SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

December 9, 2005 Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc. (Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) **000-26422** (Commission File Number) **94-3171943** (IRS Employer Identification Number)

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

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On December 9, 2005, Discovery Laboratories, Inc. (the "Company") entered into a Strategic Alliance Agreement with Chrysalis Technologies, a division of Philip Morris USA Inc., to develop and commercialize aerosolized surfactant replacement therapies (*a*SRT) to address a broad range of serious respiratory conditions.

Under the agreement, the Company has exclusive rights to Chrysalis' proprietary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis will assist with the development of certain combination drug-device surfactant products, and provide certain additional consultative services to the Company in connection with combination drug-device surfactant products, provided that certain terms and conditions are satisfied. Additionally, Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. The Company is responsible for *a*SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products.

The foregoing description of the strategic alliance does not purport to be complete and is qualified in its entirety by reference to the Strategic Alliance Agreement, which is filed as Exhibit 10.1 to this report and incorporated herein by reference. The Strategic Alliance Agreement has been filed in order to provide investors and the Company's stockholders with information regarding its terms and in accordance with applicable rules and regulations of the Securities and Exchange Commission. The Strategic Alliance Agreement contains representations and warranties that the parties made to and solely for the benefit of each other in the context of all of the terms and conditions of the agreement and in the context of the specific relationship between the parties. Accordingly, investors and stockholders should not rely on the representations and warranties. Furthermore, investors and stockholders should not rely on the representations and warranties as characterizations of the actual state of facts, since they were only made as of the date of the agreement. Information concerning the subject matter of such representations and warranties may change after the date of the Strategic Alliance Agreement, which subsequent information may or may not be fully reflected in the Company's reports or other filings with the Securities and Exchange Commission.

On December 11, 2005, the Company issued a press release announcing the entry into the Strategic Alliance Agreement, which is filed as Exhibit 99.1 to this report and incorporated herein by reference.

Item 8.01 Other Items.

On November 30, 2005, the Company completed an issuance of shares to Kingsbridge Capital Limited pursuant to the Committed Equity Financing Facility entered into with Kingsbridge in July 2004. Over a 15-trading day period, the Company issued 498,552 shares of its common stock to Kingsbridge at an average price per share, after taking into account the applicable discount rate provided for by the CEFF, of \$6.42, for gross cash proceeds of approximately \$3.2 million.

Shares issued or issuable to Kingsbridge under the CEFF have been registered for resale pursuant to the Company's registration statement on Form S-3 (File No. 333-118595), which was declared effective by the Securities and Exchange Commission on October 27, 2004.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Item 9.01. <u>Financial Statements and Exhibits.</u>

- (d) Exhibits:
 - 10.1 *Strategic Alliance Agreement, dated December 9, 2005
 - 99.1 Press Release of Discovery Laboratories, Inc., dated December 11, 2005

* Confidential treatment has been requested with respect to certain portions of this exhibit. Such portions have been redacted and filed separately with the Securities and Exchange Commission.

SIGNATURES

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

Discovery Laboratories, Inc.

By: /s/ Robert J. Capetola

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

Date: December 12, 2005

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by "[***]", have been separately filed with the Securities and Exchange Commission.

STRATEGIC ALLIANCE AGREEMENT

by and between

DISCOVERY LABORATORIES, INC. (a Delaware corporation)

and

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

DECEMBER 9, 2005

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STRATEGIC ALLIANCE AGREEMENT

THIS STRATEGIC ALLIANCE AGREEMENT is made as of December 9, 2005 (the "<u>Effective Date</u>"), by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("<u>Discovery</u>"), and PHILIP MORRIS USA INC., d/b/a CHRYSALIS TECHNOLOGIES, a Virginia corporation ("<u>Chrysalis</u>"). Discovery and Chrysalis shall be referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>".

WHEREAS, Discovery is currently developing a portfolio of aerosolized surfactant replacement therapies (*a*SRT) based upon its proprietary precisionengineered surfactant technology for the prevention and treatment of respiratory disorders;

WHEREAS, Chrysalis is currently developing and has expertise in the development and design of proprietary technology for the aerosolization of pharmaceutical products; and

WHEREAS, the Parties desire to enter into a strategic alliance pursuant to which they will develop certain combination drug-device surfactant products, Chrysalis will license its proprietary aerosolization technology to Discovery, and Chrysalis will provide certain additional consultative services to Discovery in connection with combination drug-device surfactant products, 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:

- 1.1 "<u>AAA</u>" means the American Arbitration Association.
- 1.2 "<u>Actual Amount</u>" has the meaning set forth in Section 8.7.2.
- 1.3 [***]
- 1.4 "<u>Additional Product Opportunities</u>" has the meaning set forth in Section 4.9.1.

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.

1.5 "<u>Aerosol Device</u>" means a device for the aerosolization of 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.

1.6 "<u>Aerosol Technology</u>" 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.

1.7 "<u>Affiliates</u>" 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 1.7, "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.

- 1.8 "<u>Agreement</u>" means this Strategic Alliance Agreement, including the Schedules attached hereto.
- 1.9 "<u>Alliance</u>" has the meaning set forth in Article 2.
- 1.10 "<u>Alliance Manager</u>" has the meaning set forth in Section 5.2.1.
- 1.11 "<u>Base Hospital General Product</u>" has the meaning set forth in Section 4.2.
- 1.12 "<u>Base NICU Product</u>" has the meaning set forth in Section 4.2.

1.13 "Base Supported Product Development Projects" means a Supported Product Development Project with respect to a Base NICU Product or a Base Hospital General Product.

1.14 "<u>Breaching Party</u>" has the meaning set forth in Section 17.1.1 and 17.1.2, as applicable.

1.15 "<u>Business Day</u>" 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.

1.16 "<u>Chrysalis</u>" has the meaning set forth in the Preamble hereto.

1.17 "<u>Chrysalis Intellectual Property</u>" has the meaning set forth in Section 9.1.1.

1.18 "<u>Chrysalis Patents</u>" means all Patents owned by Chrysalis or to which Chrysalis otherwise has rights that claim or are directed to the Chrysalis Technology.

1.19 "<u>Chrysalis Technology</u>" means (a) Chrysalis' proprietary Aerosol Technology (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 relating to such Aerosol Technology, including, without limitation, the Chrysalis Patents.

1.20 "<u>Chrysalis Technology Improvements</u>" means any Inventions created or reduced to practice **[***]** in the performance of the Alliance or exercise of the license granted pursuant to this Agreement, which Inventions relate primarily to the Chrysalis Technology.

1.21 "<u>Clinical Trials</u>" 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.

1.22 "<u>Combined Net Sales</u>" means with respect to any Contract Year, the total Net Sales of all of the Supported Products during such Contract Year.

1.23 "<u>Committees</u>" has the meaning set forth in Section 5.1.

1.24 "<u>Confidential Information</u>" means all information received by either Party or its Affiliates from or on behalf of the other Party or its Affiliates relating to this Alliance 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, know-how, 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.

1.25 "<u>Contract Month</u>" 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.

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.

1.26 "<u>Contract Quarter</u>" 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.

1.27 "<u>Contract Year</u>" 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.

1.28 "<u>Design Review Board</u>" has the meaning set forth in Section 5.7.

1.29 "<u>Diligent Commercialization 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 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.

1.30 "Diligent Development 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 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.

1.31 "<u>Discovery</u>" has the meaning set forth in the Preamble hereto.

1.32 "<u>Discovery Intellectual Property</u>" has the meaning set forth in Section 9.1.2.

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

1.34 "<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.

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

1.36 "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.

1.37 "<u>Dispute</u>" has the meaning set forth in Section 20.1.

1.38 "<u>Dollars</u>" and "<u>\$</u>" means, unless otherwise specified, United States Dollars.

1.39 "<u>Drug Product</u>" means Pulmonary Surfactant(s) or other pharmacological agent(s), together with any excipients or inactive ingredients, formulated for use in a Licensed Product.

1.40	" <u>Effective Date</u> " has the meaning set forth in the Preamble hereto.
1.40	<u>Effective Dute</u> has the meaning set forth in the realible hereto.

1.41 "Estimated Amount" has the meaning set forth in Section 8.7.1.

1.42 [***]

1.43 "<u>Exchange Act</u>" has the meaning set forth in Section 19.1.

1.44 "<u>Exclusive Field</u>" means 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.

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

1.46 "<u>First Access Product</u>" has the meaning set forth in Section 10.1.

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.

1.47 "<u>First Access Product Presentation</u>" has the meaning set forth in Section 10.3.

1.48 "<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.

1.49 "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).

1.50 "<u>GAAP</u>" means generally accepted accounting principles in the United States of America.

1.51 "<u>Hospital General Products</u>" has the meaning set forth in Section 4.2.

1.52 "<u>Hospital Setting</u>" means a hospital-setting in the delivery room, NICU, PICU, CCU, emergency department, surgical care unit and/or intermediate care unit.

- 1.53 "<u>Indemnitee</u>" has the meaning set forth in Section 15.2.1.
- 1.54 "<u>Indemnitor</u>" has the meaning set forth in Section 15.2.1.
- 1.55 "<u>Independent Product</u>" means any Licensed Product other than a Supported Product.
- 1.56 "<u>Infringement Notice</u>" has the meaning set forth in Section 9.6.1.

1.57 "<u>Intellectual Property</u>" 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.

1.58 "<u>Invention</u>" 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).

