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

FORM 10-K

x **Annual Report pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004

o **Transition report pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**94-3171943**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2600 KELLY ROAD, SUITE 100, WARRINGTON, PENNSYLVANIA 18976-3646
(Address of principal executive offices) (Zip Code)

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

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

Title of each class	Name of each exchange on which registered
None	None

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

Common Stock, $.001 par value and,
Preferred Stock Purchase Rights
(Title of class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES x NO o

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on NASDAQ National Market under the symbol DSCO on June 30, 2004, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $381 million. For the purposes of determining this amount only, the registrant has defined affiliates to include: (a) the executive officers named in Part III of this Annual Report on Form 10-K; (b) all directors of the registrant; and (c) each shareholder that has informed the registrant by February 29, 2004 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 14, 2005, 53,511,946 shares of the registrant's common stock were outstanding.

Portions of the information required by Items 10 through 14 of Part III of this Annual Report on Form 10-K are incorporated by reference to the extent described herein from our definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2004 fiscal year.

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

FORWARD LOOKING STATEMENTS

The statements set forth under Item 1: “Business” and elsewhere in this report, including in Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operation - Risks Related to Our Business” and those incorporated by reference herein which are not historical, including, without limitation, statements concerning our research and development programs and clinical trials, the possibility of submitting regulatory filings for our products under development, the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products, the research and development of particular compounds and technologies and the period of time for which our existing resources will enable us to fund our operations, constitute “Forward Looking Statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: risk that financial conditions may change; risks relating to the progress of our research and development; the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies); risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all; risk that our internal sales and marketing organization will not succeed in developing market awareness of our products; risk that our internal sales and marketing organization will not be able to attract or maintain qualified personnel; risk of delay in the FDA’s or other health regulatory authorities’ approval of any applications we file; risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; risks relating to the ability of our third party contract manufacturers to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies; risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of our clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies; and the other risks and certainties detailed in Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operation - Risks Related to Our Business,” and in the documents incorporated by reference in this report. 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.

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

DISCOVERY LABORATORIES, INC.
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For the Fiscal Year Ended December 31, 2004

PART I

ITEM 1. BUSINESS.

COMPANY SUMMARY

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary precision-engineered lung surfactant technology as Surfactant Replacement Therapies (SRTs) for respiratory diseases. Surfactants are compositions produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactants is involved in a number of respiratory diseases.

Our technology produces a precision-engineered, peptide-containing surfactant that is designed to closely mimic the function of human lung surfactant. We believe that through this SRT technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the Neonatal Intensive Care Unit (NICU), critical care unit and other hospitalized settings, where there are few or no approved therapies available.

In February 2005, we received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for clearance to market Surfaxin^{Ò} (lucinactant), our lead product, for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants. The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that we must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. Based on the nature of the observations contained in the Approvable Letter, we currently anticipate that we will respond to the FDA with a "Class 2" response. A "Class 2" response allows the FDA up to six months following the completion of the labeling and manufacturing issues outlined in the Approvable Letter. We have also filed a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMEA) for clearance to market Surfaxin for the same indication in Europe.

In addition to the New Drug Application (NDA) we filed for Surfaxin for RDS, we are conducting several NICU therapeutic programs in an effort to enhance the potential commercial and medical value of our SRT by addressing the most prevalent respiratory disorders affecting infants in the NICU. The programs we are conducting include therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs confronting the neonatal community. We are conducting three Phase 2 clinical trials - Surfaxin for Bronchopulmonary Dysplasia (BPD) in premature infants, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) for Neonatal Respiratory Failures, and a prophylactic/early treatment trial for Surfaxin for the treatment of Meconium Aspiration Syndrome (MAS) in full term infants.

In an effort to enhance the potential commercial and medical value of our SRT, we are also developing SRT to address unmet respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial for the treatment of ARDS in adults in the intensive care unit (ICU), for which we announced preliminary data on December 7, 2004. With our aerosolized surfactant formulations, we have completed a Phase 1b trial and are preparing to initiate a Phase 2 trial for patients with moderate to severe asthma (development name DSC-104). In addition, we are evaluating the development of aerosolized formulations of our precision-engineered SRT to potentially treat Acute Lung Injury (ALI), Chronic Obstructive Pulmonary Disease (COPD) and rhinitis/sinusitis.

In anticipation of the potential approval of Surfaxin for RDS in the United States, we are presently building sales and marketing capabilities to execute the launch of Surfaxin. This specialty pulmonary United States sales and marketing organization will focus initially on opportunities in the NICU and, as products may be developed, the focus will be expanded to critical care and hospital settings. We plan on implementing our commercialization strategy for Surfaxin in Europe and the rest of the world through corporate partnerships.

In addition, our long-term commercial strategy includes building manufacturing capabilities for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs in the United States and Europe. To support a long-term manufacturing strategy for the production of clinical and commercial supply of our precision-engineered surfactant drug product, we are evaluating further development and scale-up of our current contract manufacturer, Laureate Pharma, Inc. (Laureate), alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet our production needs as they expand. Upon marketing approval, if at all, we intend to rely on outside manufacturers for production of our products.

SURFACTANT TECHNOLOGY

Our precision-engineered surfactant replacement technology was invented at The Scripps Research Institute and was exclusively licensed to Johnson & Johnson which, together with its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, developed it further. We acquired the exclusive worldwide sublicense to the technology in October 1996.

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. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli, or air sacs, that line the inside of the lungs. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. In addition to lowering aveolar surface-tension, surfactants play other important roles in human respiration including, but not limited to, lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

Presently, the FDA has approved surfactants as replacement therapy only for RDS in premature infants, a condition in which infants are born too soon and thus have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Although they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for RDS in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, however, this product does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there can potentially be significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

Our precision-engineered surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a precision-engineered peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the surfactant protein that is most important for the proper functioning of the respiratory system. Our products have the ability to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various medical indications.

We believe that our precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and has no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially fulfill significant unmet medical needs. In addition, we believe that our precision-engineered surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient’s lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”).

Aerosolized Surfactant Formulations

Many respiratory diseases are associated with an inflammatory event that causes surfactant dysfunction and a loss of patency of the conducting airways. Scientific data support the premise that the therapeutic use of surfactants in aerosol form has the ability to reestablish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. Surfactant normally prevents moisture from accumulating in the airways’ most narrow sections and thereby maintains the patency of the conducting airways.

We are currently developing aerosolized formulations of our precision-engineered surfactant to potentially treat patients who could benefit from surfactant-based therapy to improve lung function and maintain proper airflow through the respiratory system. We are conducting a Phase 2 trial for aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) for Neonatal Respiratory Failures. In addition, we have completed a Phase 1b trial using a proprietary aerosolized surfactant formulation and are preparing to initiate a Phase 2 trial for patients with moderate to severe asthma (development name DSC-104). We are also evaluating the development of aerosolized formulations of our precision-engineered SRT to potentially treat ALI, COPD, and rhinitis/sinusitis.

Products for the Neonatal Intensive Care Unit

Surfaxin® (Lucinactant) for Respiratory Distress Syndrome in Premature Infants

RDS is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for the infant to undergo surfactant replacement therapy or mechanical ventilation. RDS is experienced in approximately half of the babies born between 28 and 32 weeks gestational age. The incidence of RDS approaches 100% in babies born less than 26 weeks gestational age. Surfaxin is the first precision-engineered, protein B-based agent that mimics the surface-active properties of human surfactant. To treat premature infants suffering from RDS, surfactants, including Surfaxin, are delivered in a liquid form and injected through an endotracheal tube (a tube inserted into the infant's mouth and down the trachea).

For RDS, we conducted a Phase 3 pivotal trial, which formed the basis of our New Drug Application to the FDA that was filed in April 2004, and a supportive Phase 3 trial.

The pivotal Phase 3 trial enrolled 1,294 patients and was designed as a multinational, multicenter, randomized, masked, controlled, prophylaxis, event-driven, superiority trial to demonstrate the safety and efficacy of Surfaxin over Exosurf®, an approved, non-protein containing synthetic surfactant. Survanta®, a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. Key trial results were assessed by an independent adjudication committee comprised of leading neonatologists and pediatric radiologists. This committee provided a consistent and standardized method for assessing critical efficacy data in the trial. An independent Data Safety Monitoring Board (DSMB) was responsible for monitoring the overall safety of the trial and no major safety issues were identified. We anticipate the publication of the results of this trial in a leading, peer reviewed journal in April 2005.

The supportive, multinational Phase 3 clinical trial enrolled 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf®, a porcine (pig) derived surfactant and the leading surfactant used in Europe. This trial demonstrated the overall safety and non-inferiority of Surfaxin to Curosurf.

In February 2005, we received an Approvable Letter from the FDA for clearance to market Surfaxin, our lead product, for the prevention and treatment of RDS in premature infants. The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that we must meet primarily involve finalizing labeling and correcting certain manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. Based on the nature of the observations contained in the Approvable Letter, we currently anticipate that we will respond to the FDA with a "Class 2" response. A "Class 2" response allows the FDA up to six months following the completion of the labeling and manufacturing issues outlined in the letter to complete its review of our response.

With respect to the manufacturing issues mentioned above, in January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate, our contract manufacturer of Surfaxin, citing certain observations concerning Laureate's compliance with current Good Manufacturing Practices (cGMPs) in connection with its review of our NDA for Surfaxin for RDS. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, a cGMP Action Plan was submitted to the FDA on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of marketing clearance for Surfaxin, we anticipate that the potential approval and commercial launch of Surfaxin for the United States will occur in the first quarter of 2006. Our other clinical programs currently in progress are not affected by this inspection report and remain on track. However, if the inspection observations noted in the Form 483 are not resolved in the time period stated above, a delay may occur in these programs.

In October 2004, the European Medicines Evaluation Agency validated our Marketing Authorization Application that we had filed previously for clearance to market Surfaxin for the same indication in Europe. This validation indicated that the Marketing Authorization Application was complete and that the review process had begun. We anticipate the potential approval of Surfaxin for Europe will occur in the first quarter of 2006.

There are over 3,000,000 premature infants born annually worldwide. More than 750,000 of these premature infants are considered "very low birth weight" infants (less than 1,250 grams), of which, approximately 550,000 are considered at significant risk for RDS. Due to limitations associated with the animal-derived surfactant products that are currently approved to treat RDS in premature infants, access to such therapy is mainly limited to the approximately 150,000 very low birth weight infants born in the United States and Western Europe. This results in hundreds of thousands of premature infants born in the world each year who need, but do not receive, effective surfactant replacement therapy.

The FDA has granted us Orphan Drug Designation for Surfaxin for RDS. Orphan drugs are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of orphan drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. Most recently, the Commission of the European Communities has designated Surfaxin as an Orphan Medicinal Product for the prevention and treatment of RDS in premature infants. This designation allows us exclusive marketing rights for Surfaxin for indications of RDS in Europe for 10 years (subject to revision after six years) following marketing approval by the European Medicines Evaluation Agency. In addition, the designation enables us to receive regulatory assistance in the further development process of Surfaxin, and to access reduced regulatory fees throughout its marketing life.

Surfaxin® for the Prevention of Bronchopulmonary Dysplasia

BPD is a costly syndrome associated with surfactant and SP-B deficiency, and the prolonged use of mechanical ventilation and oxygen supplementation, usually associated with a premature infant being treated for RDS. Presently there are no approved drugs for the treatment of BPD. These babies suffer from abnormal lung development and typically have a need for respiratory assistance - oftentimes, for many months, as well as comprehensive care spanning years. It is estimated that the cost of treating an infant with BPD in the United States can approach $250,000 with approximately 50,000 infants developing BPD in the United States and Europe each year.

We are currently conducting a double-blind, controlled Phase 2 BPD clinical trial that will enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study objective is to determine the safety and tolerability of a series of Surfaxin doses administered in the first weeks of life as a therapeutic approach for the prevention of BPD and to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or BPD. Infants will be randomized to receive several doses of Surfaxin which will be administered in liquid form and injected through the patient's endotracheal tube, or the current standard of care - mechanical ventilation and support therapies. The trial will be conducted at approximately 25 sites throughout the United States, as well as sites in Latin America and Europe. The results of this trial are expected to be available in the first quarter of 2006.

