and other similar facilities, and (iii) an institution setting which is used to provide long-term care for people with chronic illness or disability, including hospice settings and nursing homes.

"Indemnitee" has the meaning set forth in Section 12.2.1.

"Indemnitor" has the meaning set forth in Section 12.2.1.

"Infringement Notice" has the meaning set forth in Section 7.6.1.

"Intellectual Property" means all know how, Inventions, Patents, copyrights, trademarks, trade secrets and any other intellectual property rights in the Territory that may be secured in any place under laws now or hereafter in effect.

"Invention" means any new or improved apparatus, process, information, product, invention, discovery, idea, suggestion, material, data, equipment, design, circuit component, drawing, tooling, prototype, report, computer software, documentation or other intellectual property or know-how (whether or not patentable) discovered, produced, conceived, created or reduced to practice by either or both Parties (or their Affiliates, sublicensees, subcontractors, successors or assigns).

"Law" means any applicable statute, law, ordinance, regulation, order, or rule of any federal, state, local, foreign, or other governmental agency or body or of any other type of regulatory body (including common law) or securities exchange or automated quotation system.

"<u>Licensed Product</u>" means a combination drug-device product using or otherwise practicing the PMPSA Technology and delivering Pulmonary Surfactants (alone or in combination with [***]).

"Losses" has the meaning set forth in Section 12.1.1.

"Major Markets" means [***].

"Marketing Authorization" means, with respect to each country in the Territory, the principal Regulatory Approval required to market the Licensed Product in such country (e.g., the NDA), including satisfactory pricing and reimbursement approval, when applicable.

"NDA" shall mean a new drug application, biologics license application, pre-market approval application, or a pre-market clearance under FDCA Section 510k that may be filed with the FDA in the United States or any comparable application that may be filed with any equivalent Regulatory Authority in the Territory.

"Net Sales" means, with respect to Licensed Products and Substitute Products, as applicable, sold by Discovery, its Affiliates and sublicensees in the Territory, the [***] amount [***] for Licensed Products or Substitute Products, as applicable, by Discovery, its Affiliates, and any sublicensees of Discovery in arms-length, commercial transactions in the Territory with customers that are Third Parties, less the following deductions to the extent included in such [***] amount:

[***

Any discretionary rebates, discounts or other adjustments to the [***] amount shall be commercially reasonable and consistent with standard industry practices. Net Sales (including each applicable deduction from the [***] amount) shall be determined from the books and records of Discovery maintained in accordance with GAAP consistently applied.

"Non-Breaching Party" has the meaning set forth in Section 14.3.1.

"Other Product" has the meaning set forth in Section 2.1.2.

"Party" and "Parties" have the meanings set forth in the Preamble hereto.

"Patents" means all patents and patent applications, and all patents issuing thereon (including utility, model and design patents and certificates of invention), together with all reissue patents, patents of addition, divisions, renewals, continuations, continuations-in-part, substitutions, additions, extensions (including supplemental protection certificates), registrations, confirmations, re-examinations, and foreign counterparts of any of the foregoing in the Territory.

"Person" means any natural person, corporation, company, partnership, limited liability company, proprietorship, trust or estate, joint venture, association, or other legal entity.

- "PMPSA" has the meaning set forth in the Preamble hereto.
- "PMPSA Intellectual Property" has the meaning set forth in Section 7.1.1.
- "PMPSA Patents" means all Patents owned by PMPSA in the Territory or to which PMPSA otherwise has rights in the Territory, as of the Effective Date, that claim or are directed to the PMPSA Technology.
- "PMPSA Technology." means (a) PMPSA's proprietary Aerosol Technology owned or controlled by PMPSA in the Territory as of the Effective Date (including without limitation the technologies, devices, processes, equipment, materials and know-how relating to the aerosolization of liquid forms of drug products and the Aerosol Devices and Disposable Dose Packs therefor) and (b) all Intellectual Property owned by or licensed to PMPSA in the Territory as of the Effective Date relating to such Aerosol Technology, including, without limitation, the PMPSA Patents.
- "PMPSA Technology Improvements" means any rights in the Territory in and to any Inventions created or reduced to practice [***] in the performance of the Agreement or exercise of the license granted pursuant to this Agreement, or [***] under the Amended and Restated Chrysalis/Discovery Agreement or in the exercise of the license granted pursuant to the Amended and Restated Chrysalis/Discovery Agreement, in each case which Inventions relate primarily to the PMPSA Technology.
- "Pulmonary Surfactant" means surface active agents designed for deposition in the lungs in order to exert a physiological or pharmacological affect to prevent or treat Respiratory Indications.
- "Regulatory Approval" means any approvals (including, where necessary for the marketing, use, or other distribution of a drug, medical device, or combination drug and medical device in a regulatory jurisdiction, pricing, and reimbursement approvals), licenses, registrations, or authorizations or equivalents necessary for the manufacture, use, storage, import, export, clinical testing, transport, marketing, sale, and distribution of the Drug Product or Aerosol Device and any Licensed Product in a regulatory jurisdiction anywhere in the Territory, including Marketing Authorizations.
- "Regulatory Authority" means any federal, national, multinational, state, provincial, or local regulatory agency, department, bureau, or other governmental entity with authority to regulate the marketing and sale of a pharmaceutical product, delivery system or device in a country in the Territory.
 - $\hbox{$"\underline{Respiratory\ Indications"$ means all\ respiratory\ dysfunctions,\ failures,\ syndromes,\ diseases,\ disorders,\ or\ conditions.}$
 - "Royalty Credit" has the meaning set forth in Section 6.7.2.

"Royalty Report" means the reports to be delivered by Discovery to PMPSA pursuant to Section 6.6 with respect to each Contract Month and pursuant to Section 6.7 with respect to each Contract Quarter, which reports shall give such particulars of each of the Licensed Products and Substitute Products sold by Discovery and its Affiliates and sublicensees during the preceding Contract Month in the Territory in the case of Section 6.6 and during the preceding Contract Quarter in the case of Section 6.7 on a country-by-country basis as are reasonably pertinent to perform an accounting of royalties under this Agreement.

"SEC" has the meaning set forth in Section 8.3.

"Substitute Product" means any Aerosol Device, Disposable Dose Packet or Drug Product (other than a Licensed Product) sold by Discovery, its Affiliates and sublicensees for use within the Exclusive Field.

"Target Indications" means the following Respiratory Indications: [***].

"Target Populations" means human patients [***] receiving forms of treatment for the applicable Respiratory Indication that are typically and principally provided [***].

"Taxes" has the meaning set forth in Section 6.13.

"Term" has the meaning set forth in Article 13.

"Territory" means all countries in the world, except the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, and Northern Mariana Islands.

"Third Party" means any Person other than PMPSA or Discovery or their respective Affiliates.

"Third Party Claim" has the meaning set forth in Section 12.1.1.

"<u>Valid Claim</u>" means a claim of an issued and unexpired patent, which claim has not been held unpatentable, invalid, or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise, which claim, but for the licenses granted herein, would be infringed by the sale of a Licensed Product.

ARTICLE 2 LICENSE

2.1 License.

- 2.1.1 <u>Exclusive License.</u> Subject to the terms, conditions, and limitations of this Agreement, PMPSA hereby grants to Discovery an exclusive right and royalty-bearing license or sublicense, as applicable, in the Territory, with the right to grant sublicenses solely as set forth in Section 2.3, under the PMPSA Technology and PMPSA Technology Improvements to make and have made, to use and have used, to develop and have developed, to sell and have sold, to offer for sale and have offered for sale, to import and export and have imported and exported Licensed Products in the Exclusive Field in the Territory during the Term.
- 2.1.2 Non-Exclusive, Research License. Subject to the terms, conditions, and limitations of this Agreement, PMPSA hereby grants to Discovery a non-exclusive, royalty-free, research only license or sublicense, as applicable, in the Territory, with the right to grant sublicenses solely as set forth in Section 2.3, under the PMPSA Technology and PMPSA Technology Improvements to [***]. An "Other Product" means a combination drug-device product using or otherwise practicing the PMPSA Technology and [***] as an active ingredient in humans, alone or in combination with [***] ([***]).
- 2.1.3 Other Products. In the event Discovery wishes to obtain a license under the PMPSA Technology and PMPSA Technology Improvements to develop and commercialize an Other Product for [***], Discovery shall provide PMPSA with written notice of the same. Such written notice shall include a description of the Other Product and shall specify the [***]. Within [***] days of receipt of such notice, and in the exercise of reasonable discretion and good faith, PMPSA shall notify Discovery in writing whether it is willing to grant Discovery such a license under the PMPSA Technology and PMPSA Technology Improvements. In the event PMPSA is willing to grant Discovery a license under the PMPSA Technology Improvements to develop and commercialize such Other Product for [***], PMPSA and Discovery shall use reasonable efforts to enter into a written amendment to this Agreement pursuant to which PMPSA shall grant to Discovery such a license on the same terms and conditions set forth herein.
- Limitations. The license granted pursuant to Section 2.1 shall be exclusive only to the extent that PMPSA has the right to grant an exclusive license with respect to the Licensed Product in question. No right or license outside of the Exclusive Field is granted and all such rights are expressly reserved by PMPSA. No right or license is or shall be granted under this Agreement by implication. All such rights or licenses are or shall be granted only as expressly provided in this Agreement. Discovery shall not practice the PMPSA Technology in the Territory except as expressly licensed herein. Nothing herein shall limit the ability of PMPSA to perform any research or development work on or using the PMPSA Technology. Notwithstanding any other provision of this Agreement, no rights with respect to any trademarks, trade names, service marks or logos of PMPSA are granted pursuant to this Agreement.
- 2.3 <u>Sublicensing Rights</u>. The license granted to Discovery pursuant to Section 2.1 by PMPSA shall include the right of Discovery to grant sublicenses, subject to terms and conditions set forth in Section 17.6. Discovery shall provide PMPSA with prompt written notice of any sublicenses granted hereunder.