1.59 "<u>Joint Inventions</u>" has the meaning set forth in Section 9.1.3.

1.60 "Joint Patents" means all Patents that claim or are directed to any Joint Inventions.

1.61 "<u>Law</u>" 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.

1.62 "<u>Licensed Product</u>" means a combination drug-device product using or otherwise practicing the Chrysalis Technology and delivering Pulmonary Surfactants (alone or in combination with other pharmaceutical compounds).

1.63 "<u>Losses</u>" has the meaning set forth in Section 15.1.1.

1.64 "<u>Major Markets</u>" means [***].

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

1.66 "<u>NDA</u>" shall mean (a) 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.

1.67 "<u>Net Sales</u>" means, with respect to Licensed Products, as applicable, sold by Discovery, its Affiliates and sublicensees, the [***] amount [***] for Licensed Products by Discovery, its Affiliates, and any sublicensees of Discovery in arms-length, commercial transactions 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.

- 1.68 "<u>NICU</u>" means neonatal intensive care unit.
- 1.69 "<u>NICU Products</u>" has the meaning set forth in Section 4.2.
- 1.70 "<u>Non-Breaching Party</u>" has the meaning set forth in Section 17.1.1 and 17.1.2, as applicable.
- 1.71 "<u>Party</u>" and "<u>Parties</u>" have the meanings set forth in the Preamble hereto.
- 1.72 "<u>Party Vote</u>" has the meaning set forth in Section 5.6.3.

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.

1.73 "<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.

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

1.75 "<u>Phase 2 Completion Point</u>" has the meaning set forth in Section 10.2.

1.76 "<u>Project Plan</u>" means a plan for the overall development and commercialization of Licensed Products pursuant to a Supported Product Development Project.

1.77 "<u>Project Team</u>" has the meaning set forth in Section 5.4.1.

1.78 "<u>Pulmonary Surfactant</u>" 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.

1.79 "<u>Regulatory Approval</u>" 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.

1.80 "<u>Regulatory Authority</u>" 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, including the FDA in the United States.

1.81 "<u>Regulatory Data</u>" 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). "<u>Respiratory Indications</u>" means all respiratory dysfunctions, failures, syndromes, diseases, disorders, or conditions.

1.82 <u>"Right of First Access</u>" has the meaning set forth in Section 10.1.

1.83 "<u>Royalty Credit</u>" has the meaning set forth in Section 8.7(b).

1.84 "<u>Royalty Report</u>" means the reports to be delivered by Discovery to Chrysalis pursuant to Section 8.6 with respect to each Contract Month and pursuant to Section 8.7 with respect to each Contract Quarter, which reports shall give such particulars of each of the Licensed Products sold by Discovery and its Affiliates and sublicensees during the preceding Contract Month in the case of Section 8.6 and during the preceding Contract Quarter in the case of Section 8.7 on a country-by-country basis as are reasonably pertinent to perform an accounting of royalties under this Agreement.

1.85 "<u>SEC</u>" has the meaning set forth in Section 11.3.

1.86 "<u>Steering Committee</u>" has the meaning set forth in Section 5.3.1.

1.87 "Supported Product" means: (i) the NICU Product, (ii) the Hospital General Product, and (iii) any other Licensed Products deemed to be Supported Products pursuant to Section 4.9.

1.88 "Supported Product Development Projects" has the meaning set forth in Section 4.1.

1.89 "<u>Target Indications</u>" means the following Respiratory Indications: Respiratory Distress Syndrome (RDS); Chronic Lung Disease (BPD); Transient Tachypnea; Hypoxemia; Pulmonary Hypertension; Pneumonia; Bronchiolitis; Diaphragmatic Hernia; Acute Lung Injury (ALI); Acute Respiratory Distress Syndrome (ARDS); Lung Transplantation; Respiratory Syncitial Virus (RSV); and, Cystic Fibrosis.

1.90 "<u>Target Populations</u>" means human patients in a Hospital Setting receiving forms of treatment for the applicable Respiratory Indication that are typically and principally provided within a Hospital Setting. For the sake of clarity, Target Populations shall not include patients or forms of treatment which are typically rendered outside a Hospital Setting or in ambulatory or chronic care modalities, even if such forms of treatment are also administered in a Hospital Setting.

1.91 "<u>Taxes</u>" has the meaning set forth in Section 8.13.

1.92 "<u>Term</u>" has the meaning set forth in Article 16.

1.93 "<u>Territory</u>" means all countries in all continents of the world.

1.94 "<u>Third Party</u>" means any Person other than Chrysalis or Discovery or their respective Affiliates.

1.95 "<u>Third Party Claim</u>" has the meaning set forth in Section 15.1.1.

1.96 "<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.

1.97 "<u>Working Group</u>" has the meaning set forth in Section 5.5.

ARTICLE 2 SCOPE OF ALLIANCE

The Parties agree to enter into this Agreement for the general purpose of developing and licensing for manufacturing and commercialization by Discovery certain combination drug-device products to promote and enhance human health on the terms and conditions set forth herein (the "<u>Alliance</u>"). To facilitate the development of such products, pursuant to this Agreement, Chrysalis is granting Discovery a license under the Chrysalis Technology, Chrysalis and Discovery have agreed to work together to develop certain combination drug-device products and Chrysalis has agreed to provide certain additional consultative services to Discovery, all on the terms and conditions set forth herein. Except as set forth in this Agreement or otherwise agreed to in writing, the Parties shall have no rights and obligations with respect to the Alliance. The Parties agree at all times to act in good faith and in a cooperative manner and, subject to any contractual or legal restrictions, to share such information as reasonably necessary to facilitate each Party's performance of its obligations hereunder under this Agreement.

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, with the right to grant sublicenses solely as set forth in Section 3.3 under the Chrysalis Technology and Joint Patents to make and have made, to use and have used, 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 Limitations. 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 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 21.6. 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.

3.5 <u>Exclusivity</u>. In light of the substantial investments and undertakings to be made by each Party in connection with the Alliance in order to successfully develop and bring to market products to enhance human health, each Party agrees that the Alliance shall be exclusive in the Exclusive Field. Accordingly, during the Term, neither Party shall without the other Party's prior written consent directly or indirectly offer for sale or sell, or grant any third party the right to offer for sale or sell any Aerosol Device, Disposable Dose Packet or Drug Product for use in the Exclusive Field other than a Licensed Product.

ARTICLE 4 PRODUCT DEVELOPMENT

4.1 In General. In light of Chrysalis' substantial expertise regarding the Chrysalis Technology and Discovery's substantial expertise regarding Pulmonary Surfactants, Discovery desires to have Chrysalis work with Discovery on the development of certain of the Licensed Products. The Parties have agreed to work together on Supported Product projects (the "Supported Product Development Projects") with the objective of developing Licensed Products on the terms and conditions set forth in this Article 4.

4.2 <u>Supported Product Development Projects</u>. As of the Effective Date, the Parties have agreed to work together on the following Supported Product Development Projects to develop aerosolized Pulmonary Surfactant products for use in the Hospital Setting: (i) a project to develop an initial aerosolized Pulmonary Surfactant product for the prevention and treatment of Respiratory Indications in neonates in the NICU (the initial Licensed Product resulting therefrom, the "<u>Base NICU Product</u>" and, together with any other NICU-related Licensed Products, the "<u>NICU Products</u>"); and (ii) a project to develop an initial aerosolized Pulmonary Surfactant product for the prevention and treatment of Respiratory Indications in patients outside of the NICU (the initial Licensed Product resulting therefrom, the "<u>Base Hospital General Product</u>" and, together with any other non-NICU-related Licensed Products, the "<u>Hospital General Products</u>"). As soon as practicable after the Effective Date, the Project Team shall mutually agree upon and submit to the Steering Committee for approval a Project Plan for each of the Base Supported Product Development Projects. Licensed Products that may be developed other than the Base NICU Product and the Base Hospital General Product shall be treated as Additional Product Opportunities as provided for in Section 4.9.

4.3 Project Plans. The Project Plans for each Supported Product Development Project shall, subject to the Steering Committee's right to modify or add to the following requirements in its discretion, include: (i) a list of development activities (including preclinical studies, toxicology work, Clinical Trials, Clinical Trial material requirements, specifications and other key activities required for obtaining Marketing Authorizations and timelines for the performance of the development activities; (ii) a reasonably detailed and specific budget for such development activities; and (iii) Discovery's plan for commercialization (including timing and plans for Discovery obtaining Marketing Authorizations in the Major Markets). The Parties acknowledge that the Project Plan budgets are intended to provide an estimation of expenditures and resource deployment and are not required to disclose sensitive data on either Party's cost structure (for the sake of clarity, Parties are expected to provide reasonable detail on such items as aggregate costs for relevant cost categories (e.g., personnel and overhead expenses) but are not expected to provide data regarding individual personnel costs or line-by-line overhead cost classifications). The Project Team shall be responsible for the preparation of the budget for each Project Plan. The Project Plans for each Supported Product Development Project shall be updated, amended and modified as deemed necessary by the Project Team, but no less frequently than each Contract Year. Updated Project Plans shall be submitted by the Project Team to the Steering Committee for approval in a timely fashion by a date that is determined from time-to-time by the Steering Committee that shall conform to the greatest practicable extent the Parties' respective internal budgeting cycles. Neither Party will pursue development tasks or product studies relating to Supported Product Development Projects not provided for in the Project Plans prior to presenting such proposals to the Steering Committee and

4.4 <u>Development Responsibilities and Consulting Services</u>.