Aerosolized Surfactant Replacement Therapy for Respiratory Dysfunction in Premature Infants

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in Neonatal Intensive Care Units. On top of the approximately 550,000 premature infants born annually worldwide at risk for RDS, there are another approximately 1 million premature infants, 300,000 of which are in the US and Europe, born annually at risk for a range of other respiratory problems associated with surfactant dysfunction. These infants are usually at a birth weight greater than 1,250 grams and neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the highly invasive process of inserting a breathing tube down the patient's trachea). This reluctance is due to the perceived risks by many neonatologists regarding the intubation of these larger babies, such as the risk of trauma and the need of paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits clearly outweigh the risks. We believe that there is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from respiratory disorders including BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

We are currently conducting an open label, Phase 2, multicenter pilot study to evaluate aerosolized SRT delivered via nasal continuous positive airway pressure (nCPAP) in premature infants. This trial will be conducted at up to four centers in the United States and will enroll approximately 20 infants with a gestational age of 28-32 weeks who are suffering from RDS. Patients will receive, in two treatment regimens, aerosolized SRT delivered via nCPAP within thirty minutes of birth. Our overall program is to begin with a pilot study to evaluate the safety and tolerability of aerosolized SRT delivered via our proprietary nCPAP technology, initially within patients who suffer from RDS followed by additional studies to include other neonatal respiratory failures within the NICU. Results of this Phase 2 pilot study are anticipated to be available in the third quarter of 2005.

*Surfaxin*Ò *for Meconium Aspiration Syndrome in Full-Term Infants*

Meconium Aspiration Syndrome (often referred to as MAS) is an inflammatory condition in which full-term infants are born with meconium in their lungs that depletes the natural surfactant in their lungs. Meconium is a baby's first bowel movement in its mother's womb and, when inhaled, MAS can occur. MAS can be life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. There are no approved therapies for this condition and the standard of care principally consists of mechanical ventilation. Surfaxin has been shown to not only remove inflammatory and infectious infiltrates from the lungs when using our proprietary lavage (or "lung wash") but to also replenish the vital surfactant levels in the babies' lungs.

We are conducting a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or early treatment for patients who are at risk of developing MAS but have not shown symptoms of compromised respiratory function. Surfaxin is administered as a liquid bolus through an endotracheal tube as well as by our proprietary lavage (lung-wash) technique.

Products for the Critical Care Unit and other Hospital Settings

*Surfaxin*Ò *for Acute Respiratory Distress Syndrome in Adults*

ARDS is a life-threatening disorder for which no approved therapies exist anywhere in the world. It is characterized by an excess of fluid in the lungs and decreased oxygen levels in the patient. One prominent characteristic of this disorder is the destruction of surfactants naturally present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock (a toxic condition caused by infection) and events such as smoke inhalation, near drowning, industrial accidents and other traumas.

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of Surfaxin for the treatment of adults with ARDS. In December 2004, we announced what we believe to be encouraging preliminary data from this trial and that we were modifying the trial protocol to allow for increased enrollment of up to 160 patients. Patients will be randomized to either receive Surfaxin or the current standard of care, which is mechanical ventilation and support therapies.

Surfaxin is administered to patients in high concentration and large volume via a proprietary sequential lavage technique, or lung wash, delivered through a bronchoscope to each of the 19 segments of the lung. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving sufficient amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation sooner. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Key secondary endpoints include mortality at the end of Day 28 and safety and tolerability of Surfaxin and the bronchoscopic lavage procedure. Results of the Phase 2 trial are anticipated to be available in the first quarter of 2006.

The current standard of care for ARDS includes placing patients on mechanical ventilators in intensive care units at a cost per patient of approximately $8,500 per day, typically for an average of 21 to 28 days. There are estimated to be between 150,000 and 200,000 adults per year in the United States suffering from ARDS with similar numbers afflicted in Europe. Presently, the mortality rate is estimated to be between 30% to 40%.

The FDA has granted us Fast-Track Status and Orphan Drug Designation for Surfaxin for the treatment of ARDS in adults. The EMEA has granted us Orphan Product designation for Surfaxin for the treatment of ALI in adults (which in this circumstance is a larger patient population that encompasses ARDS). We were awarded and received a $1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of ARDS and ALI in adults.

Aerosolized Surfactant (development name DSC 104) for Severe, Acute Asthma

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system occurs when the airway muscles tighten, while inflammation is a swelling of the airways usually due to an allergic reaction caused by an airborne irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma — airway constriction occurs when there is a surfactant dysfunction in the airways of the deep lung of the type that develops during an asthma attack. We believe that surfactant replacement therapy has the potential to relieve the constriction in the airways associated with asthma.

According to information provided by the American Lung Association, asthma afflicts more than 20 million people in the United States and its incidence rate continues to rise. Asthma is a chronic disease; it is prevalent in people of all ages and an estimated 12 million people have experienced an asthma attack within the past year. In the United States alone, there are roughly 1 million hospital outpatient visits, approximately 1.8 million emergency room visits and 9.3 million physician visits each year due to asthma. Asthma ranks within the top 10 prevalent activity-limiting health conditions costing $14 billion in United States healthcare costs annually.

Asthma may require life-long therapy to prevent or treat episodes. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available asthma medications include inhaled and oral steroids, bronchodilators and leukotriene antagonists. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Oral steroids can cause serious side effects when used for prolonged periods and, thus, are typically limited to severe asthmatic episodes and chronic, severe asthma. We believe that supplying surfactant as an inhaled aerosol may relieve airway obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

In 2004, we completed a Phase 1b clinical trial to evaluate the safety and lung tolerability and deposition characteristics of our precision-engineered lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. This masked, placebo-controlled, randomized, Phase 1b study included six healthy subjects and eight mild-persistent asthmatic patients. Results demonstrated that DSC-104 was safe and well tolerated, did not induce bronchospasm and was deposited to both the central and peripheral regions of the lungs in the mild-persistent asthmatic group and the healthy volunteers. We are preparing a Phase 2 trial for patients with moderate to severe asthma (development name DSC-104). We initially anticipated initiating this trial in the first half of 2005. Recently, we have reordered our aerosolized SRT pipeline development programs to prioritize our Phase 2, pilot study to evaluate aerosolized SRT delivered via nCPAP in premature infants. We now expect to initiate our DSC-104 trial for moderate to severe asthma in the fourth quarter of 2005.

Aerosolized Surfactant for Acute Lung Injury

ALI is associated with conditions that either directly or indirectly injure the air sacs of the lung. ALI is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer. The most serious manifestation of ALI is ARDS.

Among the causes of ALI are complications typically associated with certain major surgeries, mechanical ventilator induced lung injury (often referred to as VILI), smoke inhalation, pneumonia and sepsis. There are an estimated 1 million patients at risk in the United States for Acute Lung Injury annually and there are no currently-approved therapies.

We are evaluating aerosolized formulations of our precision-engineered surfactant to potentially treat ALI. We believe that our proprietary precision-engineered aerosol surfactant may be effective as a preventive measure for patients at risk for ALI. This prophylactic approach may result in fewer patients requiring costly intensive care therapy, thereby eliminating long periods of therapy and offering cost savings in the hospital setting.

STRATEGIC ALLIANCES

Quintiles Transnational Corp. (Quintiles), and PharmaBio Development Inc. (PharmaBio)

In November 2004, we reached an agreement with Quintiles Transnational Corp. to restructure our business arrangements and terminate our commercialization agreements for Surfaxin in the United States. We now have full commercialization rights for Surfaxin in the United States. Under the commercialization agreement we entered into with Quintiles in 2001, Quintiles and its affiliates would have provided commercialization services for seven years post-launch, with an obligation to fund such services up to $10 million per year. Quintiles was entitled to a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS for 10 years following launch. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and our obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS to Quintiles has been terminated. In addition, we have entered into a three-year limited preferred-provider arrangement with Quintiles. The existing secured revolving credit facility of $8.5 million with PharmaBio, Quintiles strategic investment group affiliate, will remain available to us and the original maturity date of December 10, 2004, is now extended until December 31, 2006. In connection with the restructuring of the business arrangements with Quintiles and termination of the commercialization agreement, we issued 850,000 warrants to QFinance, Inc., a subsidiary of Quintiles, for no additional consideration, to purchase shares of our common stock at an exercise price equal to $7.19 per share. The warrants have a 10-year term and are exercisable for cash only.

Laboratorios del Dr. Esteve, S.A. (Esteve)

In December 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve S.A. for the development, marketing and sales of our products in Europe and Latin America. Under the revised collaboration, we have regained full commercialization rights in key European markets, Central America and South America. Esteve will focus on Andorra, Greece, Italy, Portugal and Spain, and now has development and marketing rights to a broader portfolio of our potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and our other Surfactant Replacement Therapies that is increased from those provided for in our previous collaborative arrangement. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory.

Esteve has also agreed to make stipulated cash payments to us upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In consideration for regaining commercial rights in the restructuring, we issued to Esteve 500,000 shares of common stock for no cash consideration and granted to Esteve rights to additional potential SRT products in our pipeline. We also agreed to pay to Esteve 10% of up-front cash and milestone fees that we receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of our other Surfactant Replacement Therapies in the territory for which we had previously granted a license to Esteve. Any such up-front and milestone fees that we may pay to Esteve are not to exceed $20 million in the aggregate. This restructured collaboration supersedes the existing sublicense and supply agreements we had entered into with Esteve in March 2002.

LICENSING ARRANGEMENTS; PATENTS AND PROPRIETARY RIGHTS

Patents and Proprietary Rights

Johnson & Johnson and The Scripps Research Institute

Our precision-engineered surfactant platform technology, including Surfaxin, is based on the proprietary peptide, sinapultide, (a 21 amino acid protein-like substance that closely mimics the essential human lung protein SP-B). This technology was invented at The Scripps Research Institute and was exclusively licensed to, and further developed by, Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical. We have received an exclusive, worldwide sublicense from Johnson & Johnson and Scripps for, and have rights to, a series of over 30 patents and patent filings (worldwide) which are important, either individually or collectively, to our strategy for commercializing our precision-engineered surfactant technology for the diagnosis, prevention and treatment of disease. The sublicense gives us the exclusive rights to such patents for the life of the patents.

Patents covering our proprietary precision-engineered surfactant technology that have been issued or are pending worldwide include composition of matter, formulation, manufacturing and uses, including the pulmonary lavage, or “lung wash” techniques. Our most significant patent rights principally consist of five issued United States patents: U.S. Patent No. 5,407,914; U.S. Patent No. 5,260,273; U.S. Patent No. 5,164,369; U.S. Patent No. 5,789,381; and U.S. Patent No. 6,013,619 (along with corresponding issued and pending foreign counterparts). These patents relate to precision-engineered pulmonary surfactants (including Surfaxin), certain related peptides (amino acid protein-like substances) and compositions, methods of treating respiratory distress syndromes with these surfactants and compositions, and our proprietary pulmonary lavage method of treating RDS with these surfactants. We also have certain pending United States and foreign patent applications that relate to methods of manufacturing certain peptides which may be used in the manufacture of Surfaxin and other aspects of our precision-engineered surfactant technology.

In September 2003, we were issued United States Patent No. 6,613,734, which covers a wide variety of combinations of peptides, proteins and other molecules related to our proprietary precision-engineered pulmonary surfactant technology. The patent also includes methods of making and using these molecules.

In September 2002, we were granted European Patent No. 0590006, which covers claims directed to compositions that contain sinapultide for use as a therapeutic surfactant for treating RDS and related conditions. We also have been granted European Patent Nos. 0350506 and 0593094 covering certain other surfactant peptides, including sinapultide and related peptides.

U.S. Patent No. 6,013,619 was issued to Scripps and licensed to us, and covers methods of using any engineered surfactants (including Surfaxin) or animal- or human-derived surfactants in pulmonary lavage for RDS. Our proprietary pulmonary lavage techniques (using surfactant) include lavage via a bronchoscope in adults as well as direct pulmonary lung lavage via an endotracheal tube in newborn babies with MAS. Scientific rationale supports the premise that our proprietary lavage technique may provide a clinical benefit to the treatment of ALI and ARDS in adults and MAS in full-term infants by decreasing the amount of infectious and inflammatory debris in the lungs, restoring the air sacs to a more normal state and possibly resulting in patients getting off mechanical ventilation sooner.

All such patents, including our relevant European patents, expire on various dates beginning in 2008 and ending in 2017 or, in some cases, possibly later.