2.4 <u>Retained Rights</u>. Any rights of each Party not expressly granted to the other Party under the provisions of this Agreement shall be retained by each Party, and, subject to any applicable terms, conditions, and limitations of this Agreement, each Party shall retain the right to: (a) exploit such Party's own Intellectual Property relating to Licensed Products to develop, manufacture, and commercialize products outside the Exclusive Field; (b) exploit such Party's own Intellectual Property relating to Licensed Products for other purposes outside the Exclusive Field unrelated to the Licensed Products; and (c) perform its obligations and exercise its rights under this Agreement.

ARTICLE 3 PRODUCT DEVELOPMENT

- 3.1 <u>Licensed Product Development and No PMPSA Obligations With Respect to the Development of Licensed Products</u>. Discovery shall be solely responsible for the development of Licensed Products and PMPSA shall have no obligations with respect to the development of Licensed Products unless PMPSA agrees otherwise in writing. PMPSA acknowledges and agrees that Discovery may partner with third parties with respect to the development of Licensed Products.
- 3.2 <u>Notice of Development of Licensed Products.</u> Discovery shall provide PMPSA with written notification of its intention to proceed with Phase II Clinical Trials for a Licensed Product. Such written notification shall include sufficient detail for PMPSA to understand the nature of such Licensed Product to be developed by Discovery.
- 3.3 <u>Development Effort</u>. Discovery shall use Diligent Development Efforts to develop at least one Licensed Product and to otherwise carry out its responsibilities under this Agreement relating to such Licensed Product promptly and expeditiously in accordance with all Laws. Notwithstanding the foregoing, the Parties acknowledge that the development of pharmaceutical products is inherently speculative and there is no guarantee that Discovery will be successful in developing any commercially viable Licensed Products, or that the development of any Licensed Products will proceed as anticipated.
 - 3.4 Costs. Discovery shall be solely responsible for all costs incurred by Discovery in connection with the development of Licensed Products hereunder.
- 3.5 <u>Design Configurations</u>. The Parties agree that any Aerosol Device and Disposable Dose Packet configuration developed for use outside the Exclusive Field shall be distinct in appearance from those for use with the Licensed Products and shall not be interchangeable with the Aerosol Device or Disposable Dose Packet of the Licensed Products. Without limiting the generality of the foregoing, and provided PMPSA has received appropriate prior written notification from Discovery describing the packaging for the Disposable Dose Packets and Licensed Products in sufficient detail for PMPSA to comply with this Section 3.5, PMPSA shall not offer for sale or sell, nor authorize any Third Party to offer for sale or sell, any pharmaceutical product (i) in packaging similar in appearance to the Disposable Dose Packet for a Licensed Product, or (ii) in packaging that is interchangeable with the Disposable Dose Packet of a Licensed Product for purposes of use in an Aerosol Device.

3.6 <u>Status Updates.</u> Upon the reasonable request of PMPSA, Discovery shall provide PMPSA with an update on the status of the development of Licensed Products hereunder; provided that in no event shall Discovery be required to provide an update more often than once a Contract Quarter.

ARTICLE 4 COMMERCIALIZATION

- 4.1 <u>Exclusive Right to Sell the Licensed Products</u>. The Parties agree that during the Term, Discovery shall have the exclusive right to market and have marketed, sell and have sold, and offer for sale or have offered for sale any Licensed Products in the Territory.
- 4.2 <u>Responsibility For Commercialization Matters</u>. Discovery shall have the sole responsibility and assumes all liabilities for all activities associated with the commercialization of the Licensed Products in the Territory, including, without limitation, (a) preparing, submitting and seeking Marketing Authorizations for the Licensed Products, (b) sales, advertising and marketing of the Licensed Product, (c) scientific and medical affairs, (d) customer service and distribution related services, such as order taking, shipping, billing, accounts receivable, returns, allowance activities and product support; (e) Phase IV Clinical Trials, (f) commercial manufacture of the Licensed Product; and (g) branding of the Licensed Products.
 - 4.3 Commercialization.
- 4.3.1 <u>Diligent Commercialization Efforts.</u> Discovery shall use Diligent Commercialization Efforts to bring the Licensed Products to market and to market and sell the Licensed Products in the Territory with a particular focus on obtaining Marketing Authorizations for and commercializing Licensed Products in the Major Markets. Discovery shall promptly notify PMPSA of the receipt of any Marketing Authorization for a Licensed Product in the Territory.
- 4.3.2 <u>Commercialization Initiation</u>. With respect to each Licensed Product, the First Commercial Sale in each country constituting the Major Markets shall occur within [***] of receipt of the relevant Marketing Authorization for such country for such Licensed Product. Should Discovery materially fail to achieve any such commercialization initiation within [***] of having received written notice of such failure from PMPSA [***].
- 4.4 <u>Status Updates.</u> Upon PMPSA's reasonable request, Discovery shall provide PMPSA with an update on the status of the commercialization of Licensed Products in the Territory hereunder; provided that in no event shall Discovery be required to provide an update more often than once a Contract Quarter.

ARTICLE 5 REGULATORY MATTERS

- 5.1 <u>Responsibility and Consultation</u>. Discovery shall be responsible for preparing, submitting, seeking and maintaining all Regulatory Approvals for the Licensed Products in the Territory, including without limitation Marketing Authorizations.
- 5.2 <u>Regulatory Updates and Communications</u>. Within thirty (30) days after the end of each Contract Quarter, Discovery shall provide PMPSA with a written update on the status of the Regulatory Approvals for the Licensed Products in the Territory. In addition, Discovery shall provide PMPSA with a copy of any medical device reports relating to the use of Licensed Products in the Territory and a copy (if in writing) or a description (if oral) of any significant contact or communication from any Regulatory Authority relating to a material safety issue with the PMPSA Technology, in each case, promptly after Discovery's receipt of the same.
- 5.3 Records. Except to the extent otherwise required by law, the Parties acknowledge and agree that PMPSA shall have no obligation to maintain any records relating to the PMPSA Technology or the Licensed Product.
- 5.4 <u>Product Liability Litigation</u>. Discovery shall promptly inform PMPSA of the initiation of any (i) recalls, corrections or removals of Licensed Products in the Territory, and (ii) litigation or investigations in the Territory relating to the Licensed Product involving a claim of death or bodily injury (or allegations thereof) to an individual and shall provide PMPSA with regular written updates with respect thereto. If any such recalls, corrections, removals, litigation or investigations relate to the PMPSA Technology, then PMPSA shall have the right to audit the books, records and facilities relating to such Licensed Products (solely to the degree that Discovery has the right to grant any such access and solely to the degree such books, records and facilities relate to such litigation and investigation), and Discovery shall reasonably cooperate with PMPSA in connection therewith.

ARTICLE 6 FINANCIAL PROVISIONS

6.1 Royalties with Respect to Licensed Products and Substitute Products. In consideration of the rights granted and payments made to Discovery herein, Disco	very
shall pay royalties to PMPSA on Net Sales of Licensed Products and Substitute Products in the Territory in an amount equal to [***] of the Net Sales for such Licensed Products	ucts
and Substitute Products.	

or greater than the following for each Contract Quarter of the applicable Contract Year:
[***] (the "Minimum Royalty"), then PMPSA shall have the right to terminate this Agreement pursuant to Section 14.2; provided, that Discovery can cure any such royalty
shortfall by paying PMPSA [***] after the end of the applicable Contract Quarter the difference between the Minimum Royalty due for the applicable Contract Quarter and the
actual royalties paid by Discovery hereunder for such Contract Quarter (the "Royalty Shortfall"). The royalty payments required to be paid in any given Contract Quarter pursuant
to Section 6.1 shall be subject to an effecting reduction by Discovery in an amount equal to the Doyalty Shortfall, provided, however, that (i) no such effect shall be applied until

Minimum Royalties. Commencing [***] and continuing thereafter throughout the Term, if the royalties paid by Discovery to PMPSA hereunder are not equal to

to Section 6.1 shall be subject to an offsetting reduction by Discovery in an amount equal to the Royalty Shortfall; provided, however, that (i) no such offset shall be applied until the royalty payments for such Contract Quarter exceed the Minimum Royalties for such Contract Quarter, and (ii) such offset may be made only to the extent such Royalty Shortfall has not previously been subject to offset pursuant to this Section.