4.4.1 <u>Direction and Oversight</u>. All development activities in connection with Supported Product Development Projects shall be conducted under the direction and oversight of the Steering Committee and the Project Team. In order to facilitate effective management of the projects each Party shall have lead responsibility for particular aspects of the development as set forth below in Sections 4.4.2 and 4.4.3(b), as appropriate. Each Party shall also reasonably support the other Party as provided for in the relevant Project Plan to facilitate such other Party's ability to perform its development responsibilities. Chrysalis shall also provide consulting to Discovery with respect to certain of Discovery's responsibilities as set forth below in Section 4.4.3(c).

4.4.2 <u>Responsibilities of Discovery</u>. The specific activities to be undertaken by Discovery in connection with each project and the Supported Products developed pursuant thereto shall be as set forth in the applicable Project Plan. Discovery shall act as the lead Party for, and shall be principally responsible for performing, the following activities with respect to each project: (i) drug product formulation development; (ii) development and implementation of analytical methods for quality assurance/control of Drug Product, Aerosol Device and Disposable Dose Packet; (iii) manufacturing of Supported Products, including manufacturing of the Drug Product, Aerosol Device and Disposable Dose Packet; (iv) filling of Disposable Dose Packet; (v) development of procedures for final release testing and testing of Supported Products; (vi) pre-clinical and clinical development and trials; (vii) regulatory activities relating to the Supported Products, including without limitation submissions to regulatory authorities; (viii) medical affairs, such as adverse event reporting and pharmacovigilance. Discovery shall also be solely responsible for manufacturing and commercializing the Supported Products.

4.4.3 <u>Responsibilities of Chrysalis</u>.

(a) <u>In General</u>. The specific activities to be undertaken by Chrysalis in connection with each Supported Product Development Project and the Supported Products developed pursuant thereto shall be as set forth in the applicable Project Plan.

(b) <u>Development Activities</u>. Chrysalis shall act as the lead Party for, and shall be principally responsible for performing, the following development activities with respect to each Supported Product Development Project: (i) unfilled Disposable Dose Packet development, including the container closure system, aerosolization capillary and patient interface; (ii) Aerosol Device development, including the control unit and pump; and (iii) design and development of filling equipment.

(c) <u>Consulting Services</u>. In addition to the development activities to be performed by Chrysalis, Chrysalis shall also provide certain consulting services to Discovery as set forth in the Project Plan with respect to each Supported Product. In particular, Chrysalis shall provide consulting services to Discovery regarding: (i) manufacturing development for the Aerosol Device and Disposable Dose Packet; (ii) the development and implementation of quality control specifications and processes for the Aerosol Device and Disposable Dose Packet; (iii) training and set-up of the Aerosol Device and Disposable Dose Packet for preclinical and clinical studies; (iv) the development of Discovery's organizational infrastructure to manage manufacturing of the Supported Products; and (v) troubleshooting and corrective measures regarding the Aerosol Device and Disposable Dose Packet.

4.5 <u>Development Effort</u>. Each Party shall use Diligent Development Efforts to develop the Supported Products in accordance with the Project Plans therefor and to otherwise carry out its responsibilities under this Agreement relating to such Supported Products 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 Alliance will be successful in developing any commercially viable Supported Products, or that the development of any Supported Products will proceed as anticipated or in accordance with the Project Plans.

4.6 <u>Development Milestone</u>. As soon as practicable after the Effective Date, Discovery and Chrysalis shall mutually agree in writing with respect to each of the Base Supported Product Development Projects on a particular development milestone related to the development activities to be performed by Chrysalis in connection therewith (e.g., the delivery of an initial Aerosol Device and related Disposable Dose Packet design validated by a prototype) (such event, the "<u>Development Milestone</u>") and the date by which such Development Milestone should reasonably be achieved (the "<u>Milestone Date</u>"). Chrysalis shall use Diligent Development Efforts to achieve the Development Milestone by the Milestone Date. To the extent any delay in achieving such Development Milestone is caused by Discovery or other factors beyond Chrysalis' reasonable control, the Milestone Date shall be equitably extended by the Steering Committee to take into account such delays. If, after taking into account any such equitable adjustments to the Milestone Date, Chrysalis fails to achieve the Development Milestone Date Wilestone Date Product Development Project for a particular Base NICU Product or Base Hospital General Product, then the royalty payments to Chrysalis hereunder in connection with all NICU Products or Hospital General Products, as the case may be, shall be modified as provided in Section 8.1(c).

4.7 <u>Skilled Personnel</u>. Each Party shall promptly assign responsibilities for the various operational aspects of the Alliance, including without limitation, pursuant to Supported Product Development Projects, to portions of their respective organizations which have expertise reasonably appropriate to perform such functions. Each Party shall be solely responsible for making all decisions regarding its staffing and personnel.

4.8 <u>Costs</u>. Except as otherwise expressly provided in this Agreement, each Party shall be solely responsible for all costs incurred by such Party in the performance of its obligations in connection with a Supported Product Development Project. Each Party shall internally budget for its development costs and shall provide resources (financial, personnel and otherwise) in accordance with the budgets set forth in the applicable Project Plans to satisfy their respective responsibilities under such Project Plan.

4.9 Additional Licensed Product Opportunities.

4.9.1 <u>Additional Product Opportunities.</u> In the event that Discovery desires to (a) exercise the rights granted pursuant to Section 3.1 or (b) develop or commercialize any Licensed Product other than the Base NICU Product and the Base Hospital General Product (each, an "<u>Additional Product Opportunity</u>"), then the following shall apply: (i) should Discovery, in its sole discretion, develop any such Additional Product Opportunity independently of Chrysalis (either on its own or with Third Parties), such Additional Product Opportunity shall be deemed to be a Supported Product for the purposes of determining the application of royalties provided for in Section 8.1; (ii) should Discovery, in its sole discretion, offer Chrysalis the opportunity to assist with the development of any such Additional Product Opportunity and (X) should Chrysalis agree to so assist on the terms and conditions provided for in this Agreement, then such Additional Product Opportunity shall be deemed to be a Supported Product of royalties provided for in Section 8.1; or (Y) should Chrysalis choose not to assist, then such Additional Product Opportunity shall be as provided for in Section 8.2.

4.9.2 Procedure. Additional Product Opportunities presented by Discovery to the Steering Committee shall be in a reasonably detailed manner to enable Chrysalis to conduct an evaluation of the potential market and collaborative opportunity with respect thereto. Reasonably promptly following the presentation of any such Additional Product Opportunity, Chrysalis shall make the determination (a) to participate in the development of the Licensed Product that is the subject of the Additional Product Opportunity (in which case such Licensed Product will become a Supported Product Development Project), or (b) not to participate in the development of the Licensed Product that is the subject of the Additional Product). In the event Chrysalis fails to notify Discovery of its decision to participate in such Additional Product Opportunity within sixty (60) days after such presentation, Chrysalis shall be deemed to have elected not to participate. In the event Chrysalis elects to participate in the development of such Licensed Product, the Parties shall commence a Supported Product Development Project with respect to such Supported Product shall be as mutually agreed and set forth in a Project Plan as soon as practicable after each such election. The Parties intend that Chrysalis' and Discovery's responsibilities with respect to such Supported Product shall be reasonably comparable to those set forth in Sections 4.4.2 and 4.4.3 except as otherwise mutually agreed taking into account the particular needs with respect to the development of such Supported Product.

4.10 Design Configurations. Throughout the Term, unless otherwise mutually agreed to by the Parties, it shall be a design objective of the Alliance to minimize the number of different configurations of the Disposable Dose Packets and Aerosol Devices in the Exclusive Field. Furthermore, 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, neither Party shall offer for sale or sell, or authorize any Third Party to offer for sale or sell, any pharmaceutical product (other than a Licensed Product) (i) in the Disposable Dose Packet for a Licensed Product, (ii) in packaging similar in appearance to the Disposable Dose Packet for a Licensed Product, or (iii) in packaging that is interchangeable with the Disposable Dose Packet of a Licensed Product for purposes of use in an Aerosol Device.

ARTICLE 5 GOVERNANCE AND COMMITTEE STRUCTURE

5.1 <u>General</u>. The Alliance shall be governed by the Steering Committee, Alliance Managers, a Project Team and such Working Groups as mutually agreed to by the Parties and as provided in this Article 5. The Steering Committee and the Project Team are collectively referred to herein as the "Committees."

5.2 <u>Alliance Managers</u>.

5.2.1 <u>Appointment and Roles</u>. Promptly after the Effective Date, and in any event within thirty (30) days thereafter, each of the Parties shall appoint a single individual to act as that Party's alliance manager (the "<u>Alliance Manager</u>"). The role of the Alliance Managers is to act as a single point of contact for its respective Party. The Alliance Managers shall have the right to attend all Committee meetings and shall support the Committee chairpersons in the discharge of their responsibilities. Alliance Managers shall be nonvoting participants in such Committee meetings, unless they are also appointed members of such Committee; provided, however, that an Alliance Manager may bring any matter to the attention of any Committee if such Alliance Manager reasonably believes that such matter warrants such attention.

5.2.2 <u>Changes in Alliance Managers</u>. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among the Committees.