The Scripps Research Institute Research Agreement

Our research funding and option agreement with Scripps expired in February 2005. Pursuant to this agreement, we funded a portion of Scripps' research efforts and are entitled to an option to acquire an exclusive worldwide license to the technology developed from the research program during the term of the agreement. Scripps owns all of the technology that it developed pursuant to work performed under the agreement. To the extent we do not exercise our option, we have the right to receive 50% of the net royalty income received by Scripps for inventions that we jointly develop under the agreement.

See Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business”: “ - If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products”; “ - Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us”; “ - Intellectual property rights of third parties could limit our ability to market our products”; and “ - If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

MANUFACTURING AND DISTRIBUTION - THIRD PARTY SUPPLIERS

Manufacturing

Our precision-engineered surfactant product candidates, including Surfaxin, must be manufactured in a sterile environment and in compliance with current good manufacturing practice requirements (cGMPs) set by the FDA and other relevant worldwide regulatory authorities. These product candidates are manufactured through the combination of sinapultide, which is provided by BACHEM California, Inc., and PolyPeptides Laboratories, Inc., and certain other active ingredients, including certain lipids, that are provided by other suppliers such as Genzyme Pharmaceuticals, a division of the Genzyme Corporation, and Avanti Polar Lipids with our own specialized equipment under the direction and supervision of our manufacturing and quality control personnel. Our surfactant drug products, including Surfaxin, are manufactured at the sterile facilities of our contract manufacturer, Laureate, using these ingredients with our own specialized equipment under the direction and supervision of our manufacturing and quality control personnel. The termination, disruption or expiration of the manufacturing relationships with any of these parties would have a material adverse effect on our business.

In January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate, our contract manufacturer of Surfaxin, citing certain observations concerning Laureate's compliance with current Good Manufacturing Practices (cGMPs) in connection with its review of our NDA for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, a cGMP Action Plan was submitted to the FDA on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of our NDA for Surfaxin, we anticipate that the commercial launch of Surfaxin for the United States will occur in the fourth quarter of 2005. Our other clinical programs currently in progress are not affected by this inspection report and remain on track. However, if the inspection observations noted in the Form 483 are not resolved in the time period stated above, a delay may occur in these programs. We do not expect that the foregoing will have an effect on our European regulatory filings.

We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of our cGMP Action Plan dated January 31, 2005, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the treatment of RDS in premature infants. We expect these capabilities to allow us to provide adequate supply of Surfaxin and our other Surfactant Replacement Therapies for our planned clinical trials.

To support a long-term manufacturing strategy for the production of clinical and commercial supply of our precision-engineered surfactant drug product, we are evaluating further development and scale-up of our current contract manufacturer, Laureate, alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet our production needs as they expand. Upon marketing approval, if at all, we intend to rely on outside manufacturers for production of our products after marketing approval.

Should the proper financial and other resources be available, our manufacturing process for our precision-engineered surfactant drug product allows us to scale-up production of our precision-engineered surfactant drug product, including Surfaxin. The scaling up of the currently-approved, animal-derived products is significantly less efficient, if at all possible. By scaling up our production, we should be able to produce sufficient drug products to potentially treat diseases with larger patient populations, such as ARDS in adults, Neonatal Respiratory Failures in premature infants, asthma, ALI, COPD and other broader respiratory diseases and upper airway disorders.

Manufacturing or quality control problems have already and may again occur at Laureate or our other contract manufacturers, causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's GMP requirements necessary to continue manufacturing our ingredients or drug product. If any such suppliers or manufacturers of our products fail to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business": " - We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates"; " - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products"; and " - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitor's drug product, which may not be readily available."

Distribution

We are currently evaluating third party distribution capability in order to commercialize Surfaxin in the United States.

Our collaboration with Esteve provides that Esteve has the responsibility for distribution in Andorra, Greece, Italy, Portugal and Spain. We will need to evaluate third party distribution capabilities in other parts of the world prior to commercializing those regions. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates" and " - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products".

COMPETITION

We are engaged in highly competitive fields of pharmaceutical research. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We expect to compete with, among others, conventional pharmaceutical companies. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete."

Currently, the FDA has approved surfactants as replacement therapy only for the treatment of RDS in premature infants, a condition in which infants are born with an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from a chemical extraction process of pig and cow lungs. Curosurf® is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta®, marketed by the Ross division of Abbott Laboratories, Inc., is derived from minced cow lung that contains the cow version of surfactant protein B. Forest Laboratories, Inc., markets its calf lung surfactant extract, Infasurf®, in the United States.

There is presently only one approved synthetic surfactant available, Exosurf®, marketed by GlaxoSmithKline, plc. However, this product does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer.

With respect to the development of lung surfactants for the treatment of other respiratory diseases and upper airway disorders, with the exception of one porcine-derived surfactant drug candidate under development by Leo Pharma A/S in Denmark, we are not aware of any other lung surfactant currently under development.

There are no drugs currently approved that are specifically indicated for the treatment of ARDS in adults or MAS in full-term infants. Current therapy consists of general supportive care and mechanical ventilation. There are a significant number of other potential therapies in development for the treatment of ARDS in adults that are not surfactant related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin.

Our precision-engineered surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain our precision-engineered peptide, sinapultide. We believe that our precision-engineered surfactant can be manufactured less expensively than the animal-derived surfactants, in sufficient quantities, in exact and consistent pharmaceutical grade quality, and has no potential to cause adverse immunological responses in young and older adults, all important attributes to potentially meet significant unmet medical needs. Our products also have the ability to be more precisely formulated, such as in the form of aerosolized liquids or dry powders to address various medical indications. In addition, we believe that our precision-engineered surfactant might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

GOVERNMENT REGULATION

The testing, manufacture, distribution, advertising and marketing of drug products are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in a particular country.

The regulatory process, which includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and efficacy and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources and gives larger companies with greater financial resources a competitive advantage over us. Delays or terminations of clinical trials we undertake would likely impair our development of product candidates. Delays or terminations could result from a number of factors, including stringent enrollment criteria, slow rate of enrollment, size of patient population, having to compete with other clinical trials for eligible patients, geographical considerations and others.

The FDA review process can be lengthy and unpredictable, and we may encounter delays or rejections of our applications when submitted. Generally, in order to gain FDA approval, we first must conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound's efficacy and to identify any safety problems. The results of these studies are submitted as part of an IND (Investigational New Drug) application that the FDA must review before human clinical trials of an investigational drug can start.

Clinical trials are normally done in three sequential phases and generally take two to five years or longer to complete. Phase 1 consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase 2 usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage and identify possible common adverse effects and safety risks. Phase 3 consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase 4 clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

After completion of clinical trials of a new drug product, FDA and foreign regulatory authority marketing approval must be obtained. A New Drug Application submitted to the FDA generally takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time. The testing and approval processes require substantial time and effort and we may not receive approval on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. For marketing outside the United States, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. None of our products under development have been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any such products under development. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude us, or our licensees or marketing partners, from marketing our products, or limit the commercial use of our products, and thereby would have a material adverse effect on our business, financial condition and results of operations. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business": " - Our technology platform is based solely on our proprietary precision-engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business"; and " - The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain."

The FDA has granted us Fast-Track Approval Designation for the indications of ARDS and MAS. Fast-Track Status facilitates the development and expedites the review of new drugs intended for treatment of life-threatening conditions for which there are presently no medical options or an unmet medical need by providing for the FDA's review of the New Drug Application within six months following filing. We have also received Orphan Drug Designation from the FDA's Office of Orphan Products Development for Surfaxin as a treatment for RDS in premature infants, MAS in full-term infants, and ARDS in adults. Surfaxin has received designation as an Orphan Product for MAS and ALI (which, in this circumstance, encompasses ARDS) from the EMEA.

EMPLOYEES

We have approximately 90 full-time employees, primarily employed in the United States, Europe and Latin America. Our future success depends in significant part upon the continued service of our key scientific personnel and executive officers and our continuing ability to attract and retain highly qualified scientific and managerial personnel. There is a competitive market for such personnel and we may not be able to retain our key employees or attract, assimilate or retain other highly qualified technical and managerial personnel in the future. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business - We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file with the Commission at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549, 233 Broadway, New York, New York 10279, and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661- 2511. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Our Commission filings are also available to the public from the Commission's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Executive Vice President, Chief Financial Officer at our address as set forth above.

We maintain a Website at "http://www.DiscoveryLabs.com" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 2. PROPERTIES.

Our principal offices are leased and located at 2600 Kelly Road, Suite 100,Warrington, Pennsylvania 18976-3646. The telephone number of our executive office is (215) 488-9300 and the facsimile number is (215) 488-9301. We also lease space in Doylestown, Pennsylvania, for our analytical laboratory. We currently lease our research facility, which is located in Mountain View, California, to principally develop aerosolized formulations of our proprietary precision-engineered surfactant.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions other than disputes arising in the ordinary course of our business that would not, if determined adversely to us, have a material adverse effect on our business and operations.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2004.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the Nasdaq National Market under the symbol "DSCO." As of February 7, 2005, the number of stockholders of record of shares of our common stock was 173 and the number of beneficial owners of shares of our common stock was approximately 12,000. As of February 7, 2005, there were 48,444,690 shares of our common stock issued and outstanding; and as of March 14, 2005, 53,511,946 shares of our common stock were issued and outstanding.

The following table sets forth the quarterly price ranges of our common stock for the periods indicated, as reported by Nasdaq.

	Low	High
First Quarter 2003	$1.32	$2.94
Second Quarter 2003	$1.56	$7.40
Third Quarter 2003	$6.12	$8.50
Fourth Quarter 2003	$5.40	$10.75
First Quarter 2004	$9.94	$13.90
Second Quarter 2004	$8.25	$13.22
Third Quarter 2004	$5.75	$9.90
Fourth Quarter 2004	$6.42	$9.52
First Quarter 2005 (through February 7, 2005)	$5.84	$8.60

We have not paid dividends on our common stock. It is anticipated that we will not pay dividends on our common stock in the foreseeable future.

Sales of Unregistered Securities

In the quarter ended December 31, 2004, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 3,167 shares of our common stock at various exercise prices ranging from $7.00 to $8.32 per share. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker-dealers were involved in the sale and no commissions were paid by us. Information relating to compensation plans under which our common stock is authorized for issuance is set forth in Part III, Item 12 of this Annual Report on Form 10-K.

We have a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, we allowed for periodic discretionary matches of newly issued shares of common stock to be made by the Company with the amount of any such match determined as a percentage of each individual participant's cash contribution. For the quarter ended December 31, 2004, shares issued by us as a discretionary match totaled 8,116 shares of common stock.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our consolidated statement of operations for the years ended December 31, 2004, 2003 and 2002 and with respect to the consolidated balance sheets as of December 31, 2004 and 2003 have been derived from audited consolidated financial statements included as part of this Annual Report on Form 10-K ("Form 10-K"). The statement of operations data for the years ended December 31, 2001 and 2000 and the balance sheet data as of December 31, 2002 and 2001 and 2000 are derived from audited financial statements not included in this Form 10-K. The following selected consolidated financial data should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Form 10-K.

Consolidated Statement of Operations Data:
(in thousands, except per share data)

	For the year ended December 31,				
	2004	2003	2002	2001	2000
Revenues from collaborative agreements	$ 1,209	$ 1,037	$ 1,782	$ 1,112	$ 741
Operating Expenses:					
Research and development	25,793	19,750	14,347	8,007	7,494
General and administrative	13,322	5,722	5,458	5,067	5,145
Corporate partnership restructuring charges	8,126	-	-	-	-
Total expenses	47,241	25,472	19,805	13,074	12,639
Operating loss	(46,032)	(24,435)	(18,023)	(11,962)	(11,898)
Other income and expense	(171)	155	580	816	1,037
Net loss	$ (46, 203)	$ (24,280)	$ (17,443)	$ (11,146)	$ (10,861)
Net loss per common share - basic and diluted	$ (1.00)	$ (0.65)	$ (0.64)	$ (0.51)	$ (0.58)
Weighted average number of common shares outstanding	46,179	37,426	27,351	22,038	18,806

Consolidated Balance Sheet Data:
(in thousands)

	For the year ended December 31,				
	2004	2003	2002	2001	2000
ASSETS					
Current Assets:					
Cash/cash equivalents and marketable securities	$ 32,654	$ 29,422	$ 19,152	$ 16,696	$ 18,868
Prepaid expenses and other current assets	688	668	327	1,582	149
Total Current Assets	33,342	30,090	19,479	18,278	19,017
Property and equipment, net of depreciation	4,063	2,414	1,231	822	697
Other assets	232	211	352	965	3
Total Assets	$ 37,637	$ 32,715	$ 21,062	$ 20,065	$ 19,717
LIABILITIES AND STOCKHOLDERS' EQUITY					
Credit facility, current portion	$ -	$ 2,436	$ -	$ -	$ -
Other current liabilities	8,823	4,593	3,202	1,794	2,399
Total Current Liabilities	8,823	7,029	3,202	1,794	2,399
Deferred revenue	134	672	1,393	615	851
Credit facility, non-current portion	5,929	-	1,450	-	-
Capitalized lease	1,654	711	256	33	31
Total Liabilities	16,540	8,412	6,301	2,442	3,281
Stockholders' Equity	21,097	24,303	14,761	17,623	16,436
Total Liabilities and Stockholders' Equity	$ 37,637	$ 32,715	$ 21,062	$ 20,065	$ 19,717
Common Stock, $0.001 par value, issued and outstanding	48,434	42,491	32,818	25,546	20,871

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

This Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operation" should be read in connection with our Consolidated Financial Statements. See Item 15: "Exhibits and Financial Statement Schedules."