6.3 Prohibition on Bundling. Notwithstanding any other provision of this Agreement to the contrary, Discovery hereby covenants that it will not include or bundle any Licensed Products and Substitute Products or components thereof as part of a multiple product offering with any other products or services if it would result in the price of the

Licensed Product or Substitute Product or any components thereof being discounted from the then-applicable sale price in such jurisdiction, nor shall Discovery permit its Affiliates or sublicensees to do so, except with the prior written consent of PMPSA. In the event any such bundled sales occur, the Net Sales with respect to such bundled transactions shall be deemed to be the-then current average Net Sales for the Licensed Product or Substitute Product in such jurisdiction in arms length transactions or in the event

6.4 <u>Fixed Consideration</u>. In the event that Discovery receives any fixed payment, fee or other consideration from a Third Party (i) in consideration of any discount, credit or similar allowance granted to such Third Party in connection with the purchase of any Licensed Product(s) or Substitute Product(s) or (ii) in lieu of any royalties with respect to any Licensed Product(s) or Substitute Product(s), then Discovery shall pay to PMPSA a royalty equal to the product of (a) such consideration multiplied by (b) the royalty rate set forth in Section 6.1 Discovery shall report on the amount of any such consideration, and the royalty payable thereon in U.S. Dollars, in the Royalty Report. For the avoidance of doubt, this Section 6.4 shall not apply with respect to any fixed payment, fee or other consideration from a Third Party in respect of development fees, milestone payments or other similar payments in transactions that incorporate a market-rate royalty structure.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

there are no unbundled transactions, the fair market value of such Net Sales.

6.5	Treatment of Partial Product Sales. In the event that portions of a Licensed Product or Substitute Product are sold separately (e.g., Aerosol Device, Disposable
Dose Packet, Dru	g Product), the royalties payable pursuant to this Article 6 shall be paid [***].

- 6.6 <u>Royalty Reports.</u> Within [***] days after the end of each Contract Month (beginning with [***] Licensed Product or Substitute Product, as the case may be), Discovery shall deliver to PMPSA a preliminary Royalty Report. [***] The Royalty Report shall include at least the following items, separately stated as to each of the Licensed Products and Substitute Products, as applicable:
- (i) the quantity of each of the Licensed Products and Substitute Products (delineated as Aerosol Devices and Disposable Dose Packets) invoiced by Discovery and its Affiliates and sublicensees during such Contract Month and the [***] amount therefor;
 - (ii) the allowable deductions therefrom and an itemization of each specific deduction [***];
- (iii) the calculation of royalties, if any, thereon in a manner consistent with the amounts set forth in the Royalty Report prepared in accordance with this Section 6.6.
 - 6.7 Payment of Estimated and Actual Amounts.
- 6.7.1 <u>Payment of Estimated Amounts</u>. Simultaneous with the issuance of the preliminary Royalty Report, Discovery shall make payment of estimated amounts due to PMPSA hereunder with respect to such Contract Month (the "Estimated Amount").
- 6.7.2 Quarterly Reconciliation and True-Up. Within [***] days following each Contract Quarter, Discovery shall calculate the actual amount due to PMPSA hereunder with respect to the immediately preceding Contract Quarter (the "Actual Amount") and provide to PMPSA a true and accurate Royalty Report for such Contract Quarter, setting forth the corrected calculations for such Contract Quarter. If the Estimated Amounts paid to PMPSA pursuant to Section 6.7.1 for the three Contract Months comprising the immediately preceding Contract Quarter exceeds the Actual Amount for such Contract Quarter, Discovery shall notify PMPSA and such excess amount (the "Royalty Credit") shall, at the discretion of Discovery, be available to offset future royalties payable to PMPSA by Discovery. If such Actual Amount exceeds such Estimated Amount, Discovery shall promptly pay such excess amount to PMPSA. [***]
- 6.8 Pass-Through Royalties. Each Party shall be solely responsible for paying any royalties which may be due to Third Parties with respect to such Party's Intellectual Property.

6.9	Records	and	Audits
6.9	Records	and	Audits

- 6.9.1 Records. Discovery shall keep, and shall require its Affiliates and sublicensees to keep, such records as are necessary to determine accurately the sums due to each other under this Agreement. Such records shall be retained by Discovery for the Term and for three (3) years thereafter.
- 6.9.2 Audit. At the written request of PMPSA, with reasonable advance notice, Discovery shall make available for inspection, review, and audit, by an internationally recognized independent certified public accounting firm appointed by PMPSA and reasonably acceptable to Discovery, such records of Discovery as may be reasonably necessary to verify Discovery's accounting reports and payments made or to be made pursuant to this Agreement; provided, however, that such audits may not be performed by PMPSA more than once per Contract Year in the absence of a reasonable basis for concern regarding compliance with the Agreement or any applicable Laws. If such accountants identify a discrepancy, then the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date of receiving such accountant's written report, or as otherwise agreed upon by the Parties, plus, in the event of any underpayment, interest calculated in accordance with Section 6.12.
- 6.9.3 Audit Confidentiality. PMPSA shall cause any accountants selected by it to enter into a confidentiality agreement acceptable to Discovery obligating such accountants to retain all such information in confidence pursuant to such confidentiality agreement. Such accountants shall not reveal to PMPSA the details of its review, except for such information as is required to be disclosed under this Agreement, and such details shall be treated as Confidential Information. Each Party agrees to hold in strict confidence all information concerning payments and reports, and all information learned in the course of any audit or inspection (and not to make copies of such reports and information), except to the extent necessary for such Party to reveal such information in order to enforce its rights under this Agreement or if disclosure is required by Law, regulation or judicial order.
- 6.9.4 <u>Costs of Audits.</u> PMPSA shall pay for such inspections, except that in the event the adjustment shown by such inspection is greater than [***] percent ([***]%) of the original royalty amounts in question, Discovery shall pay for such inspection.
- 6.10 <u>Foreign Exchange</u>. For the purpose of computing the Net Sales for Licensed Products and Substitute Products sold in a currency other than Dollars, such amounts shall be converted into Dollars each Contract Month in the then standard manner used by Discovery in the preparation of its audited financial statements, consistently applied. Such method of currency conversion used by Discovery shall be a commercially reasonable method consistent with industry standards, and Discovery shall disclose to PMPSA [***] prior to First Commercial Sale of a Licensed Product or Substitute Product in a country such method of currency conversion.

Notwithstanding anything herein to the contrary, at PMPSA's option, with respect to any particular country in the Territory, Discovery shall pay royalties for Licensed Products and Substitute Products sold in such country in such country's local currency. Discovery shall not change such method of currency conversion disclosed to PMPSA pursuant to this Section 6.10 without obtaining PMPSA's prior written consent, such consent not to be unreasonably withheld.

6.11	Manner of Payments. All sums due to PMPSA under this Agreement shall be payable by electronic funds transfer in immediately available funds to such bank
account(s) as PMI	PSA shall designate at least two (2) Business Days in advance.

- 6.12 <u>Late Payments.</u> Any amounts not paid when due under this Agreement shall be subject to interest from and including the date payment is due through and including the date upon which PMPSA has collected immediately available funds in an account designated by PMPSA at an annual rate equal to the sum of [***] percent ([***]%) plus the annual prime rate of interest quoted in the Money Rates section of the East Coast edition of the *Wall Street Journal* calculated daily on the basis of a 365-day year, or similar reputable data source, or, if lower, the highest rate permitted under applicable law. Notwithstanding the foregoing, any payment of amounts by Discovery representing the excess of Actual Amount over Estimated Amount, calculated in accordance with Section 6.7, shall not be subject to this Section 6.12.
- 6.13 Tax Withholding. Any taxes, levies, or other duties ("Taxes") paid or required to be withheld under the appropriate local tax Laws by Discovery on account of monies payable to PMPSA under this Agreement shall be deducted from the amount of monies otherwise payable to PMPSA under this Agreement and paid by Discovery to the proper taxing authority. Discovery shall secure and send to PMPSA within a reasonable period of time proof of any such Taxes paid or required to be withheld by Discovery for the benefit of PMPSA. The Parties shall cooperate reasonably with each other to (i) ensure that any amounts required to be withheld by Discovery are reduced in amount to the fullest extent permitted by Law and (ii) to resolve such other Party's taxation concerns.

ARTICLE 7 INTELLECTUAL PROPERTY

7.1 Ownership.

7.1.1 PMPSA Intellectual Property. PMPSA shall own (i) all Intellectual Property owned or controlled by PMPSA relating to the PMPSA Technology or Licensed Products that was existing or conceived prior to the Effective Date, (ii) all Intellectual Property developed by PMPSA outside of the performance of this Agreement or to which PMPSA otherwise obtains rights from a Third Party (including without limitation all Intellectual Property relating to the PMPSA Technology or the Licensed Products); (iii) all Inventions conceived, created and reduced to practice solely by or on behalf of PMPSA in the course of the performance of this Agreement, except Discovery Technology Improvements; and (iv) all PMPSA Technology Improvements (collectively, "PMPSA Intellectual Property").