5.2.3 <u>Additional Responsibilities of Alliance Mangers</u>. Each Alliance Manager, with respect to its Party, shall also: (i) coordinate the relevant functional representatives of the Parties in developing and executing strategies and plans for the Supported Products in an effort to ensure consistency and efficiency throughout the Territory; (ii) provide a single point of communication for seeking consensus both internally within the respective Parties' organizations and between the Parties regarding key strategy and plan issues with respect to the development of the Supported Products; (iii) plan and coordinate cooperative efforts and internal and external communications; and (iv) take responsibility for ensuring that governance activities, such as the conduct of required Committee meetings and production of meeting minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

5.3 <u>Steering Committee</u>.

5.3.1 <u>Formation and Purpose</u>. Discovery and Chrysalis hereby establish a Steering Committee ("<u>Steering Committee</u>") that shall generally operate by the procedures set forth in Section 5.6. The Steering Committee shall have overall responsibility for the Alliance, including for:

	(i)	managing the overall relationship and development activities for the Supported Products;
	(ii)	overseeing the Project Team;
	(iii)	reviewing, commenting on, and approving or rejecting Project Plans and updates or amendments thereto;
	(iv)	facilitating the flow of information between the Parties and coordinating the activities of the Parties;
Committee by the Project	(v) Team;	attempting to resolve disputes, if any, with respect to general Alliance matters and any disputes referred to the Steering
	(vi)	discussing and making recommendations with respect to Intellectual Property developed under the Alliance; and
by the Parties.	(vii)	performing such other functions as appropriate to further the purposes of this Agreement and the Alliance as determined

5.3.2 <u>Membership, Chairmanship and Meetings</u>. The Steering Committee shall be comprised of representatives of each Party and initially shall consist of senior representatives from each Party having the technical knowledge and decision making authority appropriate for supervising such Party's responsibilities under this Agreement. Each Party shall designate its respective Steering Committee members within thirty (30) days of the Effective Date. Discovery shall designate the Chairperson of the Steering Committee. The Steering Committee shall meet at least every six (6) months.

5.4 <u>Project Team</u>.

5.4.1 <u>Formation and Purpose</u>. Reasonably promptly after the Effective Date, Discovery and Chrysalis shall establish a project team ("<u>Project Team</u>") consisting of representatives designated by each Party. The Project Team shall generally operate by the procedures set forth in Section 5.6.

5.4.2 <u>Specific Responsibilities of the Project Team</u>. In furtherance of its responsibility for overseeing, coordinating and expediting the development of the Supported Products in the Territory, the Project Team shall have responsibility for:

(i) developing Project Plans (including preparation of the applicable budget and related operational plans) for the development of Licensed Products for manufacture by Discovery and technology transfer regarding Licensed Products in coordination with the Design Review Board;

(ii) managing the day-to-day activities related to the operational plans in order to fulfill Project Plans;

(iii) reviewing, amending and updating individual Project Plans on an annual basis as well as more frequently as shall be necessary or advisable to take into account completion, commencement or cessation of development not then contemplated by the Project Plan and submitting such amended or updated Project Plan to the Steering Committee for approval;

- (iv) monitoring the progress of development of any Supported Product;
- (v) facilitating the exchange of all development information;
- (vi) working together to assure a smooth transition from development to Discovery's manufacturing and commercialization;
- (vii) reporting on a regular basis to the senior management of each Party as well as to the Steering Committee; and
- (viii) overseeing any Working Groups established by the Project Team.

5.4.3 <u>Membership, Chairmanship and Meetings</u>. The Project Team shall be comprised of representatives from each Party possessing the appropriate experience and expertise and responsible for: Aerosol Device, Disposable Dose Packet and Drug Product development; quality control/assurance; regulatory affairs; project management; clinical affairs. The initial members of the Project Team for each Party shall be designated promptly following the Effective Date. The Project Team shall be jointly chaired by the Parties. The Project Team shall meet no less than monthly.

5.5 <u>Working Groups</u>. From time to time, the Committees may establish sub-committees or directed teams (each, a "<u>Working Group</u>") on an "asneeded" basis to oversee particular projects or activities. Each such Working Group shall be constituted and shall operate as the applicable parent Committee determines. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the applicable parent Committee that established such Working Group. In no event shall the authority of the Working Group exceed that specified for the relevant Committee in this Article 5. The Parties agree and acknowledge that Alliance Managers shall have access to all members of the Working Groups, at reasonable times and places, so as to be able to have appropriate oversight and direct interaction with such Working Group members.

5.6 <u>General Committee Membership and Procedures</u>.

5.6.1 <u>Membership and Meetings</u>. With respect to the Parties' Committee representatives, each representative may serve on more than one Committee as appropriate in view of such representative's expertise. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Meetings of any Committee may be held by audio or video teleconference with the consent of each Party. All Committee representatives shall be given prior notice of any Committee meetings. Each meeting shall require that representatives from each Party be in attendance before business may be conducted.

5.6.2 <u>Ad Hoc Participants</u>. Other employees of each Party (including the Alliance Managers) may attend meetings of any Committee as nonvoting participants with the reasonable consent of the other Party. In addition, with the consent of both Parties, consultants or advisors to a Party may attend Committee meetings as nonvoting observers; provided that such Third Party representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of each Party and that are at least as stringent as those set forth in Article 11. Each Party shall be responsible for all of its own expenses of participating in any Committee.

5.6.3 Decision-Making. Each Party's representatives on a Committee shall, collectively, have one vote (the "Party Vote") on all matters brought before such Committee, which Party Vote shall be determined by majority vote of such representatives present at any meeting. Except as expressly provided in this Section 5.6.3, each Committee shall operate as to matters within its jurisdiction by unanimous vote (although the vote of the representatives present at a meeting underlying the Party Vote need not be unanimous); provided that only the Steering Committee in accordance with Section 21.15, shall have the authority to amend or modify, or waive compliance with, this Agreement. If a Committee fails to achieve a unanimous vote with respect to any matter, such dispute shall be resolved in accordance with Article 20.

5.6.4 <u>Meeting Agendas and Minutes</u>. The chairperson(s) of each Committee shall be responsible for calling meetings and preparing, and circulating an agenda in advance of each meeting of such Committee. Each Party shall disclose to the chairperson(s) of each Committee proposed agenda items for a meeting, along with appropriate information for such proposed agenda item, at least three (3) Business Days in advance of each meeting of the applicable Committee; provided that under exigent circumstances requiring Committee input, a Party may provide its agenda items to the chairperson(s) of each Committee within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting. The Alliance Managers, or the particular Committee representatives of each Party designated by such Alliance Managers, shall be responsible for, on an alternate basis, preparing and issuing minutes of each meeting within ten (10) days of each Committee meeting; provided, however, that the minutes will not be finalized until both Parties review and confirm the accuracy of such minutes in writing.

5.6.5 <u>Interactions between Committees and Internal Teams</u>. The Parties recognize that while they will establish Committees and Working Groups for the purpose of the Alliance, each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Each Committee and Working Group shall establish procedures to facilitate communications between such Committee or Working Group and the relevant internal committee, team, or board of each Party in order to maximize the efficiency of the Alliance, including by requiring appropriate members of such Committees to be available at reasonable times and places and upon reasonable prior notice for making appropriate oral reports to, and responding to reasonable inquiries from, the relevant internal committee, team, or board of each Party.

5.7 <u>Design Review Board</u>. Discovery shall have the right to designate one or more (as agreed by the Parties) representatives to participate in the design review board established by Chrysalis to oversee the design of Aerosol Devices for use in the Alliance (the "<u>Design Review Board</u>"). The role and voting power of such representative shall be mutually determined by the Parties.

ARTICLE 6 COMMERCIALIZATION

6.1 <u>Exclusive Right to Sell the Licensed Products</u>. The Parties agree that during the Term, subject to Discovery's achievement of the commercialization milestones and minimums in this Article 6, 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.

6.2 <u>Responsibility For Commercialization Matters</u>. Discovery shall have the sole responsibility for all activities associated with the commercialization of the Licensed Products, 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.

6.3 <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 with a particular focus on obtaining Marketing Authorizations for and commercializing Supported Products in the Major Markets. Discovery shall promptly notify Chrysalis of the receipt of any Marketing Authorization for a Licensed Product.

6.3.1 <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 Chrysalis [***].

6.3.2 <u>Commercialization Milestones</u>. Discovery shall meet certain mutually agreed upon commercialization milestones (determined in the best faith of the Parties) with respect to minimum sales levels to be achieved for each Licensed Product in each of the Major Markets. Such commercialization milestones shall be established no later than [***] prior to the First Commercial Sale of such Licensed Product in each of the Major Markets and shall equal Discovery's good faith estimate of total Net Sales for [***] after the First Commercial Sale of such Licensed Product, which estimate shall be the same as the estimate used by Discovery for its financial projections and other business purposes (the "Estimated Sales"). The Estimated Sales for [***] shall be reviewed for compliance [***] prior to the end of [***], and may be reduced for purposes of this calculation of Estimated Sales by up to [***] percent ([***]%) for [***] in the event that Discovery's good faith estimate of such sales has gone down [***] percent ([***]%) or more. Should Discovery fail to satisfy [***] percent ([***]%) of the Estimated Sales levels (taking into account any adjustment in the [***] forecast as provided above) with respect to the subject Licensed Product on a country-by-country basis in the Major Markets for [***].