Overview

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as precision-engineered Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our technology produces a precision-engineered surfactant that is designed to mimic the essential properties of natural human lung surfactant. We believe that through our technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

We have received an Approvable Letter from the U.S. FDA for Surfaxin^{Ò} (lucinactant), our lead product, for the prevention of RDS in premature infants, and have filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. We anticipate potential approval and commercial launch of Surfaxin in the United States and potential EMEA approval to occur in the first quarter of 2006.

In addition to Surfaxin for RDS, in an effort to enhance the potential commercial and medical value of our SRT by addressing the most prevalent respiratory disorders affecting infants in the NICU, we are conducting several NICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal community. We are conducting three Phase 2 clinical trials - Surfaxin for BPD in premature infants, aerosolized SRT administered through nCPAP for Neonatal Respiratory Failures, and Surfaxin for the prophylactic/early treatment of MAS in full term infants.

In an effort to enhance the potential commercial and medical value of our SRT, we are also developing SRT to address unmet respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial for the treatment of ARDS in adults in the intensive care unit (ICU), for which we announced preliminary data in December 2004. With our aerosolized surfactant formulations, we have completed a Phase 1b trial and are preparing to initiate a Phase 2 trial for patients with moderate to severe asthma (development name DSC-104). In addition, we are evaluating the development of aerosolized formulations of our precision-engineered SRT to potentially treat Acute Lung Injury, COPD and rhinitis/sinusitis.

In anticipation of the potential approval of Surfaxin for RDS in the United States, we are presently implementing a long-term commercial strategy which includes:

(i) manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States and Europe. We are investing in the further development and scale-up of our current contract manufacturer of our SRT, Laureate, and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and building our own manufacturing facility. In January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate citing certain observations concerning Laureate's compliance with current Good Manufacturing Practices (cGMPs) in connection with the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, Discovery and Laureate submitted a cGMP Action Plan to the FDA on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of our NDA, we anticipate that the commercial launch of Surfaxin will occur in the first quarter of 2006. Our other clinical programs currently in progress are not affected by this inspection report and remain on track. However, if the inspection observations noted in the Form 483 are not resolved in the time period stated above, a delay may occur in these programs. We do not expect that the foregoing will have an effect on our European regulatory filings;

(ii) building sales and marketing capabilities to execute the launch of Surfaxin in the United States, if approved. We are building our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated launch of Surfaxin, is intended to allow us to fully control our own sales and marketing operation, establish a strong presence in the NICU, and optimize company economics; and

(iii) implementing our commercialization strategy for Surfaxin in Europe and the rest of the world through corporate partnerships.

Since our inception, we have incurred significant losses and, as of December 31, 2004, we had an accumulated deficit of $143,061,000 (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, financial, business development, pre-launch commercialization sales and marketing, legal and general corporate activities and related expenses. See Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations."

Historically, we have funded our operations with working capital provided principally through public and private equity financings and strategic collaborations. As of December 31, 2004, we had cash and investments of $32,654,000, a secured revolving credit facility of $8,500,000 with PharmaBio, of which $2,571,000 was available for borrowing and $5,929,000 was outstanding, and a $9,000,000 capital equipment lease financing arrangement, of which $5,958,000 was available for borrowing, $3,042,000 has been drawn, and $2,454,000 was outstanding. We also had up to $67.8 million available under the Committed Equity Financing Facility (CEFF), subject to the terms and conditions thereof and to the terms and conditions of the Placement Agent Agreement we entered into with SG Cowen & Co. LLC (as discussed below). See Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.”

Research and Development

Research and development expenses for the years ended December 31, 2004, 2003 and 2002 were $25,793,000, $19,750,000, and $14,347,000, respectively. Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. Our research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations, and other direct clinical trials activities. These cost categories typically include the following expenses:

Research and Pre-Clinical Operations

Research and pre-clinical operations reflects activities associated with research prior to the initiation of any potential human clinical trials. These activities predominantly represent projects associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and aerosol delivery systems to potentially treat a range of respiratory disorders prevalent in the NICU and the hospital. Research and pre-clinical operations costs primarily reflect expenses incurred for personnel, consultants, facilities and research and development arrangements with collaborators.

Manufacturing Development

Manufacturing development primarily reflects costs incurred to prepare current good manufacturing procedures (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Included in manufacturing development are activities with external contract manufacturing resources (including further development and scale-up of our current contract manufacturer of our SRT, Laureate, and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and building our own manufacturing facility), personnel costs, depreciation, and expenses associated with technology transfer, process development and validation, quality control and assurance activities, and analytical services.

Unallocated Development — Clinical and Regulatory Operations

Clinical and regulatory operations reflect the preparation, implementation, and management of our clinical trial activities in accordance with current good clinical practices (cGCPs). Included in unallocated clinical development and regulatory operations are costs associated with personnel, supplies, facilities, fees to consultants, and other related costs for clinical trial implementation and management, clinical quality control, and regulatory compliance activities, data management and biostatistics.

Direct Expenses — Clinical Trials

Direct expenses of clinical trials includes patient enrollment costs, external site costs, expense of clinical drug supply, and external costs such as contract research consultant fees and expenses.

The following summarizes our research and development expenses by the foregoing categories for the years ended December 31, 2004, 2003 and 2002:

(Dollars in thousands)	**Year Ended December 31,**		
Research and Development Expenses:	**2004**	**2003**	**2002**
Research and pre-clinical operations	$ 2,916	$ 1,958	$ 1,683
Manufacturing development	7,010	4,268	834
Unallocated development - clinical and regulatory operations	8,588	5,966	3,275
Direct clinical trial expenses	7,279	7,558	8,555
Total Research and Development Expenses	**$ 25,793**	**$ 19,750**	**$ 14,347**

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical or pre-clinical development and the status and anticipated completion date of each of our lead SRT programs is discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operation - Plan of Operations,” below. Successful completion of development of our Surfactant Replacement Therapies is contingent on numerous risks, uncertainties and other factors, which are described in detail in the section entitled “Risk Factors”.

These factors include:

- Completion of pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant raw materials on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Performance of third-party collaborators on whom we rely for the commercialization and manufacture of Surfaxin;
- Timely resolution of the cGMP-related matters at Laureate, our contract manufacturer for Surfaxin and certain of our other Surfactant Replacement Therapies presently under development, that were noted by the FDA in its inspectional report on Form FDA-483; and
- Obtaining manufacturing, sales and marketing capabilities for which we presently have limited resources.

As a result of the amount and nature of these factors, many of which are outside our control, the success, timing of completion, and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things,

- Slow patient enrollment;
- Long treatment time required to demonstrate effectiveness;
- Lack of sufficient clinical supplies and material;
- Adverse medical events or side effects in treated patients;
- Lack of effectiveness of the product candidate being tested; and
- Lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

Corporate Partnership Agreements

Quintiles Transnational Corp., and PharmaBio Development Inc.

In 2001, we entered into a commercialization agreement with Quintiles Transnational Corp., and its strategic investment group affiliate, PharmaBio Development Inc., to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. Quintiles was obligated to hire and train a dedicated United States sales force that would have been branded in the market as Discovery's. PharmaBio agreed to fund up to $70 million of the sales and marketing costs for commercialization of Surfaxin in the United States for seven years. Additionally, the collaboration allowed for this sales force to transfer to us at the end of the seven year term, with an option to acquire it sooner. Under the agreement, we were to receive 100% of the revenues from sales of Surfaxin and agreed to pay PharmaBio a commission on net sales in the United States of Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants and all "off-label" uses for 10 years following first launch of the product in the United States. PharmaBio also extended to us a secured revolving credit facility of up to $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as we achieved certain milestones.

In November 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate the commercialization agreement for Surfaxin in the United States. We now have full commercialization rights for Surfaxin in the United States. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and our obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS to Quintiles has been terminated.

In connection with obtaining full commercialization rights for Surfaxin, we issued 850,000 warrants to PharmaBio to purchase shares of our common stock at an exercise price equal to $7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to us, if exercised, equal to approximately $6.0 million. We valued the warrants at their fair value on the date of issuance and incurred a non-cash charge of $4.0 million in connection with the issuance. This charge is a component of Corporate Partnership Restructuring Charges on the Income Statement that were realized during the fourth quarter of fiscal year 2004. The existing secured revolving credit facility of $8.5 million with PharmaBio, will remain available and the original maturity date of December 10, 2004 is now extended until December 31, 2006. See "Liquidity and Capital Resources".

Laboratorios del Dr. Esteve, S.A. (Esteve)

In 1999, we entered into a corporate partnership with Esteve to develop, market and sell Surfaxin, primarily in southern Europe. In 2002, we significantly expanded our relationship with Esteve by entering into a new collaboration arrangement, which superseded the 1999 agreement, and expanded the territory covered by those original agreements to all of Europe, Central and South America, and Mexico. Esteve was obligated to provide certain commercialization services for Surfaxin for the treatment of RDS in premature infants, MAS in full-term infants and ARDS in adult patients. Our exclusive supply agreement with Esteve provided that Esteve would purchase all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for ARDS and make certain milestone payments to us upon the attainment of European marketing regulatory approval for Surfaxin. In connection with the 2002 expanded agreement, Esteve purchased 821,862 shares of our common stock at $4.867 per share for $4.0 million in gross proceeds and paid us a non-refundable licensing fee of $500,000. We have accounted for the license fees and reimbursement of research and development expenditures associated with the Esteve collaboration as deferred revenue.

In December 2004, we reached an agreement with Esteve to restructure our corporate partnership for the development, marketing and sales of our products in Europe and Latin America. This restructured partnership supersedes the existing sublicense and supply agreements we had entered into with Esteve in March 2002. Under the revised partnership, we have regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for RDS in premature infants and ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of our potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and our other Surfactant Replacement Therapies that is increased from those provided for in our previous collaborative arrangement. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory. Esteve has agreed to make stipulated cash payments to us upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In consideration for regaining commercial rights in the 2004 restructured partnership, we issued to Esteve 500,000 shares of common stock for no cash consideration, valued at $3.5 million. We incurred a non-cash charge, including the value of the shares issued and other costs related to the restructuring, of $4.1 million. This charge is a component of Corporate Partnership Restructuring Charges on the Income Statement. We also granted to Esteve rights to additional potential SRT products in our pipeline. We also agreed to pay to Esteve 10% of cash up-front and milestone fees that we may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of our other SRTs in the territory for which we had previously granted a license to Esteve. Payments to Esteve in respect of any such up-front and milestone fees are not to exceed $20 million in the aggregate.

Plan of Operations

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products, manufacturing, commercialization, and general and administrative activities.

We anticipate that during the next 12 to 24 months we will:

(i) increase our research, development and regulatory activities in an effort to develop a broad pipeline of potential SRT for respiratory diseases. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in the “Risks Related to Our Business” - “Our technology platform is based solely on our proprietary, precision-engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement therapies may be delayed, or fail, which will harm our business”; - “The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.”

Our major research and development projects include:

SRT for Neonatal Respiratory Failures

In addition to Surfaxin for RDS, in an effort to enhance the potential commercial and medical value of our SRT by addressing the most prevalent respiratory disorders affecting infants in the NICU, we are conducting several NICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal community. We are conducting three Phase 2 clinical trials - Surfaxin for BPD in premature infants, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) for Neonatal Respiratory Failures, and Surfaxin for the prophylactic/early treatment of MAS in full term infants.