- 7.1.2 <u>Discovery Intellectual Property.</u> Discovery shall own (i) all Intellectual Property owned or controlled by Discovery relating to Discovery Technology or the Licensed Products that was existing or conceived prior to the Effective Date or is developed by Discovery outside of the performance of this Agreement, (ii) all Intellectual Property relating to Discovery Technology or the Licensed Products developed by Discovery outside of the performance of this Agreement or exercise of the license granted hereunder or to which Discovery otherwise obtains rights from a Third Party, and (iii) all Inventions conceived, created and reduced to practice solely by or on behalf of Discovery in the course of the performance of this Agreement or exercise of the license granted hereunder, except PMPSA Technology Improvements; (iv) all Inventions conceived, created and reduced to practice jointly by or on behalf of the Parties in the course of the performance of this Agreement or exercise of the license granted hereunder, except PMPSA Technology Improvements; and (v) all Discovery Technology Improvements (collectively "<u>Discovery Intellectual Property</u>").
 - 7.2 Disclosure, Assignment, License and Exploitation.
- 7.2.1 <u>Disclosure</u>. Each Party shall cause all personnel conducting work or exercising rights on its behalf under the Agreement to, promptly disclose to the other Party all Intellectual Property in which the other Party has an ownership interest pursuant to Section 7.1, and to assign any and all right, title and interest in all such Inventions and Intellectual Property in accordance with this Agreement. Each Party shall maintain records in sufficient detail and in good scientific manner appropriate for patent prosecution purposes to properly reflect all work done and results achieved in conducting its work hereunder, and shall respond to reasonable requests of the other Party for information regarding Intellectual Property in which the other Party has an ownership interest.
- 7.2.2 Assignment and License. In the event PMPSA conceives, creates or reduces to practice any Discovery Technology Improvements, PMPSA shall promptly notify Discovery and PMPSA shall assign all right, title and interest in and to such Discovery Technology Improvements to Discovery. In the event Discovery conceives, creates or reduces to practice any PMPSA Technology Improvements, Discovery shall promptly notify PMPSA and Discovery shall assign all right, title and interest in and to such PMPSA Technology Improvements to PMPSA, however, such PMPSA Technology Improvements are included in the Intellectual Property licensed to Discovery pursuant to Section 2.1.
- 7.2.3 Exploitation of Intellectual Property. To the extent permitted by Law, PMPSA agrees not to exploit the PMPSA Intellectual Property in the Exclusive Field in any country in the world; provided, however, that in the event Discovery terminates this Agreement pursuant to Article 14 with respect to [***], this Section 7.2.3 shall no longer apply to PMPSA with respect to such [***] and PMPSA shall have the right to exploit the PMPSA Intellectual Property in the Exclusive Field in the Territory with respect to such [***].
- 7.3 <u>Agreement with Personnel</u>. Each Party shall have valid and enforceable written agreements with all personnel conducting work on its behalf under the Agreement containing a nondisclosure obligation comparable in scope to Article 8 and giving the other Party all rights and authority necessary to effectuate the provisions of this Article 7. Each Party shall provide copies of these agreements to the other Party upon the other Party's request as allowed by each Party's internal personnel policies.

7.4 Prosecution of Patents.

- 7.4.1 <u>Discovery and PMPSA Patent Filings</u>. Discovery and PMPSA each shall use commercially reasonable efforts to diligently prosecute and maintain their respective PMPSA Patents and Discovery Patents in the Territory; provided that solely for the purposes of this Section, Discovery Patents shall mean those Discovery Patents that claim or are directed to Discovery Technology. Within forty-five (45) days of a Party's receipt of an allowance or grant of a Patent, the Party prosecuting the Patent shall inform the other Party of such allowance or grant, and provide the other Party with a copy of the allowed or granted Patent claims thereof.
- 7.4.2 <u>Patent Prosecution Costs</u>. Each Party shall bear its own costs to file, prosecute and maintain its Patents in the Territory (including, without limitation, patent term extension).
- 7.4.3 <u>Abandonment of Prosecution or Maintenance</u>. Each Party shall notify the other Party in the event it is unable for any reason to meet its obligations under this Article 7 with respect to any Patents that are subject to Section 7.4.1. Such notification shall be given within a reasonable period prior to the date on which such Patents will lapse or become abandoned. The Party receiving any notification hereunder shall then have the option, exercisable upon written notification to the Party that delivered such notification, to assume full responsibility, at its discretion and its sole cost and expense, for prosecution or maintenance of the affected Patents in such country or countries in the Territory.
- 7.5 Patent Term Extensions. Each Party shall have the right to request that the other Party file all applications and take all actions necessary to obtain patent extension pursuant to 35 U.S.C. § 156 or like foreign statutes for the respective Parties' Patents in the Territory. If the filing Party declines to pursue such patent term extensions, then as permitted by law, the other Party shall have the right (at its cost and expense) on behalf of the filing Party to file, or direct the filing of, all such applications and take all such actions necessary to obtain such patent term extensions. Each Party agrees to sign such further documents and take such further actions as may be requested by the other Party in this regard.
 - 7.6 Third Party Infringement.
- 7.6.1 Suits for Infringement. If Discovery or PMPSA becomes aware of infringement of any Patent included in the Discovery Patents or the PMPSA Patents by a Third Party in the Territory, such Party shall promptly notify the other Party in writing to that effect and provide a summary of the relevant facts and circumstances known to such Party relating to such infringement ("Infringement Notice"). Each Party shall have the right, at its sole discretion and expense, on its own behalf, to institute, prosecute, and control any action or proceeding to restrain infringement of any of its Patents. A Party instituting suit shall have control of such suit and all negotiations for its settlement or compromise; provided however, that the instituting Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof which would materially adversely affect the Intellectual Property rights with respect to a Licensed Product without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed.

- 7.6.2 Step-in Right. If, prior to the expiration of three (3) months from said Infringement Notice, the Party whose Patents are alleged to be infringed has not obtained a discontinuance of an alleged infringement by a Third Party or brought an infringement action or proceeding or otherwise taken appropriate action to abate such infringement, such Party shall notify the other Party at any time prior thereto of its intention not to bring suit against an alleged infringer. Upon such notice and if such infringement is reasonably likely to materially adversely affect a Licensed Product in the Territory, then, and in those events only, the other Party shall have the right, but not the obligation, at its sole expense to institute, prosecute, and control any action or proceeding to restrain such infringement. Each Party agrees to be joined as a party if necessary to prosecute the action or proceeding and shall provide all reasonable cooperation, including any necessary use of its name, required to prosecute such litigation. The other Party shall have control of any such suit and all negotiations for its settlement or compromise; provided, however, that the other Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the patentee Party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- 7.6.3 <u>Allocation of Recovery.</u> All damages, settlements and rewards made or obtained in connection with any suit or other legal proceeding under this Section 7.6 shall be shared among the parties as follows:
 - (i) [***
 - (ii) [***
- 7.6.4 <u>Declaratory Actions and Counterclaims</u>. In the event that an action alleging invalidity or non-infringement of any of the Discovery Patents or PMPSA Patents is brought against Discovery or PMPSA in the Territory, the Party defending such action or counterclaim, at its sole discretion, shall have the right, within thirty (30) days after the commencement of such action, to take or regain control of the action at its own expense. If the defending Party determines not to exercise this right, the other Party may take over or remain as lead counsel for the action at that Party's sole discretion. Any recovery obtained from such litigation, proceeding or settlement shall be shared in accordance with Section 7.6.3.
 - 7.7 Infringement of Third Party Rights.
- 7.7.1 Infringement Claims. With respect to any and all claims instituted by Third Parties for patent infringement involving the manufacture, use, offer for sale, or sale of a Licensed Product in the Territory during the Term, the Party named as defendant shall promptly notify the other Party of such claim, and the defending Party shall have the right, at its sole discretion and expense, to defend and control any action or proceeding with respect to such claim. The other Party agrees to be joined as a Party if necessary to defend the action or proceeding and shall provide reasonable cooperation, including any necessary use of its name, required to defend such litigation. The defending Party shall have sole control of any such suit and all negotiations for its settlement or compromise; provided, however, that the defending Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the other Party if such settlement would materially adversely affect the other Party's rights or impose any obligation on the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed.

7.7.2 <u>Step-in Right</u>. If, prior to the expiration of three (3) months from said claim being brought, or such sooner period as may be necessary to appropriately respond to said claim, the defending Party has not elected to defend such action or proceeding, or if the defending Party shall notify the other Party at any time prior thereto of its intention not to defend such action or proceeding, then, and in those events only, the other Party shall have the right, but not be obligated, at its own expense to defend and control any action or proceeding. Such other Party shall have sole control of any such suit and all negotiations for its settlement or compromise; provided, however, that the other Party shall not settle or compromise any such suit or enter into any consent order for the settlement or compromise thereof without the prior written consent of the original defending Party, which consent shall not be unreasonably withheld, conditioned, or delayed.