ARTICLE 7 REGULATORY MATTERS

7.1 Responsibility and Consultation. Discovery shall be responsible for preparing, submitting, seeking and maintaining Marketing Authorization for the Licensed Products in the United States and other jurisdictions in the Territory. Discovery shall consult with Chrysalis regarding, and keep Chrysalis regularly and fully informed with respect to such regulatory matters. Chrysalis shall provide consultant services to Discovery regarding Aerosol Device and Disposable Dose Packet related regulatory matters regarding the Supported Products. Discovery shall provide Chrysalis with advance notice of all regulatory activities regarding the Licensed Products that are initiated by Discovery and Chrysalis shall have the right to participate in any such activities. Within their respective responsibilities as outlined in Article 4, the Parties shall cooperate to provide each other all reasonable assistance and take all actions reasonably requested that are necessary to comply with any material requirement of a Law applicable to Licensed Products. Each Party shall obtain and maintain all necessary Regulatory Approvals for the performance of its obligations and lead responsibilities under this Agreement and shall take all actions necessary to comply with any material requirement of such Party's obligations and the exercise of such Party's rights with respect to the Licensed Products.

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.

7.2 <u>Regulatory Communications</u>. The Parties shall cooperate with respect to all interactions and in the drafting and review of all submissions to Regulatory Authorities. Each Party shall, immediately upon receipt of any significant contact with or communication from any Regulatory Authority relating to a Licensed Product, but in no event more than two (2) Business Days after such receipt or contact, forward a copy (if in writing) or description (if oral) of the same to the other Party and respond to all reasonable inquiries by the other Party relating thereto. Each Party shall, within two (2) Business Days of receipt thereof by such Party, provide notice to the other Party of any additional requirements which a Regulatory Authority may impose with respect to a Regulatory Approval (including, without limitation, additional clinical studies) and of all Regulatory Authority inquiries requiring a response.

7.3 <u>Meetings</u>. To the extent not prohibited by Law, each Party will have an opportunity to participate in all material meetings between the other Party and a Regulatory Authority to the extent that they pertain to the Licensed Products. To the extent practicable, the Alliance Managers and their designees shall use reasonable efforts to agree in advance on the scheduling of such meetings and on the objectives to be accomplished at such meetings, conferences, and discussions and the agenda for the meetings, conferences, and discussions with the Regulatory Authorities. Each Party shall provide the other Party at least five (5) Business Days before any such meeting with copies of all documents, correspondence, and other materials in its possession, which are relevant to the matters to be addressed at any such meeting.

7.4 <u>Sharing of Information</u>. In addition to any other reports required under this Agreement, each Party shall provide to the other Party at least once every three Contract Months copies of all updated data and information provided by such Party to a Regulatory Authority in connection with the Licensed Products in the Territory.

7.5 <u>Discovery's Right to Audit Certain Third Parties</u>. Chrysalis shall use reasonable efforts to obtain from Third Parties providing products or services relating to the Supported Product Development Projects, the right for Discovery or its representatives, with reasonable prior written notice and during regular business hours, (i) to examine and inspect such Third Party's facilities and (ii) subject to applicable law and any Third Party confidentiality restrictions or obligations, to examine and inspect data, documentation, and work products relating to the activities performed by such Third Party.

ARTICLE 8 FINANCIAL PROVISIONS

8.1 <u>Royalties with Respect to Supported Products</u>. For each individual Supported Product:

(a) <u>Royalties Prior to [***]</u>. Until [***] the First Commercial Sale of such Supported Product, Discovery shall pay royalties to Chrysalis on Net Sales of Supported Product(s) as follows depending on the Combined Net Sales attributable to all of the Supported Products during such Contract Year:

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.

Combined Net Sales of Supported Products During Such Contract Year	Royalty Rate
First \$500 million of Combined Net Sales of Supported Products in a Contract Year	[***]% of the Net Sales for the particular Supported Product
Next \$500 million of Combined Net Sales of Supported Products in a Contract Year	[***]% of Net Sales for the particular Supported Product
In excess of \$1 billion of Combined Net Sales of Supported Products in a Contract Year	[***]% of the Net Sales for the particular Supported Product;
	subject to the exception set forth in Section 8.1(c) below.

(b) <u>Royalties Commencing on [***]</u>. Starting [***] the First Commercial Sale of a particular Supported Product, Discovery shall pay royalties to Chrysalis on Net Sales of Supported Product as follows depending on the Combined Net Sales attributable to all of the Supported Products during such Contract Year:

Combined Net Sales of Supported Products During Such Contract Year	Royalty Rate
First \$500 million of Combined Net Sales of Supported Products in a Contract Year	[***]% of Net Sales for the particular Supported Product.
In excess of \$500 million of Combined Net Sales of Supported Products in a Contract Year	[***]% of Net Sales for the particular Supported Product,
	subject to the exception set forth in Section 8.1(c) below.

For the avoidance of doubt, Net Sales with respect to Independent Products shall not be taken into account in the calculation of Combined Net Sales with respect to Supported Product(s) for purposes of Sections 8.1(a) and 8.1(b).

(c) <u>Reduction for Failure to Timely Achieve Development Milestone</u>. In the event that with respect to a particular Base Supported Product Development Project, Chrysalis fails to achieve the applicable Development Milestone by its Milestone Date, after any adjustments in such dates pursuant to Section 4.6, then, unless Discovery shall be entitled to and shall elect to terminate the Agreement pursuant to Section 17.1.1 or a Supported Product Development Project pursuant to Section 17.1.2, **[***]**.

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.

8.2 <u>Royalties with Respect to Independent Products</u>. For each individual Independent Product, Discovery shall pay royalties to Chrysalis on Net Sales of Independent Product(s) in an amount equal to [***]% of Net Sales for such Independent Product.

8.3 <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 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 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 in such jurisdiction in arms length transactions or in the event there are no unbundled transactions, the fair market value of such Net Sales.

8.4 <u>Fixed Consideration</u>. In the event that Discovery receives any fixed payment, fee or other consideration from a Third Party in consideration of any discount, credit or similar allowance granted to such Third Party in connection with the purchase of any Licensed Product(s), then Discovery shall pay to Chrysalis a royalty equal to the product of (a) such consideration multiplied by (b) the royalty rate applicable to the sale of such Licensed Product(s) to such Third Party. Discovery shall report on the amount of any such consideration, and the royalty payable thereon in U.S. Dollars, in the Royalty Report.

8.5 <u>Treatment of Partial Product Sales</u>. In the event that portions of a Licensed Product are sold separately, (e.g., Aerosol Device, Disposable Dose Packet, Drug Product) the royalties payable pursuant to this Article 8 shall be paid **[***]**.

8.6 <u>Royalty Reports</u>. Within [***] days after the end of each Contract Month, 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, as applicable:

(i) the quantity of each of the Licensed 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 [***]; and

(iii) whether each such Licensed Product is a Supported Product or Independent Product;

(iv) 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 8.6.

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.

8.7 Payment of Estimated and Actual Amounts.

8.7.1 <u>Payment of Estimated Amounts</u>. Simultaneous with the issuance of the preliminary Royalty Report, Discovery shall make payment of estimated amounts due to Chrysalis hereunder with respect to such Contract Month (the "<u>Estimated Amount</u>").

8.7.2 <u>Quarterly Reconciliation and True-Up</u>. 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 8.7.1 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. [***]

8.8 <u>Pass-Through Royalties</u>. 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.

8.9 <u>Records and Audits</u>.

8.9.1 <u>Records</u>. 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.

8.9.2 <u>Audit</u>. 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 twice 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 8.12.

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.

8.9.3 <u>Audit Confidentiality</u>. 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.

8.9.4 <u>Costs of Audits</u>. Chrysalis shall pay for such inspections, except that in the event the adjustment shown by such inspection is greater than [***] percent ([***]%) of the amount incurred, Discovery shall pay for such inspection.

8.10 Foreign Exchange. For the purpose of computing the Net Sales for Licensed 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 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 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 8.10 without obtaining Chrysalis' prior written consent, such consent not to be unreasonably withheld.

8.11 <u>Manner of Payments</u>. All sums due to Chrysalis under this Agreement shall be payable by electronic funds transfer in immediately available funds to such bank account(s) as Chrysalis shall designate at least two (2) Business Days in advance.

8.12 Late Payments. 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 8.7, shall not be subject to this Section 8.12.

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.

8.13 <u>Tax Withholding</u>. Any taxes, levies, or other duties ("<u>Taxes</u>") 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 9 INTELLECTUAL PROPERTY

9.1 <u>Ownership</u>.

9.1.1 <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 Effective Date, (ii) all Intellectual Property relating to the Chrysalis Technology or the Licensed Products developed by Chrysalis outside of the performance of the Alliance 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 the Alliance, except Discovery Technology Improvements; and (iv) all Chrysalis Technology Improvements (collectively, "Chrysalis Intellectual Property").

9.1.2 <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 the Alliance, (ii) all Intellectual Property relating to Discovery Technology or the Licensed Products developed by Discovery outside of the performance of the Alliance 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 the Alliance or exercise of the license granted hereunder, except Chrysalis Technology Improvements; and (iv) all Discovery Technology Improvements (collectively "Discovery Intellectual Property").

9.1.3 Joint Intellectual Property. Inventions conceived, created and reduced to practice jointly by or on behalf of the Parties in the course of the performance of the Alliance or exercise of the license granted hereunder shall be jointly owned by the Parties, except regardless of whether such Inventions were jointly conceived, created or developed by the Parties, all Chrysalis Technology Improvements shall be owned by Chrysalis and all Discovery Technology Improvements shall be owned by Discovery, as provided in Sections 9.1.1 and 9.1.2. Any Inventions that are jointly-owned pursuant to the allocation of Intellectual Property Rights set forth in this Section 9.1.3 shall be referred to herein as the "Joint Inventions."