The Phase 2 BPD clinical trial is a double-blind, controlled trial (that will enroll up to 210 very low birth weight premature infants born at risk for developing BPD) to determine the safety and tolerability of Surfaxin administration in the first weeks of life as a therapeutic approach for the prevention of BPD. This study is designed to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or BPD. The results of this trial are expected to be available in the first quarter of 2006.

We are currently conducting an open label, Phase 2, multicenter pilot study to evaluate aerosolized SRT delivered via nCPAP in premature infants. This trial will be conducted at up to four centers in the United States and will enroll approximately 20 infants with a gestational age of 28-32 weeks who are suffering from RDS. Patients will receive, in two treatment regimens, aerosolized SRT delivered via nCPAP within thirty minutes of birth. Our overall program is to begin with a pilot study to evaluate the safety and tolerability of aerosolized SRT delivered via our proprietary nCPAP technology, initially within patients who suffer from RDS followed by additional studies to include other neonatal respiratory failures within the NICU. Results of this Phase 2 pilot study are anticipated to be available in the third quarter of 2005.

We are conducting a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or early treatment for patients who are at risk of developing MAS but have not shown symptoms of compromised respiratory function. Surfaxin is administered as a liquid bolus through an endotracheal tube as well as by our proprietary lavage (lung-wash) technique.

SRT for Critical Care and Hospital indications

In an effort to enhance the potential commercial and medical value of our SRT, we are also developing SRT to address unmet respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial for the treatment of ARDS in adults in the intensive care unit (ICU), for which we announced preliminary data in December 2004. Based on that data, the current ARDS Phase 2 protocol was modified to better establish the endpoint signal in key clinical outcomes in order to properly power and design a potential Phase 3 clinical trial. The modified protocol allows for increased enrollment of up to 160 patients. The remainder of the trial will be comprised of Surfaxin Dose Group B (lavage with bolus) and Standard of Care. Results of the Phase 2 trial are anticipated to be available in the first quarter of 2006.

During 2004, we completed a successful Phase 1b clinical trial intended to evaluate the tolerability and lung deposition of our precision-engineered lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma and are currently preparing to initiate a follow-on Phase 2 clinical trial in the fourth quarter of 2005.

In addition, we are evaluating the development of aerosolized formulations of our precision-engineered surfactant to potentially treat ALI, COPD, rhinitis, sinusitis, sleep apnea and otitis media (inner ear infection);

(ii) invest in and support a long-term manufacturing strategy for the production of our precision-engineered surfactant drug product including: (i) further development and scale-up of our current contract manufacturer, Laureate; (ii) corrective measures related to the observations cited by the FDA concerning Laureate's compliance with cGMPs in connection with its review of our NDA for Surfaxin for the prevention of RDS; (iii) securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and building our own manufacturing facility. We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of our cGMP Action Plan dated January 31, 2005, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the treatment of RDS in premature infants and all of our anticipated clinical-scale production requirements including Surfaxin for the treatment of ARDS in adults. See "Risks Related to Our Business" - "In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product which may not be readily available" and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products";

(iii) build our sales and marketing capabilities to execute the launch of Surfaxin in the U.S., if approved. We are building its own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated launch of Surfaxin, is intended to allow us to fully control our own sales and marketing operation, establish a strong presence in the NICU, and optimize company economics;

(iv) implement our commercialization strategy for Surfaxin in Europe and the rest of the world through corporate partnerships; and

(v) invest in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

We will need to generate significant revenues from product sales and or related royalties and transfer prices to achieve and maintain profitability. Through December 31, 2004, we had no revenues from any product sales, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and third party contract manufacturers and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2004, we had not generated taxable income. On December 31, 2004, net operating losses available to offset future taxable income for Federal tax purposes were approximately $140,652,000. The future utilization of such loss carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of $2,558,000. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2023.

Critical Accounting Policies

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We have identified below some of our more critical accounting policies and changes to accounting policies. For further discussion of our accounting policies see Note 2 “Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements. See Item 15: “Exhibits and Financial Statement Schedules.”

Revenue Recognition- research and development collaborative agreements

For up-front payments and licensing fees related to our contract research or technology, we defer and recognize revenue as earned over the life of the related agreement. Milestone payments are recognized as revenue upon achievement of contract-specified events and when there are no remaining performance obligations.

Revenue earned under our research and development collaborative agreement contracts is recognized over a number of years as we perform research and development activities. For up-front payments and licensing fees related to our contract research or technology, we defer and recognize revenue as earned over the estimated period in which the services are expected to be performed.

Research and Development Costs

Research and development costs are expensed as incurred. We will continue to incur research and development costs as we continue to expand our product development activities. Our research and development costs have included, and will continue to include, expenses for internal development personnel, supplies and facilities, clinical trials, regulatory compliance and reviews, validation of processes and start up costs to establish commercial manufacturing capabilities. Once a product candidate is approved by the FDA, if at all, and we begin commercial manufacturing, we will no longer expense certain manufacturing costs as research and development costs for any such product.

Results of Operations

The net loss for the years ended December 31, 2004, 2003 and 2002 were $46,203,000 (or $1.00 per share), $24,280,000 (or $0.65 per share) and $17,443,000 (or $0.64 per share), respectively.

Revenue

Revenue for the years ended December 31, 2004, 2003 and 2002 were $1,209,000, $1,037,000 and $1,782,000, respectively. These revenues are primarily associated with our corporate partnerships agreement with Esteve to develop, market and sell Surfaxin in Southern Europe. Additional collaborative revenues relate to our Small Business Innovative Research (SBIR) grant to develop Surfaxin for ALI and ARDS in adults and our Orphan Products Development grant to develop Surfaxin for MAS.

The increase from 2003 to 2004 reflects revenues associated with our alliance with Esteve to develop, market and sell Surfaxin in Southern Europe. The decrease from 2002 to 2003 reflects: (i) the conclusion of our SBIR grant for research for treatments of ALI and ARDS in adults and our Orphan Products Development grant to develop Surfaxin for MAS; and (ii) the extension of the amortization period and related revenue recognition of the funding previously provided to us in connection with our strategic alliance with Esteve.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2004, 2003 and 2002 were $25,793,000, $19,750,000 and $14,347,000, respectively.

The increase in research and development expenses for the years ended December 31, 2004, 2003 and 2002 primarily reflect:

(i) manufacturing activities, including manufacturing personnel costs to support further development and scale-up of our current contract manufacturer, Laureate and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and building our own manufacturing facility. Also included in manufacturing activities are expenses associated with the transfer and validation of our manufacturing equipment to Laureate (completed in 2004), to support the production of clinical and commercial drug supply of Surfaxin in conformance with cGMPs. Expenses related to manufacturing activities were $7,010,000, $4,268,000 and $834,000 for the years ended December 31, 2004, 2003 and 2002, respectively;

(ii) non-cash compensation charges associated with stock options granted to certain employees and non-employees of $832,000, $89,000, and $34,000 for the years ended December 31, 2004, 2003 and 2002, respectively;

(iii) development and regulatory efforts for Surfaxin - primarily the Phase 3 clinical trials for Surfaxin for the prevention of RDS in premature infants;

(iv) development activities, including drug supply, for the Phase 2 clinical trial of Surfaxin for the treatment of ARDS in adults;

(v) investment in our clinical and regulatory capabilities to manage multiple Phase 2 and anticipated Phase 3 clinical trials for other SRT products in several geographic areas, including the United States, western and eastern Europe, and South America; and

(iv)research and development activities of aerosolized formulations of our SRT technology.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2004, 2003 and 2002 were $13,322,000, $5,722,000 and $5,458,000, respectively. General and administrative expenses consist primarily of the costs of executive management, finance and accounting, business and commercial development, pre-launch commercial sales and marketing, legal, facility and other administrative costs.

The increase in general and administrative expenses for the years ended December 31, 2004, 2003 and 2002 primarily reflects:

(i) commercialization activities, including building a sales and marketing senior management team, in anticipation of the launch of Surfaxin for RDS in the United States and Europe, if approved. Expenses for commercialization activities were $5,886,000, $986,000 and $1,450,000 for the years ended December 31, 2004, 2003 and 2002, respectively. These commercialization expenses were financed by use of the secured, revolving credit facility with PharmaBio in the amounts of $2,693,000, $986,000 and $1,450,000, during the years ended December 31, 2004, 2003 and 2002, respectively. See “Liquidity and Capital Resources”;

(ii) non-cash compensation charges associated with stock options granted to certain employees and non-employees of $432,000, $119,000, and $368,000 for the years ended December 31, 2004, 2003 and 2002, respectively;

(iii) financial and information technology capabilities in preparation for the potential approval and launch of Surfaxin for RDS;

(iv) corporate governance and other regulatory compliance initiatives related to the Sarbanes-Oxley Act and other recent regulatory changes concerning public companies generally; and

(v) legal activities related to the preparation and filing of patents and other activities associated with our intellectual property in connection with the expansion of our SRT pipeline.

Corporate Partnership Restructuring Charges

In 2004, we incurred a non-cash charge of $8,126,000 related to the restructuring of our corporate partnerships with Quintiles and Esteve. There were no such charges in 2003 and 2002.

In November 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate our commercialization agreements for Surfaxin in the United States. We now have full commercialization rights for Surfaxin in the United States. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and our obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS to Quintiles has been terminated. See “Corporate Partnership Agreements”. In connection with obtaining full commercialization rights for Surfaxin, we issued a warrant to purchase 850,000 shares of our common stock at an exercise price equal to $7.19 per share, which resulted in a non-cash charge of $4.0 million.

In December 2004, we restructured our strategic alliance with Esteve for the development, marketing and sales of our products in Europe and Latin America. Under the revised collaboration, we have regained full commercialization rights in key European markets, Central America and South America for our SRT, including Surfaxin for RDS in premature infants and ARDS in adults. See “Corporate Partnership Agreements”. In consideration for regaining commercial rights in the restructuring, we issued to Esteve 500,000 shares of common stock for no cash consideration. We incurred a non-cash charge of $3.5 million related to the shares of common stock issued to Esteve and $0.6 million for other expenses associated with the restructuring, primarily the reversal of Esteve’s funding of research and development costs for ARDS under our prior agreement.

Other Income and (Expense)

Other income and (expense) for the years ended December 31, 2004, 2003 and 2002 were $(171,000), $155,000 and $580,000, respectively.

Interest income for the years ended December 31, 2004, 2003 and 2002 was $711,000, $452,000, and $724,000, respectively. The increase from 2003 to 2004 is primarily due to a higher average cash, cash equivalent and marketable securities balance. The decrease from 2002 to 2003 was primarily due to a reduction in interest earned on our cash, cash equivalents, and marketable securities due to a general reduction in earned market interest rates.

Interest expense and amortization expense for the years ended December 31, 2004, 2003 and 2002 was $882,000, $297,000, and $144,000, respectively. The increase is primarily due to interest expense associated with our secured, revolving credit facility, and capital lease financing arrangements (See “Liquidity and Capital Resources”) and amortization of premiums associated with our marketable securities.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2004, we had cash, cash equivalents, restricted cash and marketable securities of $32,654,000 as compared to $29,422,000 as of December 31, 2003. The increase from December 31, 2003, is primarily due to: (i) an underwritten public offering with net proceeds of $22,795,000, resulting in the issuance of 2,200,000 shares of common stock; (ii) use of the CEFF resulting in net proceeds of $7,091,000 and the issuance of 901,742 shares of common stock; (iii) $4,321,000 received from the exercise of outstanding options and warrants; and (iv) $5,421,000 from our secured, revolving credit facility and capital lease financing arrangements. These increases were offset by approximately $35.5 million used in operating activities and purchases of equipment during the year.

Subsequent to December 31, 2004, in February 2005, we completed a registered direct offering of 5,060,000 shares of common stock. The shares were priced at $5.75 per share resulting in our receipt of gross and net proceeds equal to $29.1 million and $27.5 million, respectively.

Committed Equity Financing Facility (CEFF)

In July 2004, we entered into a CEFF with Kingsbridge, pursuant to which Kingsbridge committed to finance up to $75,000,000 of capital to support our future growth. Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of our common stock at a discount between 6% and 10% of the volume weighted average price of our common stock and thus raise capital as required, at the time, price and in amounts deemed suitable to us. In connection with the CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of common stock at an exercise price equal to $12.0744 per share.