ARTICLE 8 CONFIDENTIAL INFORMATION

8.1 <u>Use of Confidential Information</u>. A Party receiving Confidential Information (the "<u>Receiving Party</u>.") from the other Party (the "<u>Disclosing Party</u>.") shall keep all such Confidential Information with the same degree of care it maintains the confidentiality of its own confidential information, but in no event less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement, and shall not disclose the same to any Person other than to its Affiliates and such of its and their employees or agents who have a need to know such Confidential Information to implement the terms of this Agreement, and who are subject to a nondisclosure obligation comparable in scope to this Article 8. Each Party shall advise any employee or agent who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and such Party shall ensure that all such employees and agents comply with such obligations as if they had been a Party hereto. Upon termination of this Agreement, each Party shall use commercially reasonable efforts to return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remains in such Party's or its agents' or employees' possession, except that each Party may keep one (1) copy of the Confidential Information solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 8. Notwithstanding anything to the contrary in this Agreement, Confidential Information shall not include any information or materials that the Receiving Party can demonstrate by documentary evidence:

- (i) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party;
- (ii) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;
- (iv) were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or
- (v) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party.
- 8.2 Permitted Disclosure and Use. Notwithstanding anything to the contrary in this Agreement, in the event that the Receiving Party or any of its directors, officers, employees, agents and advisors and their representatives deems it necessary or are requested or required (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative demand or other legal process by a court or other governmental authority, or by any Regulatory Authority to obtain Regulatory Approval of a Licensed Product) to disclose all or any part of any Confidential Information, the Receiving Party will provide the Disclosing Party with prompt notice of such request or requirement (which notice shall be reasonably in advance of such requested or required disclosure), as well as notice of the terms and circumstances surrounding such request or requirement, so that the Disclosing Party may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the Receiving Party shall consult with the Disclosing Party with respect to the advisability of pursuing any such order or other legal action or available steps to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Receiving Party is, in the opinion of counsel satisfactory to the Disclosing Party and its counsel, legally compelled to disclose any Confidential Information, the Receiving Party may disclose that portion of the Confidential Information which its counsel advises the Receiving Party that the Receiving Party is legally compelled to disclose any Confidential Information, the Receiving Party will use reasonable efforts to obtain and will not oppose action by the Disclosing Party to obtain, an appropriate protective order or other reliable assurance that confidential treatment will be afforded the disclosure of such Confidential Information. The Receiving Party may disclose Confidential Information belonging to

- 8.3 <u>Disclosure for SEC Filings</u>. Notwithstanding anything to the contrary in this Agreement, the Parties expressly acknowledge that Discovery may file a copy of this Agreement with the Securities and Exchange Commission (the "<u>SEC</u>") in any of its SEC reports and filings, as well as incorporate them by reference into other SEC filings. Discovery shall request confidential treatment of sensitive terms hereof to the extent such confidential treatment is reasonably available to Discovery under the prevailing circumstances. Discovery shall coordinate in advance with PMPSA with regard to the terms of this Agreement, for which Discovery shall seek to be redacted in any such SEC filings, and Discovery shall use reasonable efforts to seek confidential treatment for such mutually agreed terms and terms reasonably requested by PMPSA; provided, however, that each Party shall retain ultimate control and responsibility for their respective disclosures to the SEC and the public generally. To the extent permitted by Law, Discovery shall use reasonable efforts to provide PMPSA reasonable advance notice of any SEC filing related to this Agreement which differs materially from prior filings.
- 8.4 <u>Publications</u>. Subject to any Third Party rights existing as of the Effective Date, each Party shall submit to the other Party for review and approval all proposed academic, scientific and medical publications and public presentations relating to a Licensed Product or any research or development activities conducted as part of the Agreement for review in connection with preservation of Patents, and trade secrets and/or to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation. Written copies of such proposed publications and presentations shall be submitted to the non-publishing Party no later than sixty (60) days before submission for publication or presentation and the non-publishing Party shall provide its comments with respect to such publications and presentations within ten (10) Business Days of its receipt of such written copy. The review period may be extended for an additional thirty (30) days if the non-publishing Party can demonstrate a reasonable need for such extension including the preparation and filing of patent applications. By written agreement, this period may be further extended. The Parties will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other Persons in any publications relating to a Licensed Product or any research or development activities under this Agreement.
- 8.5 <u>Public Announcements</u>. Subject to Section 8.2 and Section 8.3, (i) neither Party will make any public announcement of any information regarding this Agreement, the Licensed Products or any research or development activities under this Agreement without the prior written approval of the other Party, and (ii) Discovery shall not make any public statements regarding its activities with PMPSA, its relationship with PMPSA or any other public statements regarding PMPSA without the prior written approval of PMPSA, provided however that each Party may disclose (a) the general stage of development, commercialization and manufacturing at any given time during the course of the Agreement, except to the extent that any such information constitutes Confidential Information, (b) any information required by Law, and (c) any other information that has been previously approved for disclosure by the other Party, without further approval from the other Party hereunder. The Parties agree and acknowledge that Discovery may, at its sole discretion, subject to its compliance with this Article 8, file a Current Report on Form 8-K with the SEC to announce the filing of the press release and file it as an exhibit thereto, as well as to incorporate it by reference into other SEC filings.

8.6 <u>Survival</u>. The obligations and prohibitions contained in this Article 8 shall survive the expiration or termination of this Agreement.

ARTICLE 9 REPRESENTATIONS, WARRANTIES AND COVENANTS

- 9.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents, warrants and covenants to the other Party that as of the Effective Date:
- 9.1.1 <u>Organization; Authority.</u> It is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has full right, corporate power and authority to enter into this Agreement, to perform its obligations under this Agreement, to grant the licenses granted by such Party pursuant to this Agreement and to carry out the provisions hereof.
- 9.1.2 <u>Consents.</u> Except for any Regulatory Approvals necessary for the development, manufacture, or commercialization of a Licensed Product, all necessary consents, approvals, orders, permits and authorizations of all government authorities and Regulatory Authorities and other Persons or Third Parties required to be obtained by it as of the Effective Date in connection with the execution, delivery, and performance of this Agreement have been obtained.
- 9.1.3 No Conflict. The execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder, and the rights, licenses and sublicenses to be granted by such Party pursuant to this Agreement, (i) do not conflict with, violate or constitute a breach or default under any requirement of Laws or regulations existing as of the Effective Date and applicable to such Party or under any instrument, judgment, order, writ, decree, contract of such Party or any of its Affiliates existing as of the Effective Date; (ii) do not give rise to any event that results in the creation of any lien, charge or encumbrance upon any assets of such Party or the suspension, revocation, impairment, forfeiture or non-renewal of any material permit, license, authorization or approval that applies to such Party, its business or operations or any of its assets or properties; or (iii) conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party.
- 9.1.4 <u>Enforceability.</u> This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to and limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (ii) judicial discretion in the availability of equitable relief.
- 9.1.5 <u>Regulatory.</u> There are no investigations, inquiries, actions or other proceedings pending before or, to such Party's knowledge, threatened, by any Regulatory Authority or other government agency with respect to any Licensed Products (or components thereof) or any facility where such Licensed Products (or components thereof) are manufactured, and such Party has not received written notice threatening any such investigation.
- 9.2 <u>Intellectual Property.</u> Discovery represents, warrants, and covenants to PMPSA that as of the Effective Date with respect to the Discovery Intellectual Property and, except with regard to PMPSA's intellectual property rights in the name "Aria," PMPSA represents, warrants, and covenants to Discovery that as of the Effective Date with respect to the PMPSA Intellectual Property:

(i)	To its present actual knowledge, it (a) holds good title to and is the legal and beneficial owner of, or (b) is the licensee of, such Intellectual Property in
the Territory free and clea	ar of any lien, mortgage, security interest, license, right, pledge, restriction on transferability, defect of title or other claim, charge, or encumbrance of any
nature whatsoever on or a	affecting any property or property interest and no Third Party has any right, title, or interest in or to such Intellectual Property in the Territory.