9.2 Disclosure, Assignment, License and Exploitation.

9.2.1 Disclosure. Each Party shall cause all personnel conducting work or exercising rights on its behalf under the Alliance to, promptly disclose to the other Party all Intellectual Property in which the other Party has an ownership interest pursuant to Section 9.1, 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.

9.2.2 <u>Assignment and License</u>. 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 of such Invention 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.

9.2.3 Exploitation of Intellectual Property. To the extent permitted by Law, except as expressly provided in this Section 9.2.3 below, Chrysalis agrees not to exploit the Chrysalis Intellectual Property or its ownership interest in the Joint Intellectual Property in a pharmaceutical product for the Target Populations for the Target Indications in a manner that competes with a Licensed Product(s) in the Hospital Setting for such Target Indications. Notwithstanding the foregoing, this Section 9.2.3 shall not limit Chrysalis' ability to exploit any Inventions conceived, created and reduced to practice solely by or on behalf of Chrysalis after the Effective Date, except Discovery Technology Improvements. To the extent permitted by Law, Discovery agrees not to exploit its ownership interest in the Joint Intellectual Property in a pharmaceutical product for the Target Populations for the Target Indications in a manner that competes with a Licensed Product(s) in the Hospital Setting for such Target Indications.

9.3 <u>Agreement with Personnel</u>. Each Party shall have valid and enforceable written agreements with all personnel conducting work on its behalf under the Alliance containing a nondisclosure obligation comparable in scope to Article 11 and giving the other Party all rights and authority necessary to effectuate the provisions of this Article 9. 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.

9.4 <u>Prosecution of Patents</u>.

9.4.1 <u>Discovery and Chrysalis Patent Filings</u>. Discovery and Chrysalis each shall use commercially reasonable efforts to diligently prosecute their respective Patents claiming a Licensed Product in the Territory. As soon as practicable prior to any contemplated filing, the Party filing a Patent claiming a Licensed Product shall submit a substantially completed draft of the applicable Patent to the other Party for its review and comment, which comments shall be considered in good faith. 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. If the other Party determines that filing one or more continuing or divisional Patents is necessary to cover such Party's rights or commercial interests, then the prosecuting Party shall file such one or more continuing or divisional patents in a timely manner prior to the expiration of any period for making such filings.

9.4.2 Joint Patent Filings. The Parties shall refer any Joint Inventions to the Steering Committee to allow the Steering Committee to determine which Party should be responsible for filing, prosecuting, and maintaining any Joint Patent related to such Joint Invention based on a good faith determination of the relative contributions of the Parties to the Joint Inventions, the relative level of interest of the Parties in the Joint Inventions and the relative extent to which the Licensed Product relating to such Joint Patents is being developed or commercialized. The Steering Committee may decide not to file a Joint Patent for any Joint Invention. The Party determined to be responsible for a Joint Patent shall use commercially reasonable efforts to diligently prosecute that Patent in the Territory. As soon as practicable prior to any contemplated filing, the Party responsible hereunder for such activities shall submit a substantially completed draft of the applicable Joint Patent, the Party responsible hereunder shall inform the other Party of such allowance or grant, and provide the other Party determines that filing one or more continuing or divisional Patents is necessary to cover the Parties' rights or commercial interests in Joint Inventions, then the responsible Party shall file such one or more continuing or divisional patents in a timely manner prior to the expiration of any period for making such filings.

9.4.3 <u>Patent Prosecution Costs</u>. Each Party shall bear its own costs to file, prosecute and maintain its Patents, or Joint Patents for which it is responsible, in the Territory (including, without limitation, patent term extension).

9.4.4 <u>Abandonment of Prosecution</u>. Each Party shall notify the other Party in the event it is unable for any reason to meet its obligations under this Article 9 with respect to any Patents covering the Licensed Products. 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.

9.5 <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 and the Joint 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.

9.6 <u>Third Party Infringement</u>.

9.6.1 <u>Suits for Infringement</u>. 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 ("<u>Infringement Notice</u>"). 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.

9.6.2 <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.

9.6.3 <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 9.6 shall be shared among the parties as follows: **[***]**

9.6.4 <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, 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 9.6.3.

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.

9.7 <u>Infringement of Third Party Rights</u>.

9.7.1 <u>Infringement Claims</u>. 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.

9.7.2 <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.

9.7.3 <u>Notice of Certification</u>. 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, Chrysalis Patents or the Joint 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 10 RIGHT OF FIRST ACCESS TO CERTAIN ADDITIONAL OPPORTUNITIES

10.1 <u>First Access Products</u>. During the five year period commencing on the Effective Date and ending on the fifth anniversary thereof, each Party shall provide the other with the first option to negotiate described in this Article 10 (the "<u>Right of First Access</u>") with respect to all First Access Product. A "<u>First Access Product</u>" shall mean a combination drug-device product comprised of an aerosolization device and an active pharmaceutical compound (other than a Pulmonary Surfactant) which pharmaceutical product (a) is intended for the treatment of a Respiratory Indication in the Hospital Setting in the Target Populations and (b) is a pharmaceutical compound that such Party has the right to market and sell and there is no restriction as to the use of Discovery or Chrysalis, as applicable, as a development or commercialization partner for combination drug-device products containing such pharmaceutical compound.

10.2 <u>Provision of Right of First Access</u>. Each Party shall provide to the other the Right of First Access within sixty (60) days of such Party's completion of a phase 2 clinical trial for FDA submission (constituting a study of a candidate drug in the target patient population of a sufficient number and sufficient length of time whereby adequate safety data is provided and there is a clear indication of dosage effects with respect to efficacy as defined in the study protocol for such drug candidate). Such completion date shall be referred to as the "Phase 2 Completion Point".

10.3 First Access Product Presentation. Within sixty (60) days after the Phase 2 Completion Point for a First Access Product, the Party which developed the First Access Product shall, in compliance with any Third Party confidentiality restrictions, present the opportunity for the treatment of the specified indication in the Target Population to the other Party in a reasonably detailed manner to enable the receiving Party to conduct an evaluation of the potential market and collaborative opportunity with respect thereto (the "<u>First Access Product Presentation</u>").

10.4 <u>Negotiation of First Access Product Arrangements</u>. Within thirty (30) days from the date of the First Access Product Presentation, the receiving Party shall notify the presenting Party in writing whether it desires to enter into negotiations with respect to a potential commercial arrangement regarding the development and/or commercialization of such First Access Product for the treatment of a Respiratory Indication in the Hospital Setting. In the event the receiving Party notifies the presenting Party of its desire to negotiate a possible commercial arrangement during such thirty (30) day period, the Parties shall promptly commence such negotiations. In the event the receiving Party fails to notify the presenting Party of its desire to negotiate a possible commercial arrangement during such thirty (30) day period, or the Parties fail, despite such negotiations to enter into definitive agreements within sixty (60) days of the date of the initiation of such negotiations, the presenting Party shall be entitled to negotiate and enter into commercial arrangements with Third Parties relating to the First Access Product for the specified indication in the Target Population, provided that any such arrangements with Third Parties shall not be on terms that are, in substance, more favorable than those offered to the receiving Party, taking into account the relative merits of the respective technologies and the development and commercialization capabilities of the prospective partners.

ARTICLE 11 CONFIDENTIAL INFORMATION

11.1 Use of Confidential Information. 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 11. 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 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 11. 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.

11.2 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. 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 will use best efforts to cause its directors, officers, employees, affiliates, agents and advisors and their representatives to comply with the terms of this Section. A Receiving Party may disclose Confidential Information belonging to a Disclosing Party to the extent such disclosure is reasonably necessary to enforce the provisions of this Agreement.

11.3 <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 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.

11.4 Publications. 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 Alliance 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.

11.5 <u>Public Announcements</u>. Subject to Section 11.2 and Section 11.3, 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, provided however that each Party may disclose (i) the general stage of development, commercialization and manufacturing at any given time during the course of the Alliance, except to the extent that any such information constitutes Confidential Information, (ii) any information required by Law, and (iii) 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 11, 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. At each Party's option, public releases by the other Party concerning the Alliance, including press releases, technical publications, regulatory filings, seminar and conference speeches and posters, interviews, videos and other public statements concerning the Alliance shall mention the other Party as a development partner.

11.6 <u>Survival</u>. The obligations and prohibitions contained in this Article 11 shall survive the expiration or termination of this Agreement.

ARTICLE 12 REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents, warrants and covenants to the other Party that as of the Effective Date:

12.1.1 <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.

12.1.2 <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.

12.1.3 <u>No Conflict</u>. 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.

12.1.4 <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.

12.1.5 <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.

12.2 <u>Intellectual Property</u>. Discovery represents, warrants, and covenants to Chrysalis that as of the 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 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 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.

(ii) To its 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.

(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.

(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; and to its knowledge (a) the manufacture, development and commercialization of the Licensed Products will not infringe the Patents of any Third Party and (b) there are no Third Party patent applications pending which, if issued, would materially adversely affect the ability to make, use or sell the Licensed Products.

(v) It has not granted any third party any license, covenant not to sue, options, or other right with respect to such Intellectual Property that would impact its ability to enforce such Intellectual Property. 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 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 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.