In December 2004, we entered into a financing, pursuant to the CEFF, resulting in proceeds of $7,200,000 and the issuance of 901,742 shares of common stock at an average price of $7.98, after taking into account the applicable discount rate provided for by the CEFF. As of December 31, 2004, $67,800,000 remained available under the CEFF.

In connection with a registered public offering that we conducted in February 2005, we entered into a Placement Agent Agreement with SG Cowen & Co. LLC (SG Cowen) pursuant to which we agreed not to access funds under the CEFF until May 26, 2005, or in an amount greater than $5 million for an additional 90-day period thereafter.

Secured, Revolving Credit Facility and Capital Lease Arrangement

Secured Credit Facility with Quintiles

We entered into a collaboration arrangement with Quintiles, in 2001, to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. In connection with the commercialization agreement, Quintiles extended to us a secured, revolving credit facility of up to $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as we achieve certain milestones. We were obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services provided by Quintiles. Principal amounts owed by us under the credit facility may have been repaid out of the proceeds of milestone payments to be paid to us by Quintiles upon the achievement of certain corporate milestones. Interest was payable quarterly in arrears at a rate of 8% annually. Outstanding principal was originally due on December 10, 2004; however, certain terms and conditions of the credit facility have been restructured as described immediately below.

In November 2004, we restructured our business arrangements with Quintiles and terminated the commercialization agreement for Surfaxin in the United States. By virtue of the termination of the commercialization agreements, we are no longer obligated to use funds advanced under the credit facility for services provided by Quintiles, and Quintiles is no longer obligated to make milestone payments to us. The existing secured, revolving credit facility remained available to borrow up to $8.5 million. The original maturity date of December 10, 2004, was extended until December 31, 2006. The interest rate remains 8% annually and payments are due quarterly in arrears. As of December 31, 2004, $5,929,000 was outstanding under the credit facility, including $3,493,000 used in 2004. Subsequent to December 31, 2004, in February 2005, we borrowed the remaining available funds and have an outstanding balance of $8.5 million. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006.

Capital Lease Financing Arrangement with GECC

We have a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation. Under this arrangement, we purchase capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finances those purchases through this capital lease financing arrangement. The arrangement was originally for financing of up to $1,000,000 with an interest rate of 12.50% per annum. In 2003, the arrangement was expanded to provide, subject to certain conditions, up to an aggregate of $4,000,000 in financing for capital purchases with an interest rate of 9.50% per annum for all lab and manufacturing equipment and 10.50% per annum on all other equipment. In 2004, the arrangement was once again expanded to provide, subject to certain conditions, up to $6.5 million in addition to the $2.5 million outstanding at that time, for total available financing of up to $9.0 million.

Under the terms of the expanded financing arrangement, $5.0 million of the $6.5 million increase is immediately available to us with the remaining $1.5 million subject to FDA approval to market our lead product, Surfaxin, for the prevention of RDS in premature infants. The funds may be drawn down through September 2005. Laboratory and manufacturing equipment is leased over 48 months with an interest rate equal to 9.39% per annum and all other equipment is leased over 36 months with an interest rate equal to 9.63% per annum. As of December 31, 2004, we had used $3,042,000 of the financing available under the line of credit and, after giving effect to principal payments, $2,454,000 was outstanding.

Lease Agreements

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

We maintain our headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, sales and marketing, and administration. The lease expires in February 2010 with total aggregate payments of $4.6 million.

We also lease approximately 18,000 square feet of office and laboratory space in Doylestown, Pennsylvania. We intend to maintain a portion of the Doylestown facility for the continuation of analytical laboratory activities and sublease the remaining portions to the greatest extend possible. To the extent that subleasing is not possible, the leases will expire according to their terms. The leases expire in March 2005 and August 2005.

We lease office and laboratory space in Mountain View, California. The facility is 16,800 square feet and houses our aerosol development operations. The lease expires in June 2008 with total aggregate payments of $804,000.

Prior to the Mountain View facility, we leased office and laboratory space in Redwood City, California. The facility was approximately 5,000 square feet and housed our aerosol development operations. In December 2004, we vacated the Redwood City facility and moved to the Mountain View facility. In February 2005, the sublease agreement for the Redwood City facility was terminated.

Working Capital

We believe our current working capital, including the net proceeds from the February 2005 registered direct public offering, is sufficient to meet our planned activities into 2006, before taking into account any amounts that may be available through use of the CEFF. In connection with a registered public offering that we conducted in February 2005, we entered into a Placement Agent Agreement with SG Cowen pursuant to which we agreed not to offer to sell any additional shares of our common stock until May 29, 2005 without the consent of SG Cowen, subject to certain exceptions. Pursuant to the Placement Agent Agreement, we also agreed to not access funds under the CEFF until May 26, 2005, or in an amount greater than $5 million for an additional 90-day period thereafter.

We will need additional financing from investors or collaborators to complete research and development and commercialization of our current product candidates under development. Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of sales and marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, technological advances, status of competitors, our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Historically, our working capital has been provided from the proceeds of private financings and strategic alliances:

December 2003 Shelf Registration Statement

In 2003, we filed a shelf registration statement with the SEC for the proposed offering from time to time of up to an aggregate 6,500,000 shares of our common stock. In February 2005, we amended the original shelf registration statement, increasing the shares available by 1,468,592 shares.

In April 2004, we completed an underwritten registered direct public offering of 2,200,000 million shares of common stock priced at $11.00 per share pursuant to the shelf registration statement, resulting in gross and net proceeds of $24.2 million and $22.8 million, respectively. As of December 31, 2004, we had 4,300,000 shares reserved for issuance under the shelf registration statement which does not take into account the amendment thereto that we filed in February 2005

In February 2005, we completed a registered direct public offering of 5,060,000 shares of our common stock. The shares were priced at $5.75 per share resulting in our receipt of gross and net proceeds equal to $29.1 million and $27.5 million, respectively. There are currently 708,592 shares reserved for potential future issuance under the shelf registration statement, as amended.

Committed Equity Financing Facility (CEFF)

In December 2004, we entered into a financing pursuant to the CEFF resulting in proceeds of $7.2 million from the issuance of 901,742 shares at an average price of $7.98, after taking into account the applicable discount rate provided for by the CEFF. Currently, there is up to $67.8 million available under the CEFF, subject to the conditions and limitations thereof and the terms of the Placement Agent Agreement with SG Cowen.

Other Financing Transactions

In June and July 2003, our common stock attained certain price performance thresholds on the Nasdaq SmallCap Market that permitted us to redeem (and thereby effectively compel the exercise thereof) three of our outstanding classes of warrants which represented, in aggregate, the right to purchase approximately 3.6 million shares of common stock. Such warrants (i.e., the Class I, Class F and Class C warrants) were previously issued by us in connection with certain private placement financings that occurred in November 2002, October 2001, and April 1999, respectively. These warrants were exercised, in accordance with their respective terms, either cashlessly or for cash, resulting in the issuance to the holders of approximately 3.3 million shares of common stock and our receipt of aggregate cash proceeds of $6.1 million.

In June 2003, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately $26,100,000. We issued 4,997,882 shares of common stock and 999,577 Class A Investor Warrants to purchase shares of common stock at an exercise price equal to $6.875 per share. The Class A Investor Warrants have a seven-year term.

In November 2002, we received approximately $11.9 million in net proceeds from the sale of 6,397,517 shares of Common Stock and 2,878,883 Class I Warrants to purchase shares of Common Stock at an exercise price of $2.425 per share. In connection with this private placement, the placement agent received fees of approximately $766,000. The Class I Warrants had a five-year term and we were entitled to redeem the Class I Warrants upon the attainment of certain price performance thresholds of the common stock. In June 2003, the price performance criteria was met and all of the Class I Warrants were redeemed, resulting in 2,506,117 shares issued and proceeds of approximately $4.3 million.

We will require substantial additional funding to conduct our business, including our expanded research and product development activities. Based on our current operating plan, we believe that our currently available resources, including amounts that may be available under our revolving credit facility with PharmaBio, our CEFF with Kingsbridge and our capital lease financing arrangement with General Electric Capital Corporation, will be adequate to satisfy our capital needs into 2006. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our revolving credit facility with PharmaBio, our CEFF with Kingsbridge and our capital lease financing arrangement with General Electric Capital Corporation, we have not entered into any additional arrangements to obtain additional financing. The sale of additional equity and debt securities may result in additional dilution to our shareholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we fail to enter into collaborative ventures or to receive additional funding, we may have to reduce significantly the scope of or discontinue our planned research, development and commercialization activities, which could significantly harm our financial condition and operating results. Furthermore, we could cease to qualify for listing of our common stock on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See “Risks Related to Our Business - “We will need additional capital, and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution”; “ - The market price of our stock may be adversely affected by market volatility”; and “ - - A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.”

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Payments due under contractual obligations at December 31, 2004 are as follows:

(Dollars in thousands)

	2005	2006	2007	2008	2009	Thereafter	Total
Credit facility with corporate partner [1]	$ —	$ 5,929	$ —	$ —	$ —	$ —	$ 5,929
Capital lease obligations [1]	1,073	886	747	225	—	—	2,931
Operating lease obligations [2]	1,214	1,161	1,193	1,078	957	160	5,763
Purchase obligations [3]	4,947	—	—	—	—	—	4,947
Employment agreements [3]	2,203	—	—			—	2,203
Total	$ 9,437	$ 7,976	$ 1,940	$ 1,303	$ 957	$ 160	$ 21,773

(1) See Item 7: *"Management's Discussion and Analysis of Financial Condition and Operations - Liquidity and Capital Resources - Secured Revolving Credit Facility and Capital Lease Arrangement"*.

(2) See Item 7: *"Management's Discussion and Analysis of Financial Condition and Operations - Liquidity and Capital Resources - Lease Agreements"*.

(3) See discussion below.

Our purchase obligations include commitments entered in the ordinary course of business, primarily commitments to purchase manufacturing equipment and services for the enhancement of our manufacturing capabilities for Surfaxin and sales and marketing services related to the potential launch of Surfaxin in the United States.

Employment Agreements

On December 31, 2004, we had employment agreements with eight officers providing for an aggregate annual salary of $2,203,000. The agreements expire in December 2005. However, commencing on January 1, 2006, and on each January 1st thereafter, the term of each agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, either we or the respective officer that is a party thereto shall have given notice that any such extension is not desired. All of the foregoing agreements provide for the issuance of annual bonuses and the granting of options subject to approval by the Board of Directors. In addition, the employment agreements contain severance arrangements providing for, in certain circumstances, cash payments, equity benefits and the continuation of certain other employee benefits.

In addition to the contractual obligations above, we have certain milestone payment obligations, aggregating $2,500,000, and royalty payment obligations to Ortho Pharmaceutical, Inc. related to our product licenses. To date, we have paid $450,000 with respect to such milestones.

Risks Related to Our Business

The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time.

Because we are a biopharmaceutical company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a biopharmaceutical company, therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of December 31, 2004, we have an accumulated deficit of approximately $143 million and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our precision-engineered surfactant platform technology is based on the scientific rationale of SRT to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently, we completed and filed an NDA with the FDA and an MAA with the EMEA based on results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the prevention of RDS in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and a Phase 2 trial for the prevention of MAS in full-term infants. We are preparing for the initiation of a Phase 2 clinical trial using aerosolized SRT via nCPAP to potentially treat premature infants in the NICU suffering from neonatal respiratory failures, a Phase 2 clinical trial using Surfaxin for the prevention of BPD, and a Phase 2 trial using DSC-104 to treat patients with moderate to severe asthma.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

—the number of clinical sites;
—the size of the patient population;
—the proximity of patients to the clinical sites;
—the eligibility criteria for the study;
—the existence of competing clinical trials; and
—the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, Laureate is our sole clinical manufacturing facility that has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies.

In January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate, citing certain observations concerning Laureate's compliance with current cGMPs in connection with the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, a cGMP Action Plan was submitted to the FDA on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of our NDA for Surfaxin, we anticipate that the commercial launch of Surfaxin will occur in the fourth quarter of 2005. We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of our Action Plan should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the treatment of RDS in premature infants and our other Surfactant Replacement Therapies for our planned clinical trials. If the FDA does not accept the cGMP Action Plan, or we or Laureate do not adequately address the initiatives set forth therein, the FDA may delay its approval of our NDA for Surfaxin or reject our NDA. Any delay in the approval of the NDA, or the rejection thereof, will have a material adverse effect on our business.