- (ii) To its present actual knowledge, the Patents included in such Intellectual Property are valid and enforceable in the Major Markets and there have been no, and such Party has no reason to believe that there will be any, inventorship challenges with respect to any of such Patents in the Major Markets.
- (iii) To its present actual knowledge, there are no infringement proceedings, actions, suits or complaints pending against nor any outstanding injunctions, judgments, orders, decrees, rulings or other charges against such Party relating to such Intellectual Property in the Territory.
- (iv) To its present actual knowledge, it has not received any form of notice from a third party of infringement of Third Party Patent rights that may affect the making, using or selling of Licensed Products in the Territory; and to its knowledge (a) the manufacture, development and commercialization of the Licensed Products in the Territory will not infringe the Patents of any Third Party in the Territory and (b) there are no Third Party patent applications in the Territory pending which, if issued, would materially adversely affect the ability to make, use or sell the Licensed Products in the Territory.
- (v) To its present actual knowledge, it has not granted any third party any license, covenant not to sue, options, or other right with respect to such Intellectual Property in the Territory that would impact its ability to enforce such Intellectual Property in the Territory. There are no existing agreements, options, commitments, or rights with, of, or to any Person to acquire or obtain any rights with respect to the Intellectual Property in the Territory that are inconsistent with the rights granted herein.
- (vi) To its present actual knowledge, each agreement pursuant to which a Third Party has granted, assigned or otherwise transferred rights with respect to such Intellectual Property in the Territory are in full force and effect, and no Party to such agreements is in breach or default thereunder, and the execution and performance of this Agreement will not result in a breach or default thereunder.
- 9.3 No Adverse Effects. Discovery represents, warrants and covenants to PMPSA that as of the Effective Date, the studies of Pulmonary Surfactants conducted by Discovery prior to the Effective Date have not shown any adverse effects or toxicity of the Pulmonary Surfactant in humans that could reasonably be anticipated to frustrate the purposes of this Agreement, and as of the Effective Date, Discovery has not been informed of any such adverse effects or toxicity.

ARTICLE 10 ADDITIONAL COVENANTS

- 10.1 <u>Compliance with Laws</u>. Each Party shall perform its responsibilities in a good scientific manner in accordance with the terms of this Agreement and in compliance in all material respects with the requirements of Laws.
- 10.2 <u>Cooperation</u>. The Parties agree that maintaining effective and open communication between the Parties on matters relating to the Agreement is important to the success of the Agreement.
- 10.3 <u>Sharing of Information</u>. Subject to applicable Law and privileges and obligations of confidentiality, the Parties agree to provide the other Party, upon such other Party's reasonable request, copies or access to all data, documentation and work products, including Clinical Trials, relating to any Licensed Product.

ARTICLE 11 DISCLAIMERS AND LIMITATION OF LIABILITY

11.1 <u>Disclaimer of Wartanties.</u> EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, CONCERNING THE DEVELOPMENT, COMMERCIALIZATION, MARKETING, OR SALE OF ANY PRODUCT INCLUDING THE SUCCESS OR POTENTIAL SUCCESS THEREOF. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS, WARRANTIES AND AGREEMENTS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

THE PARTIES UNDERSTAND THAT THE LICENSED PRODUCTS ARE THE SUBJECT OF ONGOING CLINICAL RESEARCH AND DEVELOPMENT AND THAT NEITHER PARTY CAN ASSURE THE SAFETY OR USEFULNESS OF LICENSED PRODUCTS. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY EXCEPT AS SET FORTH IN THIS ARTICLE 11 CONCERNING ITS PATENT RIGHTS OR KNOW-HOW, INCLUDING THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT THE MANUFACTURE, USE OR SALE OF ANY LICENSED PRODUCT WILL NOT INFRINGE THE PATENT RIGHTS OF THIRD PARTIES.

11.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS PERSONNEL FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, LOST PROFITS, BUSINESS, OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES AND THEIR RESPECTIVE PERSONNEL IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT EXCEPT WHERE ATTRIBUTABLE TO A WILLFUL OR INTENTIONAL BREACH OF THIS AGREEMENT. NOTHING IN THIS SECTION 11.2 IS INTENDED TO, NOR SHALL, LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER THIS ARTICLE 11, OR ANY REMEDIES OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 8.

ARTICLE 12 INDEMNIFICATION; INSURANCE

12.1 Indemnification.

- 12.1.1 Obligations of the Parties. Each of the Parties shall defend, indemnify and hold harmless the other Party, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents (collectively, the "Indemnified Parties") from and against any and all losses, costs, damages, fees, liabilities, or expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") incurred in connection with any Third Party claim, action or proceeding (a "Third Party Claim") arising out of or related to:
 - (i) any material breach by the indemnifying Party of any of its representations, warranties, covenants or obligations pursuant to this Agreement;

and

- (ii) any negligence, recklessness, willful misconduct or wrongful intentional acts or omissions of the indemnifying Party, its Affiliates, or their officers, directors, employees, contractors, consultants, agents, representatives, or sublicensees in the exercise of any of the indemnifying Party's rights or the performance of any of the indemnifying Party's obligations under this Agreement.
- 12.1.2 Additional Indemnification by PMPSA. In addition to the indemnity set forth in Section 12.1.1 above, PMPSA shall defend, indemnify and hold harmless Discovery, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claim that the PMPSA Technology infringes or misappropriates such Third Party intellectual property in the Territory to the extent such Losses are directly attributable to actual infringement or misappropriation of such Third Party's intellectual property by the PMPSA Technology, except to the extent such infringement and misappropriation is attributable to further development, modifications or enhancements of the PMPSA Technology by Discovery or due to the combination by Discovery (directly or indirectly) of the PMPSA Technology with any other technology and provided that Discovery uses all reasonable efforts to minimize any such Losses.
- 12.1.3 Additional Indemnification by Discovery. In addition to the indemnity set forth in Section 12.1.1 above, Discovery shall defend, indemnify and hold harmless PMPSA, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claim arising out of or related to any intellectual property infringement and trade secret misappropriation liability relating to the development, manufacture, or commercialization of any Licensed Product, except to the extent such Losses are due to matters for which PMPSA is required to provide indemnification pursuant to Section 12.1.2.

- 12.1.4 <u>Certain Product Liability Claims</u>. Notwithstanding Sections 12.1.1, 12.1.2, and 12.1.3, Discovery shall defend, indemnify and hold harmless PMPSA, its Affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claims arising out of or relating to the commercialization, marketing, sale, use, handling, manufacture and/or storage of any Licensed Product, including any claims that involve death or bodily injury (or allegations thereof) to any individual.
- 12.1.5 <u>Complete Indemnification</u>. As the Parties intend complete indemnification, all direct out of pocket costs and expenses reasonably incurred by an Indemnitee in connection with enforcement of Section 12.1 shall also be reimbursed by the Indemnitor.
 - 12.2 Indemnification Procedures.
- 12.2.1 Notification. In the case of a Third Party Claim as to which a Party may be obligated to provide indemnification pursuant to this Agreement (the "Indemnitor"), such Indemnified Party seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually prejudiced as a result of such failure.
- Assumption of Defense. If a Third Party Claim is made against an Indemnitee, the Indemnitor will be entitled, within one hundred twenty (120) days 12.2.2 after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee, for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of a Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, however, that if in the opinion of counsel, such counsel and opinion being satisfactory to Indemnitor and its counsel, a conflict of interest exists between the Indemnitor and an Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel (which shall be reasonably satisfactory to the Indemnitor) to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event, the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one (1) separate counsel for such Indemnitee. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnitee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnitee (including providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control of the defense of any Third Party Claim, within the one hundred twenty (120) day period set forth above, or if such good faith and diligent defense is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, after three (3) Business Days notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

- 12.2.3 Settlements. The Indemnitee may agree to any settlement, compromise, or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all liability in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise, or discharge (including the consent to entry of any judgment), and the Indemnitee may refuse in good faith to agree to any such settlement, compromise, or discharge, that provides for injunctive or other nonmonetary relief affecting the Indemnitee. The Indemnitee shall not (unless required by Law) admit any liability with respect to, or settle, compromise, or discharge, such Third Party Claim without the Indemnitor's prior written consent (which consent shall not be unreasonably withheld, conditioned, or delayed).
- Insurance. Discovery agrees to obtain and maintain commercial general liability insurance and/or self-insurance, including prior to the date a Licensed Product is first administered in humans, commercial general liability insurance and/or self-insurance for Clinical Trials and products liability, with reputable and financially secure insurance carriers, in such amounts and subject to such deductibles as are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities. Discovery shall maintain such insurance for so long as Licensed Products in the Territory continue to be developed, manufactured, or commercialized and thereafter for so long as is necessary to cover any and all Third Party Claims required to be indemnified by Discovery which Third Party Claims may arise from the development, manufacture, and/or commercialization of a Licensed Product in the Territory. Upon reasonable request by PMPSA, Discovery shall produce evidence that such insurance policies are valid, kept up to date, and in full force and effect. The insurance obligations set forth in this Section 12.3 may be satisfied by commercially reasonable self-insurance or a commercially reasonable combination of insurance and self-insurance.

ARTICLE 13 TERM

This Agreement shall become effective on the Effective Date, and unless terminated earlier in accordance with the provisions of Article 14 shall expire as follows as to each Licensed Product in each country in the Territory, on a country-by-country basis, upon the latest of: (a) the 10th anniversary of the date of the First Commercial Sale of the Licensed Product; (b) the date on which the sale of such Licensed Product ceases to be covered by a Valid Claim in such country, or (c) the date a generic form of the product is introduced in such country (the "Term").