12.3 <u>No Adverse Effects</u>. Discovery represents, warrants and covenants to Chrysalis 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 Alliance, and as of the Effective Date, Discovery has not been informed of any such adverse effects or toxicity.

ARTICLE 13 ADDITIONAL COVENANTS

13.1 <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.

13.2 <u>Cooperation</u>. The Parties agree that maintaining effective and open communication between the Parties on matters relating to the Alliance is important to the success of the Alliance. Upon reasonably advance notice, each Party shall make its employees and consultants reasonably available to consult with the other Party on any aspect of the relationship, including regulatory, scientific, technical and clinical testing issues and shall provide the other Party reasonable access to materials relating to the development of Licensed Products.

13.3 <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 14 DISCLAIMERS AND LIMITATION OF LIABILITY

14.1 <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 14 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.

14.2 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 14.2 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 14, OR ANY REMEDIES OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

ARTICLE 15 INDEMNIFICATION; INSURANCE

15.1 <u>Indemnification</u>.

(i)

15.1.1 <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 "Third Party Claim") arising out of or related to:

this Agreement;

any material breach by the indemnifying Party of any of its representations, warranties, covenants or obligations pursuant to

(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, provided, however, that each Party maintains the right to seek indemnification pursuant to this Section 15.1.1 with respect to strict liability claims by Third Parties to the extent that the other Party's negligence resulted in such strict liability claim; and

(iii) intellectual property infringement and trade secret misappropriation liability resulting from acts or omissions by the indemnifying Party, its Affiliates and sublicensees relating to the development, manufacture, or commercialization of any Licensed Product.

15.1.2 Certain Product Liability Claims. In addition to the indemnity set forth in Section 15.1.1 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 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, except to the extent such Losses are due to matters for which Chrysalis is required to provide indemnification pursuant to Section 15.1.1.

15.1.3 <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 15.1 shall also be reimbursed by the Indemnitor.

15.2 <u>Indemnification Procedures</u>.

15.2.1 <u>Notification</u>. In the case of a Third Party Claim as to which a Party may be obligated to provide indemnification pursuant to this Agreement (the "<u>Indemnitor</u>"), such Indemnified Party seeking indemnification hereunder ("<u>Indemnitee</u>") 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.

15.2.2 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.

15.2.3 <u>Settlements</u>. 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).

15.3 Insurance. Each Party 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. Each Party 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 such Party which Third Party Claims may arise from the development, manufacture, and/or commercialization of a Licensed Product in the Territory. Upon reasonable request by a Party, the other Party 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 15.3 may be satisfied by commercially reasonable self-insurance or a commercially reasonable combination of insurance.

ARTICLE 16 TERM

This Agreement shall become effective on the Effective Date, and unless terminated earlier in accordance with the provisions of Article 17 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 "<u>Term</u>").

ARTICLE 17 TERMINATION

17.1 <u>Termination for Material Breach</u>.

17.1.1 <u>Right to Terminate Agreement</u>. If a Party (the "<u>Breaching Party</u>") commits a material breach of this Agreement and fails to cure such breach within the applicable Cure Period (as provided in 17.1.3 below), the other Party (the "<u>Non-Breaching Party</u>") 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 17.1.3, 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.

17.1.2 <u>Right to Terminate Supported Product Development Projects</u>. If a Party (the "<u>Breaching Party</u>") commits a material breach of its obligations in connection with a Supported Product Development Project and fails to cure such breach within the applicable Cure Period (as provided in 17.1.3 below), the other Party (the "<u>Non-Breaching Party</u>") may, by written notice of termination within thirty (30) days after the expiration of the applicable Cure Period elect to terminate such Supported Product Development Project and/or any other Supported Product Development Project that has been affected by such material breach. In the event that Discovery terminates any Supported Product Development Project pursuant to this Section 17.1.2 due to a material breach by Chrysalis, **[***]**. If such material breach by Chrysalis also constitutes a material breach of the Agreement, Discovery may, at its option, terminate this Agreement pursuant to Section 17.1.1. In the event that Chrysalis terminates any Supported Product Development Project pursuant to this Section 17.1.2 due to a material breach by Discovery, **[***]**. If such material breach by Discovery also constitutes a material breach of the Agreement, Chrysalis may, at its option, terminate this Agreement pursuant to Section 17.1.1.

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.

17.1.3 <u>Applicable Cure Periods</u>. Upon receipt of written notice of a material breach pursuant to Section 17.1.1 or 17.1.2, and except as otherwise provided for in Section 17.1.1, 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.

17.2 <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.

17.3 Effects of Termination Generally

17.3.1 <u>Accrued Obligations; Survival.</u> 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 obligations of exclusivity set forth in Section 3.5 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 8; 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. **[***]**

17.3.2 <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.

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.

ARTICLE 18 TECHNOLOGY TRANSFER

18.1 <u>Technology Transfer</u>. Commencing **[***]** after the Effective Date, Chrysalis shall provide Discovery with a technology transfer reasonable in scope to enable the practice of the Chrysalis Technology for purposes of exercising the license rights granted hereunder. Upon expiration or termination of any Supported Product Development Project other than termination by Chrysalis pursuant to Section 17.1 or 17.2, Chrysalis shall provide Discovery with an incremental technology transfer with respect to such Supported Product Development Project reasonable to enable the practice of the Chrysalis Technology utilized in connection with such Supported Product Development Project, to the extent such technology transfer has not previously occurred.

18.2 <u>Transfer of Regulatory Files, Data and Filings</u>. In connection with the technology transfer contemplated pursuant to Section 18.1, 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. Chrysalis shall also provide to Discovery copies of and permit Discovery to reference in connection with any Licensed Products all reasonably necessary Regulatory Data relating to Licensed Product to continue the development, marketing and sale of the Licensed Product. 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 19 STANDSTILL AGREEMENT

19.1 <u>General Standstill</u>. Except as set forth in this Section 19.1, Chrysalis hereby agrees that, without the written consent of Discovery, during the Term and for a **[***]** 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 "<u>Exchange Act</u>"), 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); 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.

19.2 <u>Certain Exceptions</u>. Nothing in this Article 19 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.

19.3 Exception for an Acquisition Transaction. This Article 19 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 19 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 19 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 19 shall once again apply.

19.4 <u>Other Agreements</u>. Notwithstanding anything in this Agreement to the contrary, Discovery agrees that if, subsequent to the date hereof and prior to the end of the **[***]** period following the Term, any other party which becomes a licensee of Discovery patents or other technology does not agree to the terms contained in this Article 19, or agrees to terms that are materially less restrictive to such other party than those contained in this Article 19, then Discovery will so notify Chrysalis, and will as appropriate describe in such notice any such less restrictive terms and, if Chrysalis elects, the provisions of this Article 19 will be deemed to have been modified to delete the provisions of this Article 19 or to provide Chrysalis with the benefit of such materially less restrictive terms, as appropriate.

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.

ARTICLE 20 DISPUTE RESOLUTION

20.1 <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 unresolved by the Steering Committee (a "Dispute") shall be settled in accordance with the provisions of the Parties as provided for in Section 20.2. 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.

20.2 Escalation and Executive Negotiation. Any dispute or disagreement between the representative of Discovery and Chrysalis on the Project Team as to matters within such Project Team's jurisdiction shall, at the election of either Party, be addressed, first, with the Alliance Managers, and if the dispute is not resolved within ten (10) Business Days after such referral to the Alliance Managers, then it shall, at the election of either Party, be submitted to the Steering Committee for resolution, provided however that after the expiration or termination of this Agreement, such disputes shall be referred directly to the senior executives of the Parties as provided for in this Section 20.2. The Steering Committee shall attempt in good faith to resolve any issues presented to it. If the Steering Committee, after acting in good faith and in a diligent manner, is unable to resolve any Dispute submitted to it within a reasonable period of time and in any event within thirty (30) days of such submission, such matter shall, at the election of either Party, be referred for good faith negotiation to a senior executive of each Party.

20.3 <u>Mediation</u>. If the senior executives referenced in Section 20.2 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.

20.4 <u>Arbitration</u>.

20.4.1 <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 20.4.

20.4.2 <u>Rules and Procedures</u>. Except as expressly otherwise provided in this Agreement, any Dispute shall be finally settled by arbitration under the then-current expedited procedures applicable to the then-current Commercial Arbitration Rules of the AAA in accordance with the terms set forth in this Section 20.4. 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.

20.4.3 <u>Awards</u>. 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.

20.4.4 <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.

20.4.5 <u>No Other Forum</u>. Except as provided in Section 20.5, the provisions of this Section 20.4 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 20.4 shall pay the costs of the other Party, including, without limitation, reasonable attorney's fees and defense costs.

20.5 <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 21 MISCELLANEOUS

21.1 <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.

21.2 <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.

21.3 <u>Relationship of the Parties</u>. 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 employee-employee relationship between the Parties.

21.4 <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.

21.5 <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 21.5 shall terminate as of the date on which such agreement and the obligations regarding noncompetition have terminated or expired in accordance with its terms.

21.6 <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 11, (ii) the use of such entities does not in any way materially diminish 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 or a company engaged in the development or sale of Aerosol Technologies 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 21.7, 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.

21.7 <u>Assignment</u>. 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 21.6 (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 Chrysalis, subject only to the limitations set forth in Section 21.6 (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 21.6 (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.

21.8 <u>Further Assurances and Actions</u>. From time to time after the 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.

21.9 <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.