Laureate or other outside manufacturers may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) comply with remediation activities set forth in the cGMP Action Plan (iii) perform under any definitive manufacturing agreements with us or (iv) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs or similar requirements that the FDA or corresponding foreign regulators establish. Contract manufacturers may face manufacturing or quality control problems causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements, or those of comparable foreign regulatory authorities, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products. See also "Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available."

In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. Laureate, our contract manufacturer, may not be able to produce Surfaxin to appropriate standards for use in clinical studies. Manufacturing or quality control problems have already and may again occur at Laureate or our other contract manufacturers, causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements necessary to continue manufacturing our ingredients or drug product. If any such suppliers or manufacturers of our products fail to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products. See also "Risks Related to Our Business - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

We will need additional capital and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available financial resources will be adequate to satisfy our capital needs into the second half of 2005. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. In connection with a registered public offering that we conducted in February 2005, we entered into a Placement Agent Agreement with SG Cowen pursuant to which we agreed not to offer to sell any additional shares of our common stock until May 29, 2005 without the consent of SG Cowen, subject to certain exceptions. Pursuant to the Placement Agent Agreement, we also agreed to not access funds under the CEFF until May 26, 2005, or in an amount greater than $5 million for an additional 90-day period thereafter. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See "Risks Related to Our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders".

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to Our Business - The market price of our stock may be adversely affected by market volatility".

Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

There are 14,473,000 shares of our common stock that are reserved for issuance under the CEFF arrangement with Kingsbridge, 375,000 of which are issuable under the warrant we granted to Kingsbridge. The issuance of shares of our common stock under the CEFF and upon exercise of the warrant will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Kingsbridge sells shares of our common stock issued under the CEFF to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or either similar transactions. This could contribute to a decline in the stock price of our common stock.

We may not be able to meet the conditions we are required to meet under CEFF and we may not be able to access any portion of the remaining $67.8 million available under the CEFF. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

In order to sell Surfaxin and our other products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and comparable agencies in foreign countries that the manufacturer of the product maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA or EMEA may not accept or approve an NDA or MAA filed by a pharmaceutical or biotechnology company for such drug product. On April 13, 2004, we filed an NDA for Surfaxin for the prevention of RDS in premature infants. The FDA accepted the NDA filing and in February 2005 we received an Approvable Letter from the FDA with respect to our NDA. The Approvable Letter contains conditions that we must meet prior to obtaining final U.S. marketing approval for Surfaxin. The conditions that we must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues, however, the FDA might still reject the NDA. We have also submitted an MAA with the EMEA for clearance to market Surfaxin for the prevention and treatment of RDS in premature infants. The EMEA has validated the MAA indicating that the application is complete and that the review process has begun. However, the EMEA may not complete the review or may reject the MAA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least the first quarter of 2006, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our precision-engineered surfactant-based therapy, MAS in full-term infants and ARDS in adults, have been granted designation as "fast-track" products under provisions of the Food and Drug Administration Modernization Act of 1997. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: ARDS in adults; RDS in infants; and MAS in full-term infants. To support our development of Surfaxin for the treatment of MAS, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years.

The EMEA has granted Orphan Medicinal Product designation for three of our intended indications for Surfaxin; RDS in premature infants, MAS in full-term infants and ALI in adults.

Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain, if any. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have a collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates that is focused on key Southern European markets. Esteve will be responsible for the marketing of Surfaxin for the prevention/treatment of RDS in premature infants, MAS in full-term infants and ALI/ARDS in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining EMEA approval for commercialization of Surfaxin in Europe for the indications of ALI/ARDS. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to EMEA filings.

If Esteve or us breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to Our Business - - We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates."

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

—defend our patents and otherwise prevent others from infringing on our proprietary rights;
—protect trade secrets; and
—operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical Corporation, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also “Risks Related to Our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

Intellectual property rights of third parties could limit our ability to market our products.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

—they will breach these agreements;
—any agreements we obtain will not provide adequate remedies for the applicable type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
—our competitors will independently discover our proprietary information and trade secrets.

We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

If we successfully develop and obtain regulatory approval for Surfaxin and the other product candidates that we are currently developing, we may: (1) market and sell them through our sales force, (2) license some of them to large pharmaceutical companies and/or (3) market and sell them through other arrangements, including co-promotion arrangements.

We currently have a limited sales and marketing team and we plan to further develop our marketing and sales team as we expect to rely primarily on such team to market Surfaxin in the United States, if Surfaxin is approved by the FDA. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Additionally, we may not be able to provide adequate incentive to our sales force. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates.

Developing a marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process. We have no prior experience developing a marketing and sales team and may be unsuccessful in our attempt to do so. If we are unable to develop an internal sales and marketing operation, we may not be able to increase market awareness and sell our products.

Establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. We expect to incur significant expenses in developing our marketing and sales team. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

We may also need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our sales force and incur additional costs.

We may also rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully develop a marketing and sales team or to enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Dependence on distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including:

- we may be required to relinquish important rights to our products or product candidates;

- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;

- our distributors or collaborators may experience financial difficulties;

- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products thereby exposing us to potential expenses in terminating such distribution agreements; and

- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties in a timely manner or if they fail to perform, it could adversely affect sales of our products. We and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the providing of incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing the sales of our products.

We may be unable to either establish marketing and sales capabilities or enter into corporate collaborations necessary to successfully commercialize Surfaxin or our other potential products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing and sales resources. To achieve commercial success for Surfaxin, or any other approved product, we must either rely upon our limited marketing and sales force and related infrastructure, or enter into arrangements with others to market and sell our products. We intend to promote Surfaxin in the United States through our own dedicated marketing and sales team. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we may not be able to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

In addition, establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. Our ability to make that investment and also execute our current operating plan and attain profitability by 2006 is dependent on numerous factors, including, as described above, partnering of clinical programs at opportune times and continued prudent fiscal management. Accordingly, we may not have the funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

Moreover, Surfaxin competes, and our product candidates in development are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales operations. Because these companies are capable of devoting significantly greater resources to their marketing and sales efforts, our marketing and sales efforts may not compete successfully against the efforts of these other companies.

We have also announced our intention to market and sell Surfaxin outside of the United States through one or more marketing partners upon receipt of approval abroad. Although our agreement with Esteve provides for collaborative efforts in directing a global commercialization effort, we have somewhat limited influence over the decisions made by Esteve or their sublicensees or the resources they devote to the marketing and distribution of Surfaxin products in their licensed territory, and Esteve or their sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and we may not receive any revenues from it. Also, we may not be able to enter into marketing and sales agreements on acceptable terms, if at all, for Surfaxin in territories not covered by the Esteve agreement, or for any of our other product candidates.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. At December 31, 2004, we had employment agreements with eight officers expiring in December 2005. However, commencing on January 1, 2006, and on each January 1st thereafter, the term of these agreements shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, either we or the officer shall have given notice that such party does not wish to extend the agreement. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

—developing products;
—undertaking preclinical testing and human clinical trials;
—obtaining FDA and other regulatory approvals or products; and
—manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, there are no approved drugs that are specifically indicated for the prevention and treatment of MAS in full-term infants or ALI/ARDS in adults. Current therapy consists of general supportive care and mechanical ventilation.

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of RDS in premature infants. Exosurf® is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. This product, however, does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer. Curosurf® is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta®, marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf® in the United States for the treatment of RDS in premature infants. Although none of the four approved surfactants for RDS in premature infants is approved for ALI or ARDS in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for these indications that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered precision-engineered surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of RDS in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”) or causing adverse immunological responses in young and older adults.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

If product liability claims are brought against us, it may result in reduced demand for our products or damages that exceed our insurance coverage.

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to $10.0 million per occurrence and $10.0 million in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of December 31, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 16% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

—announcements of the results of clinical trials by us or our competitors;
—adverse reactions to products;
—governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
—changes in the United States or foreign regulatory policy during the period of product development;
—developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
—announcements of technological innovations by us or our competitors;
—announcements of new products or new contracts by us or our competitors;
—actual or anticipated variations in our operating results due to the level of development expenses and other factors;
—changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
—conditions and trends in the pharmaceutical and other industries;
—new accounting standards; and

—the occurrence of any of the risks described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business”.

Our common stock is listed for quotation on the NASDAQ National Market. During the 12-month period ended December, 2004, the price of our common stock has ranged from $5.75 to $13.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended December 31, 2004, the average daily trading volume in our common stock was approximately 505,000 shares and the average number of transactions per day was approximately 1,600. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the National Market. If the common stock were no longer listed on the National Market, investors might only be able to trade on the Nasdaq SmallCap Market, in the over-the-counter market in the Pink Sheets® (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of December 31, 2004, we had 48,434,438 shares of common stock issued and outstanding. In addition, as of December 31, 2004, up to 9,684,327 shares of our common stock were issuable upon exercise of outstanding options and warrants. In December 2003, we filed a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. In February 2005, we filed a post-effective amendment to such registration statement registering an additional 1,468,592 shares of our common stock. In February 2005 we completed a registered direct offering of 5,060,000 shares of our common stock under the two registration statements leaving 708,592 shares of our common stock available for us to sell in registered transactions under the shelf registration statement. We have no immediate plans to sell any securities under the shelf registration. However, subject to the effectiveness of the shelf registration statement, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time. Additionally, there are 14,098,000 shares of our common stock that are reserved for issuance under the CEFF arrangement with Kingsbridge. See “Risks Related to Our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholders Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Restated Certificate of Incorporation, as amended, allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a shareholders rights agreement which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the shareholders rights agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Index to Consolidated Financial Statements on Page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

(a) Evaluation of disclosure controls and procedures

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

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

(b) Management's Report on the Company's Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, we believe that our internal control over financial reporting is effective based on those criteria, as of December 31, 2004.

Our independent auditors have issued an audit report on our assessment of our internal control over financial reporting, which is included herein.

(c) Changes in internal controls

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

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

The information required by Items 10 through 14 of Part III is incorporated by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

We have adopted a Code of Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the Code of Ethics on our Internet Website at “http://www.DiscoveryLabs.com” (this is not a hyperlink, you must visit this website through an Internet browser) under the Investor Information, Corporate Policies section. We intend to make all required disclosures on a Current Report on Form 8-K concerning any amendments to, or waivers from, our Code of Ethics with respect to our executive officers and directors. Our Website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DISCOVERY LABORATORIES, INC.

Date: March 16, 2005

By: /s/ Robert J. Capetola
Robert J. Capetola, Ph.D.
President and
Chief Executive Officer

In accordance with the Exchange Act, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Name & Title	Date
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. President and Chief Executive Officer	March 16, 2005
/s/ John G. Cooper	John G. Cooper Senior Vice President and Chief Financial Officer	March 16, 2005
/s/ Kathleen A. McGowan	Kathleen A. McGowan Controller (Principal Accounting Officer)	March 16, 2005
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Chairman of the Board of Directors	March 16, 2005
/s/ Marvin E. Rosenthale, Ph.D.	Marvin E. Rosenthale, Ph.D. Director	March 16, 2005
/s/ Max E. Link, Ph.D.	Max E. Link, Ph.D. Director	March 16, 2005
/s/ Antonio Esteve, Ph.D.	Antonio Esteve, Ph.D. Director	March 16, 2005
/s/ W. Thomas Amick	W. Thomas Amick Director	March 16, 2005

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report. All management contracts or compensatory plans or arrangements are marked with an asterisk.

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Amended and Restated By-laws of Discovery.	Incorporated by reference to Exhibit 3.2 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the SEC on March 15, 2004.
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
3.4	Certificate of Amendment to the Certificate of Incorporation of Discovery, dated as of May 28, 2004.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 9, 2004.
4.1	Form of Class E Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on March 29, 2000.
4.2	Form of Unit Purchase Option issued to Paramount Capital, Inc.	Incorporated by reference to Exhibit 4.4 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999, as filed with the SEC on March 30, 2000.
4.3	Class G Warrant issued to PharmaBio Development Inc., dated as of December 10, 2001.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 19, 2001.