ARTICLE 14 TERMINAION

- 14.1 <u>Termination by Discovery.</u> Discovery may terminate this Agreement for any reason, in its entirety, [***], upon [***] days written notice to PMPSA.
- 14.2 <u>Termination Due to Failure to Meet Minimum Royalties</u>. PMPSA may terminate this Agreement upon [***] days' prior written notice to Discovery, if commencing [***] and continuing [***], Discovery does not pay PMPSA each Contract Quarter the Minimum Royalties due pursuant to Section 6.2, and Discovery does not cure such shortfall as provided for in Section 6.2; provided, however, that PMPSA shall not have a right to terminate the Agreement pursuant to this Section 14.2 for any time period in which Discovery is disputing in good faith amounts due under this Agreement.
 - 14.3 Termination for Material Breach.
- 14.3.1 Right to Terminate Agreement. If a Party (the "Breaching Party") commits a material breach of this Agreement and fails to cure such breach within the applicable Cure Period (as provided in 15.1.2 below), the other Party (the "Non-Breaching Party") may, by written notice of termination within thirty (30) days after the expiration of the applicable Cure Period, elect to terminate the Agreement. Without limiting the generality of the foregoing, and notwithstanding the Cure Period set forth in Section 14.3.2, the practice by Discovery of the PMPSA Technology outside the scope of the licenses and sublicenses granted herein, which practice does not cease within thirty (30) days after the receipt of written notice of such breach from PMPSA, shall constitute a material breach.
- 14.3.2 <u>Applicable Cure Periods</u>. Upon receipt of written notice of a material breach pursuant to Section 14.3.1, and except as otherwise provided for in Section 14.3.1, the allegedly Breaching Party shall have sixty (60) days to cure such material breach (the "<u>Cure Period</u>"), provided, however, that in the case of any material breach that cannot be reasonably cured within the sixty (60) day cure period, should the Breaching Party deliver to the Non-Breaching Party a plan for curing such material breach which is reasonably sufficient to effect a cure and uses commercially reasonable efforts to pursue such plan and effect a cure, the Cure Period shall be extended for an additional sixty (60) days.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

14.4	<u>Termination Due to Certain Events</u> . Without prejudice to any other remedies available to it at Law or in equity, either Party may, subject to the provisions set
forth herein, termin	ate this Agreement immediately upon written notice to the other Party if, at any time, the other Party shall (i) file in any court pursuant to any statute a petition
for bankruptcy or ir	nsolvency, or for reorganization in bankruptcy, or for an arrangement or for the appointment of a receiver, trustee or administrator of such Party or of its assets,
(ii) be served with a	an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, (iii)
propose or be a part	ty to any dissolution, (iv) make an assignment for the benefit of its creditors; or (v) ceases to do business in the ordinary course.

14.5 Effects of Termination Generally

- Accrued Obligations; Survival. Upon expiration or termination of this Agreement, all of the Parties' rights and obligations under this Agreement including the exclusive license in Section 2.1, shall terminate immediately except: (a) any rights that shall have accrued to the benefit of any Party prior to such termination or expiration, including the right of PMPSA to receive royalties as provided in Article 6; and (b) any rights and obligations of the Parties which are expressly indicated to survive termination or expiration of this Agreement. All of the Parties' rights and obligations under, and the provisions contained in [***] shall survive termination or expiration of this Agreement.
- 14.5.2 <u>Outstanding Payments</u>. All payments of amounts owing to either Party under this Agreement as of its expiration or termination shall be due and payable within the later of (i) to the extent such amounts can be calculated and a fixed sum determined at the time of expiration or termination of this Agreement, sixty (60) days after the date of such expiration or termination, and (ii) ten (10) days after the date in which such amounts can be calculated and a fixed sum determined.

ARTICLE 15 STANDSTILL AGREEMENT

[***] period beginning on the date of termination of this Agreement for any reason, neither PMPSA nor any of its Affiliates will (nor assist or encourage others to), directly or indirectly, without the written consent of Discovery: (i) acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift, or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or interest in any securities or direct or indirect rights, warrants, or options to acquire, or securities convertible into or exchangeable for, any securities of Discovery; (ii) directly or indirectly effect or seek, initiate, offer, or propose or participate in any (A) tender or exchange offer, merger, consolidation, or other business combination involving Discovery, or (B) any recapitalization, restructuring, liquidation, dissolution, sale of all or substantially all the assets, or other extraordinary transaction with respect to Discovery; (iii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the SEC promulgated pursuant to Section 14 of the Exchange Act) involving Discovery; (iv) form or become a member of a "group" (as defined under the Exchange Act) with respect to any voting securities of Discovery (including by depositing any securities of Discovery in a voting trust or by subjecting any securities of Discovery to any other arrangement or agreement with respect to the voting of such securities); or (v) enter into any agreements, discussions, or arrangements with any Third Party with respect to any of the foregoing.

Information marked by [***] has been omitted pursuant to a request for confidential treatment. The omitted portion has been separately filed with the Securities and Exchange Commission.

- 15.2 <u>Certain Exceptions.</u> Nothing in this Article 15 shall prohibit PMPSA's or its Affiliates' employees from purchasing securities of Discovery pursuant to (i) a pension plan established for the benefit of PMPSA's or its Affiliates' employees, (ii) any employee benefit plan of PMPSA or its Affiliates, (iii) any stock portfolios not controlled by PMPSA or any of its Affiliates that invest in Discovery among other companies, or (iv) *de minimis* passive investments not to exceed five percent (5%) of Discovery's outstanding voting securities.
- 15.3 Exception for an Acquisition Transaction. This Article 15 shall terminate (subject to revival as provided below) and PMPSA and its Affiliates shall have the right to acquire any securities of Discovery without regard to the limitations set forth in this Article 15 in the event that Discovery publicly announces a transaction, an intention or desire to effect any transaction, or the receipt of any offer, which would result in (a) the sale of all or substantially all of the assets of Discovery within the meaning of Section 271 of the Delaware General Corporation Law, or (b) Discovery common shareholders immediately prior to such transaction owning less than fifty percent (50%) of the outstanding common stock of the acquiring entity or, in the case of a merger transaction, the surviving corporation (an "Acquisition Transaction"). If the proposed Acquisition Transaction has not been consummated within six (6) months following Discovery's public announcement in respect thereof, the provisions of this Article 15 shall be revived and have full force and effect until such time as Discovery makes a subsequent public announcement regarding an Acquisition Transaction, at which time the provisions of this Article 15 shall once again apply.

ARTICLE 16 DISPUTE RESOLUTION

16.1 <u>Dispute Resolution</u>. Except as expressly otherwise provided in this Agreement, any material dispute, difference, claim, action, demand, request, investigation, controversy, threat or other question arising out of or relating to the interpretation of any provisions of this Agreement or the failure of any Party to perform or comply with any obligations or conditions applicable to such Party pursuant to this Agreement (a "<u>Dispute</u>") shall be settled in accordance with the provisions of this Article 16. If a Party intends to initiate executive negotiation, mediation or arbitration (as set forth below) to resolve a Dispute, such Party shall provide written notice to the other Party informing such other Party of such intention and the issues to be resolved.

- 16.2 <u>Executive Negotiation</u>. Promptly upon a Party's receipt of a notice by the other Party as provided in Section 16.1 with respect to a Dispute, and in any event within thirty (30) days of such receipt, the senior executives of each Party shall meet for attempted resolution of such Dispute by good faith negotiations.
- 16.3 <u>Mediation</u>. If the senior executives referenced in Section 16.2 are unable to resolve any such Dispute within ten (10) Business Days, either Party may, upon written notice to the other Party, refer such Dispute to mediation. Upon such written notice, the Parties shall mutually agree on a mediator to assist in the negotiations. If the Parties fail to mutually agree on a mediator within one week of the written notice, a mediator shall be appointed by the AAA. The Party responsible for referring the Dispute to mediation shall bear the costs of such mediation. Any settlement reached by mediation shall be resolved in writing, signed by the Parties, and shall be binding on them.

16.4 Arbitration.

- 16.4.1 <u>Referral to Arbitration</u>. In the event that a Dispute is not resolved during mediation within thirty (30) days of the selection of a mediator, either Party may refer such Dispute to final and binding arbitration by sending written notice of such election to the other Party clearly marked "Arbitration Demand," whereupon such Dispute shall be arbitrated in accordance with this Section 16.4.
- Rules and Procedures. Except as expressly otherwise provided in this Agreement, any Dispute shall be finally settled by arbitration under the thencurrent expedited procedures applicable to the then-current Commercial Arbitration Rules of the AAA in accordance with the terms set forth in this Section 16.4. The arbitration of any Dispute shall be kept confidential and shall be filed with the office of the AAA located in Washington, D.C. or such other AAA office as the Parties may agree. Such arbitration shall be conducted by three arbitrators, one appointed by each of PMPSA and Discovery and the third selected by the first two appointed arbitrators. Each arbitrator shall be a person with relevant experience in the pharmaceutical industry. PMPSA and Discovery must make their respective arbitrator appointments within ten (10) Business Days of notice being given to a Party by the other Party of its intention to resolve such Dispute through arbitration. Such appointed arbitrators shall select the third arbitrator within ten (10) Business Days of the last to occur of their respective appointments. PMPSA and Discovery shall instruct such arbitrators to render a determination of any such Dispute within sixty (60) days after the appointment of the third arbitrator. All Disputes shall be resolved by submission of documents unless the arbitration panel determines that an oral hearing is necessary.