21.10 <u>Section 365(n) of the Bankruptcy Code</u>. 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 "<u>Bankruptcy</u> <u>Code</u>"), 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.

21.11 Notices. 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 Morin & Oshinsky, LLP 1177 Avenue of the Americas, 47th Fl New York, NY 10036 Attention: Ira L. Kotel, Esq.

21.12 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 visa 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.

21.13 <u>Registration and Filing of this Agreement</u>. 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 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.

21.14 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 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.

21.15 <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 Chrysalis.

21.16 <u>Third Party Beneficiaries</u>. Except for any Third Party Indemnities under Article 15, 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.

21.17 <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 USA INC., d/b/a CHRYSALIS TECHNOLOGIES

By: /s/ John R. Nelson

Name: John R. Nelson Title: President, Operations and Technology

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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



Discovery Labs Forms a Strategic Alliance with Chrysalis Technologies to Develop Aerosolized Surfactant Replacement Therapies for Respiratory Diseases

Combination of precision-engineered lung surfactant and robust aerosolization technology holds promise to revolutionize respiratory medicine

Conference Call Monday, December 12 at 10:00 AM EST -- 866-332-5218

Warrington, PA, December 11, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), entered into a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc., for Discovery Labs to develop and commercialize aerosolized surfactant replacement therapies (aSRT) to address a broad range of serious respiratory conditions. This alliance unites two highly complementary respiratory technologies -- Discovery Labs' precision-engineered surfactant technology that mimics the most important attributes of human lung surfactant, with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. The successful application of these two proprietary technologies holds the promise, for the first time, of producing surfactant-based therapies that may revolutionize the treatment of serious respiratory conditions such as acute lung injury, neonatal respiratory failure, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others.

The alliance focuses on therapies for hospitalized patients, including those in the neonatal intensive care unit (NICU), pediatric intensive care unit (PICU) and the adult intensive care unit (ICU), and can be expanded into other hospital applications and ambulatory settings. Discovery Labs and Chrysalis will utilize their respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. Discovery Labs is responsible for aSRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products. Discovery has exclusive rights to Chrysalis 'aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis receives from Discovery Labs a tiered royalty, the base royalty applies to aggregate net sales of less than \$500 million, increases on aggregate net sales in excess of \$500 million, and increases again on aggregate net sales of alliance products in excess of \$1 billion.

Surfactants are substances that are produced naturally in the lungs, are essential for proper breathing, and their dysfunction is associated with serious respiratory diseases. Up to now the medical community has been unable to utilize the full potential of surfactant replacement therapies. Currently available surfactants are animal-derived which limits their broad use including the lack of ability to produce therapeutically meaningful aSRT. Discovery's technology is a precision-engineered pulmonary surfactant capable of being formulated to produce aerosols that retain their essential therapeutic properties allowing for the development of a potentially broad portfolio of aSRT products. Chrysalis' technology is designed with the potential to enable or enhance the delivery of such compounds to the deep lung.

Steven M. Donn, M.D., Professor of Pediatrics, Director, Neonatal-Perinatal Medicine at the University of Michigan Health System commented, "An aerosolized surfactant based therapy could transform the way the neonatal medical community addresses the array of respiratory problems that beset fragile premature infants. Presently, neonatologists have limited pharmacologic options to treat neonatal respiratory failure with many infants suffering significant morbidity and requiring costly treatments and prolonged hospital stays. Aerosolized surfactant replacement therapy represents a novel therapeutic approach that the medical community eagerly anticipates applying to help these very vulnerable babies."

Michael Matthay, M.D., Professor of Medicine and Anesthesia at the University of California, San Francisco and an internationally renowned expert in pulmonary critical care medicine, commented, "Increasingly, the medical community has focused on a comprehensive strategy to treat serious respiratory disease such as those treated by the National Heart Lung Blood Institute ARDS NETWORK, an association of clinicians and hospitals supported by the NIH to treat a life-threatening respiratory disease, acute respiratory distress syndrome (ARDS). As a component of implementing a Lung Protection Strategy, the possibility of having a novel precision-engineered surfactant delivered as an aerosol for patients early in the disease process is exciting. Additionally, this combined technology may serve as a system for pulmonary drug delivery."

Chrysalis Technologies Aerosol Generation Technology

Chrysalis Technologies has developed a proprietary aerosol generation technology that is being designed with the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications. The Chrysalis technology (covered by over 40 patents and patent applications) is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery. Aerosols are created by pumping the drug formulation through a small, heated capillary wherein the excipient system is substantially converted to the vapor state. Upon exiting the capillary, the vapor stream quickly cools and slows in velocity yielding a dense aerosol with a defined particle size. The defined particle size can be readily controlled and adjusted through device modifications and drug formulation changes.

Discovery Labs' Surfactant Replacement Technology

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the air sacs. Discovery Labs' surfactant product candidates contain a precision-engineered peptide that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the protein that is most important for the proper functioning of the respiratory system. Discovery Labs' SRT has the ability to be precisely formulated to address various medical indications.

Discovery Labs' SRT technology was invented at The Scripps Research Institute, was further developed by Johnson & Johnson, and is exclusively licensed to Discovery Labs. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. AerosurfTM, the Company's lead aerosol product, has recently completed a pilot Phase 2 clinical trial to address neonatal respiratory failure.

Robert J. Capetola, Ph.D., President and CEO of Discovery Labs, commented, "Aerosolized surfactant replacement therapy that can be reliably and consistently delivered deep into patients' lungs has the potential to transform respiratory medicine. Based on the successes we have realized to this point, we are confident about the potential of our surfactant technology -- we anticipate FDA approval of our lead product, Surfaxin for RDS in April 2006; our scientists have demonstrated that our SRT can be aerosolized at the proper particle size with the fluid dynamics capable of penetrating the deep lung; and we have successfully completed pilot Phase 2 clinical studies of our aerosolized SRT in neonates with RDS and in adults with mild to moderate asthma. To capitalize on this opportunity, it is necessary to combine our SRT technology with a robust aerosol generation technology into a comprehensive systems approach that can be engineered into products that provide optimal delivery to the lungs, functional patient interfaces and ease of use by medical practitioners.

During the past two years, our scientific team has assessed several aerosol generating technologies. This alliance is the culmination of a comprehensive feasibility evaluation, that took place over the last year, which successfully demonstrated the capabilities of Chrysalis' technology. Chrysalis' technology demonstrated an ability to consistently and reliably deliver, over extended periods of time, aerosolized surfactant at output rates that we believe are appropriate for therapeutic utility in neonates, children and adults. We now have access to a leading aerosolization technology with the product development and engineering expertise of Chrysalis - thus strengthening our capabilities to achieve our vision. Beginning in 2006, we will further advance our pipeline of aerosolized surfactant replacement therapies, starting with our lead aerosol product, Aerosurf."

The Lead Program - Aerosurf[®] for the NICU

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in the NICU. There are approximately 1.5 million premature infants born annually worldwide at risk for respiratory problems associated with surfactant dysfunction. Neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the invasive process of inserting a breathing tube down the trachea). Noted neonatologists have commented on the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from an array of respiratory disorders.

Aerosurf is Discovery Labs' precision-engineered aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants at risk for respiratory failure. In September 2005, Discovery Labs completed and announced the results of a pilot Phase 2 clinical study of Aerosurf which was designed to evaluate its feasibility, safety and tolerability for the prevention of RDS in premature infants. The study demonstrated that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated. The Phase 2 study of Aerosurf did not include the Chrysalis technology.

Discovery Labs and Chrysalis believe that the combination of their respective technologies and expertise can develop a systems approach to optimize the therapeutic application of Aerosurf for neonatologists to treat premature infants suffering from respiratory failure. Discovery Labs anticipates conducting multiple Phase 2 clinical studies of Aerosurf in 2006.

Aerosurf is an investigational drug that has not been approved by the U.S. FDA or any other world health regulatory authorities.

Conference Call Details

Discovery Labs will hold a conference call Monday at 10:00 AM EST to further discuss in greater detail the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <u>http://audioevent.mshow.com/262604</u> and <u>www.discoverylabs.com</u>. It is recommended that participants log onto one of these sites at least 15 minutes prior to the call. The Internet broadcast will be available for up to 30 days after the call at both website addresses. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 2880078.

About Chrysalis Technologies

In 2000, Chrysalis Technologies Inc. was established as a subsidiary of Altria Group, Inc. Since January of 2005, the former operations of Chrysalis have been a business division of Philip Morris USA (PM USA), a wholly owned subsidiary of Altria Group, Inc. Chrysalis has developed its aerosol generation platform for pulmonary drug delivery and is focused on the development and commercialization of this technology.

Altria Group, Inc. (NYSE: MO) owns approximately 86.5% of the outstanding common shares of Kraft Foods Inc. and 100% of the outstanding common shares of Philip Morris International Inc., Philip Morris USA Inc. and Philip Morris Capital Corporation. Altria Group, Inc. recorded 2004 net revenues of \$89.6 billion.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

Under the terms of our arrangements with Chrysalis, Discovery will be responsible for manufacturing any of the potential combination drug-device products that we may pursue. To successfully do so, Discovery will need to develop and implement certain manufacturing and technical capabilities necessary to take advantage of the relevant Chrysalis aerosolization technology and know-how that is being licensed by Discovery.

For more information, please visit our corporate website at www.Discoverylabs.com.

To the extent that statements in this press release are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain gualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers and development partners to provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in Discovery's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

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