- Awards. The decision of the arbitrators with respect to any Dispute shall be in writing and state the findings, facts and conclusions of law upon which the decision is based. Any such decision and award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party submits itself to the jurisdiction of any such court for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder. The arbitrators shall have the power to grant all legal and equitable remedies except specific performance and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No Party shall seek punitive damages or specific performance in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum, provided however, that the foregoing does not preclude suits or limit damages associated with infringement.
- 16.4.4 <u>Costs</u>. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrators shall be equally shared between PMPSA and Discovery unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party or Parties (including reasonable attorneys' fees) against the other Party or Parties, as the case may be.
- 16.4.5 No Other Forum. Except as provided in Section 16.5, the provisions of this Section 16.4 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising under this Agreement. Any Party commencing a lawsuit in violation of this Section 16.4 shall pay the costs of the other Party, including, without limitation, reasonable attorney's fees and defense costs.
- 16.5 <u>Right to Injunctive and Other Relief.</u> Nothing in this Agreement, shall prohibit either Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by the other Party which would cause irreparable harm to the first Party. Nothing in this Agreement shall prevent a Party from seeking any remedies available at law or in equity in any court of competent jurisdiction in the event of the practice of such Party's Intellectual Property outside the scope of the rights granted herein.

ARTICLE 17 MISCELLANEOUS

- 17.1 <u>Choice of Law.</u> This Agreement shall be governed by and interpreted under, and any action or proceeding shall apply, the Laws of the State of New York excluding (i) its conflicts of Laws principles, other than Section 5-1401 of the New York General Obligations Law (ii), the United Nations Conventions on Contracts for the International Sale of Goods and (iii) the 1974 Convention on the Limitation Period in the International Sale of Goods and any Protocols thereto, done at Vienna, April 11, 1980.
- 17.2 <u>Severability</u>. If, under Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement, this Agreement shall endure except for such provision. The Parties shall consult one another and use their best efforts to agree upon a valid and enforceable provision that is a reasonable substitute for such invalid or unenforceable provision in view of the intent of this Agreement.

- 17.3 Relationship of the Parties. Each Party shall bear its own fees, expenses, and disbursements, including the fees and expenses of their respective counsel, accountants, bankers, and other experts, in connection with the subject matter of this Agreement and costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the Parties' legal relationship under this Agreement shall be that of independent contractors. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a partnership, joint venture, agency, or employer-employee relationship between the Parties.
- 17.4 <u>Parties in Interest</u>. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective legal representatives, successors, and permitted assigns of the Parties hereto. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the Parties hereto, or their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement.
- 17.5 <u>Enforcement of Certain Agreements</u>. Each Party shall use commercially reasonable efforts at its expense to enforce the provisions of any confidentiality agreements and agreements with respect to noncompetition existing as of the Effective Date with any of its present or former employees, agents, consultants or independent contractors of Discovery that relate to any Licensed Product; provided, however, that the obligation with respect to any agreement related to this Section 17.5 shall terminate as of the date on which such agreement and the obligations regarding noncompetition have terminated or expired in accordance with its terms.
- 17.6 <u>Use of Affiliates, Subcontractors, Sublicensees and Distributors.</u> Each Party shall have the right to use Affiliates, subcontractors, sublicensees and distributors in exercising its rights and carrying out its obligations under this Agreement, provided, however, that (i) such entities agree in writing to be bound by the provisions of Article 8, (ii) the use of such entities does not in any way materially diminish the other Party's rights or otherwise modify the other Party's rights or obligations hereunder without such other Party's prior written consent, (iii) Discovery may not delegate, sublicense, assign, or otherwise transfer any of its rights or obligations hereunder to any entity (including any Affiliate) that competes with any tobacco product of PMPSA or its Affiliates without PMPSA's prior written consent, (iv) PMPSA may not delegate, assign or otherwise transfer any of its rights or obligations hereunder to a company engaged in pulmonary critical care medicine, without Discovery's prior written consent and (v) except with respect to rights, benefits and obligations assigned as permitted pursuant to Section 17.7, each Party shall be liable for any actions or omissions of its Affiliates, subcontractors, sublicensees and distributors in connection with this Agreement and the Intellectual Property and Confidential Information of the other Party to the same extent as if such actions or omissions were conducted by the Party itself.

- 17.7 Assignment. PMPSA may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any Affiliate of PMPSA without the prior written consent of Discovery subject only to the limitations set forth in Section 17.6 (iv) above. Discovery may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any Affiliate of Discovery without the prior written consent of PMPSA, subject only to the limitations set forth in Section 17.6 (iii) above, provided, however, notwithstanding such an assignment, Discovery shall remain responsible for the performance of the indemnification obligations set forth herein. No Party may assign or otherwise transfer this Agreement or any or all right, benefit or obligation hereunder (whether by operation of Law or otherwise) to any other Person other than an Affiliate without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed; except that, subject to the limitations set forth in Section 17.6 (iii) and (iv) above, either Party may assign or otherwise transfer any or all of its rights and interests hereunder in connection with the sale of all or substantially all of its assets or business to which this Agreement relates, whether by way of merger, sale of stock, sale of assets or other similar transaction, provided that the assignee or transferee expressly agrees to assume all of the obligations hereunder.
- 17.8 <u>Further Assurances and Actions</u>. From time to time after the Effective Date, Discovery and PMPSA shall execute, acknowledge and deliver to each other any further documents, assurances, and other matters, and will take any other action consistent with the terms and conditions of this Agreement, that may reasonably be requested by a Party and necessary or desirable to carry out the purpose and intent of this Agreement. PMPSA and Discovery shall cooperate and use all reasonable efforts to make all other registrations, filings, and applications, to give all notices, and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications, authorizations, permits, and waivers, if any, and to do all other things necessary or desirable for the consummation of this Agreement.
- 17.9 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.
- 17.10 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Reform Act of 1978, 11 U.S.C. §§ 101 et seq., as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under Section 365(n) of the Bankruptcy Code.

17.11 <u>Notices</u>. All notices that are required or permitted hereunder shall be in writing and shall be sufficient if personally delivered or sent by mail or Federal Express or other delivery service. Any notices shall be deemed given upon the earlier of the date when received at, or the third day after the date when sent by registered or certified mail or the day after the date when sent by Federal Express to, the address set forth below, unless such address is changed by notice to the other Parties hereto:

If to PMPSA:

Vice President and Associate General Counsel Intellectual Property Law Group Philip Morris International
Avenue de Rhodanie 50
Case Postale 1171
1001 Lausanne
Switzerland
Fax: +41(0)58-242-0101

If to Discovery:

Discovery Laboratories, Inc. 2600 Kelly Road, Suite 100 Warrington, PA 18976 Attention: David L. Lopez, Esq., CPA

with a copy to:

Dickstein Shapiro LLP 1177 Avenue of the Americas New York, NY 10036 Attention: Ira L. Kotel, Esq.

- 17.12 Construction. Unless the context of this Agreement clearly requires otherwise, (i) references to any gender include all genders, (ii) "or" has the inclusive meaning frequently identified with the phrase "and/or," (iii) "including" has the inclusive meaning frequently identified with the phrase "including but not limited to" or "including without limitation", and (iv) references to "hereunder" or "herein" relate to this Agreement and (v) all terms defined in the singular shall have the same meaning in the plural and vice versa. The section and other headings contained in this Agreement are for reference purposes only and shall not control or affect the construction of this Agreement or the interpretation thereof in any respect. Section, subsection, Schedule and Exhibit references are to this Agreement unless otherwise specified. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP.
- 17.13 Registration and Filing of this Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Regulatory Authority, including the SEC or the U.S. Federal Trade Commission, in accordance with Law, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

- 17.14 Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to Force Majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, Force Majeure is defined as causes beyond the control of the Party, including, without limitation, acts of God; acts, regulations, or laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event Discovery or PMPSA, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled and the thirty (30) days thereafter. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any Force Majeure.
- 17.15 <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Discovery and PMPSA.
- 17.16 <u>Third Party Beneficiaries</u>. Except for any Third Party Indemnities under Article 12, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party hereto, and no such Third Party (except for such Indemnitees, as such) shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.
- 17.17 <u>Execution in Counterparts; Facsimile Signatures</u> This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and both of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto as of the day and year first written above.

PHILIP MORRIS PRODUCTS S.A.

By: /s/ Frances Bruttin

Name: Frances Bruttin Title: VP Applied Science

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola, Ph.D.

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

CERTIFICATIONS

I, Robert J. Capetola, certify that:

- I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying 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: May 8, 2008

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

President and Chief Executive Officer

CERTIFICATIONS

I, John G. Cooper, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying 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: May 8, 2008

/s/ John G. Cooper

John G. Cooper

Executive Vice President and Chief Financial Officer

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2008 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2008

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

President and Chief Executive Officer

/s/ John G. Cooper

John G. Cooper

Executive Vice President and Chief Financial Officer

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

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