Exhibit No.	Description	Method of Filing
4.4	Class H Warrant issued to PharmaBio Development Inc., dated as of December 10, 2001.	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 19, 2001.
4.5	$284,657.37 Promissory Note, dated December 27, 2002, issued to General Electric Capital Corporation.	Incorporated by reference to Exhibit 4.9 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
4.6	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.7	Class B Investor Warrant issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.9	$8,500,000 Amended and Restated Promissory Note, amended and restated as of November 3, 2004, by and between Discovery and PharmaBio Development Inc.	Incorporated by reference to Exhibit 4.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.10	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
10.1	Form of Registration Rights Agreement between Discovery, Johnson & Johnson Development Corporation and The Scripps Research Institute.	Incorporated by reference to Exhibit F to Exhibit 2.1 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, as filed with the SEC on March 31, 1998.
10.2+	Sublicense Agreement, dated as of October 28, 1996, between Johnson & Johnson, Ortho Pharmaceutical Corporation and Acute Therapeutics, Inc.	Incorporated by reference to Exhibit 10.6 to Discovery's Registration Statement on Form SB-2, as filed with the SEC on January 7, 1997 (File No. 333-19375).

Exhibit No.	Description	Method of Filing
10.3	*Restated 1993 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.4	*1995 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.5	*Amended and Restated 1998 Stock Incentive Plan of Discovery (amended as of May 11, 2004).	Incorporated by reference to Exhibit 4.1 to Discovery's Registration Statement on Form S-8, as filed with the SEC on June 8, 2004 (File No. 333-116268).
10.6	Registration Rights Agreement, dated June 16, 1998, among Discovery, Johnson & Johnson Development Corporation and The Scripps Research Institute.	Incorporated by reference to Exhibit 10.28 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.7	Stock Exchange Agreement, dated June 16, 1998, between Discovery and Johnson & Johnson Development Corporation.	Incorporated by reference to Exhibit 10.29 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.8	Form of Proprietary Information and Inventions, Non-Solicitation and Non Competition Agreement.	Incorporated by reference to Exhibit 10.50 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.9*	Form of Notice of Grant of Stock Option under the 1998 Stock Incentive Plan.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-QSB for the quarter ended September 30, 1999, as filed with the SEC on November 17, 1999.
10.10+	Research Funding and Option Agreement, dated March 1, 2000, between The Scripps Research Institute and Discovery.	Incorporated by reference to Exhibit 10.55 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999, as filed with the SEC on March 31, 2000.

Exhibit No.	Description	Method of Filing
10.11	Master Security Agreement, dated as of December 23, 2002, between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.32 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
10.12	Amendment, dated as of December 23, 2002, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.33 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
10.13+	Technology Transfer and Manufacturing Agreement dated as of October 3, 2003, between Discovery and Laureate Pharma, L.P. (now Laureate Pharma, Inc.).	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 22, 2003.
10.14	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 2.4 to Discovery's Form 8-A12G, as filed with the SEC on February 6, 2004.
10.15	Common Stock Purchase Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
10.16	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
10.17	Agreement, dated as of November 3, 2004, by and between Discovery, Quintiles Transnational Corp. and PharmaBio Development Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, as filed with the SEC on November 9, 2004.
10.18	Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of November 3, 2004, by and between Discovery and PharmaBio Development Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, as filed with the SEC on November 9, 2004.

Exhibit No.	Description	Method of Filing
10.19	Amended and Restated Security Agreement, dated as of December 10, 2001, amended and restated as of November 3, 2004, by and between Discovery and PharmaBio Development Inc.	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, as filed with the SEC on November 9, 2004.
10.21	Employment Agreement, dated as of January 1, 2004, between Discovery and Robert J. Capetola, Ph.D.	Filed herewith.
10.22	Employment Agreement, dated as of January 1, 2004, between Discovery and John G. Cooper.	Filed herewith.
10.23	Employment Agreement, dated as of January 1, 2004, between Discovery and David L. Lopez, Esq., CPA.	Filed herewith.
10.24	Employment Agreement, dated as of May 24, 2004, between Discovery and Mark Osterman.	Filed herewith.
10.25	Employment Agreement, dated as of January 1, 2004, between Discovery and Christopher J. Schaber, Ph.D.	Filed herewith.
10.26	Employment Agreement, dated as of January 1, 2004, between Discovery and Robert Segal, M.D.	Filed herewith.
10.27	Employment Agreement, dated as of January 1, 2004, between Discovery and Deni M. Zodda, Ph.D.	Filed herewith.
10.28+	Amended and Restated Sublicense and Collaboration Agreement made as of December 3, 2004, between Discovery and Laboratorios Del Dr. Esteve, S.A.	Filed herewith.

Exhibit No.	Description	Method of Filing
10.29+	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Discovery and Laboratorios Del Dr. Esteve, S.A.	Filed herewith.
21.1	Subsidiaries of Discovery.	Incorporated by reference to Exhibit 21.1 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, as filed with the SEC on March 31, 1998.
23.1	Consent of Ernst & Young LLP.	Filed herewith.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

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

CONTENTS Page

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Discovery Laboratories, Inc.
Warrington, Pennsylvania

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the “Company”) as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company’s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2005, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

Philadelphia, Pennsylvania

March 11, 2005

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Discovery Laboratories, Inc.
Warrington, Pennsylvania

We have audited management's assessment, included in the accompanying Management's Report on the Company's Internal Control over Financial Reporting, that Discovery Laboratories, Inc. and subsidiary (the "Company") maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balances sheets of the Company as of December 31, 2004 and 2003, and the related consolidated statement of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 of the Company and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 11, 2005

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,264,000	$ 29,422,000
Restricted cash	646,000	—
Available-for-sale marketable securities	2,744,000	—
Note receivable, current portion	3,000	3,000
Prepaid expenses and other current assets	685,000	665,000
Total Current Assets	33,342,000	30,090,000
Property and equipment, net of accumulated depreciation	4,063,000	2,414,000
Note receivable, non-current portion	190,000	192,000
Other assets	42,000	19,000
Total Assets	$ 37,637,000	$ 32,715,000
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,969,000	$ 4,210,000
Credit facility, current portion	—	2,436,000
Capitalized leases, current portion	854,000	383,000
Total Current Liabilities	8,823,000	7,029,000
Deferred revenue	134,000	672,000
Credit facility, non-current portion	5,929,000	—
Capitalized leases, non-current portion	1,654,000	711,000
Total Liabilities	16,540,000	8,412,000
Shareholders' Equity:		
Common stock, $.001 par value; 80,000,000 authorized; 48,434,438 and 42,491,438 issued and outstanding at December 31, 2004 and December 31, 2003, respectively	49,000	43,000
Additional paid-in capital	167,627,000	122,409,000
Unearned portion of compensatory stock options	(461,000)	(2,000)
Accumulated deficit	(143,061,000)	(96,858,000)
Treasury stock (at cost; 313,383 and 167,179 shares of common stock at December 31, 2004 and 2003, respectively)	(3,054,000)	(1,289,000)
Accumulated other comprehensive income	(3,000)	—
Total Shareholders' Equity	21,097,000	24,303,000
Total Liabilities & Shareholders’ Equity	$ 37,637,000	$ 32,715,000

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

	Year Ended December 31,		
	2004	**2003**	**2002**
Revenues:			
Contracts, licensing, milestones and grants	$ 1,209,000	$ 1,037,000	$ 1,782,000
Expenses:			
Research & development	25,793,000	19,750,000	14,347,000
General & administrative	13,322,000	5,722,000	5,458,000
Corporate partnership restructuring charges	8,126,000	—	—
Total expenses	47,241,000	25,472,000	19,805,000
Operating Loss	(46,032,000)	(24,435,000)	(18,023,000)
Other income and expenses:			
Interest income, dividends, realized gains, and other income	711,000	452,000	724,000
Interest expense	(882,000)	(297,000)	(144,000)
Other (expense) / income, net	(171,000)	155,000	580,000
Net Loss	$ (46,203,000)	$ (24,280,000)	$ (17,443,000)
Net loss per common share - basic and diluted	$ (1.00)	$ (0.65)	$ (0.64)
Weighted average number of common shares outstanding - basic and diluted	46,178,981	37,426,034	27,350,835

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2004, 2003, and 2002

	Common Stock					Treasury Stock			
	Shares	Amount	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Deficit	Shares	Amount	Accumulated Other Comprehensive (Loss)	Total
Balance - January 1, 2002	**25,546,293**	**$ 26,000**	**$ 73,163,000**	**$ (264,000)**	**$ (55,135,000)**	**(38,243)**	**$ (239,000)**	**$ 72,000**	**$ 17,623,000**
Comprehensive loss:									
Net loss					(17,443,000)				(17,443,000)
Other comprehensive loss - unrealized loss on marketable securities available-for-sale								105,000	105,000
Total comprehensive loss									(17,338,000)
Issuance of common stock, stock option exercises	77,925		60,000						60,000
Issuance of common stock, payment for services	6,086		26,000						26,000
Compensation charge on modification of options			171,000						171,000
Compensation charge on vesting of options and warrants			63,000	169,000					232,000
Issuance of common stock, March 2002 private financing	821,862		2,666,000						2,666,000
Private financing expenses			(5,000)						(5,000)
Issuance of common stock, November 2002 private financing	6,397,517	7,000	11,937,000						11,944,000
Change in value of Class H warrants			(618,000)						(618,000)
Issuance of common stock, warrant exercises	6,843								
Balance - December 31, 2002	**32,856,526**	**33,000**	**87,463,000**	**(95,000)**	**(72,578,000)**	**(38,243)**	**(239,000)**	**177,000**	**14,761,000**
Comprehensive loss:									
Net loss					(24,280,000)				(24,280,000)
Other comprehensive loss - unrealized gain on marketable securities available-for-sale								(177, 000)	(177,000)
Total comprehensive loss									(24,457,000)
Issuance of common stock, stock option exercises	993,001	1,000	1,940,000						1,941,000
Issuance of common stock, warrant exercises	3,789,875	4,000	6,846,000						6,850,000
Compensatory stock options and warrants granted/earned			20,000	(17,000)					3,000
Compensation charge on modification of options				75,000					75,000
Compensation charge on vesting of options and warrants			79,000	25,000					104,000
Earned portion of compensatory stock options				10,000					10,000
Issuance of common stock, June 2003 private financing	4,997,882	5,000	25,925,000						25,930,000
Issuance of common stock, 401k employer match	21,333		86,000						86,000
Change in value of Class H warrants			50,000						50,000
Shares tendered for exercise of stock options						(128,936)	(1,050,000)		(1,050,000)
Balance - December 31, 2003	**42,658,617**	**43,000**	**122,409,000**	**(2,000)**	**(96,858,000)**	**(167,179)**	**(1,289,000)**	**—**	**24,303,000**
Comprehensive loss:									
Net loss					(46,203,000)				(46,203,000)
Other comprehensive loss - unrealized gain on marketable securities available-for-sale								(3,000)	(3,000)
Total comprehensive loss									(46,206,000)
Issuance of common stock, stock option exercises	1,271,493	1,000	2,500,000						2,501,000
Issuance of common stock, warrant exercises	1,193,405	1,000	1,819,000						1,820,000
Issuance of common stock, 401(k) employer match	22,564		196,000						196,000
Expense related to stock options			1,723,000	(459,000)					1,264,000
Issuance of common stock, April 2004 financing	2,200,000	2,000	22,793,000						22,795,000
Issuance of warrants, October 2004 Quintiles restructuring			3,978,000						3,978,000
Issuance of common stock, December 2004 Esteve restructuring	500,000	1,000	3,465,000						3,466,000
Issuance of common stock, December 2004 draw on CEFF	901,742	1,000	7,090,000						7,091,000
Financing expenses			(63,000)						(63,000)
Change in value of Class H warrants			(48,000)						(48,000)
Shares tendered for exercise of stock options			1,765,000			(146,204)	(1,765,000)		—
Balance - December 31, 2004	**48,747,821**	**$ 49,000**	**$ 167,627,000**	**$ (461,000)**	**$(143,061,000)**	**$(313,383)**	**(3,054,000)**	**$ (3,000)**	**$ 21,097,000**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2004	**2003**	**2002**
Cash flow from operating activities:			
Net loss	$ (46,203,000)	$ (24,280,000)	$ (17,443,000)
Adjustments to reconcile net loss to net cash used			
In operating activities:			
Depreciation and amortization	816,000	416,000	285,000
Realized (gains) losses on marketable securities	—	(114,000)	(174,000)
Non-cash charge for issuance of common stock and warrants related to corporate partnership restructurings	7,443,000	—	—
Non-cash stock compensation expense	1,264,000	192,000	403,000
Stock issued for 401(k) match	196,000	86,000	—
Expenses paid using treasury stock and Common Stock	—	—	26,000
Loss on disposal of fixed assets	12,000	—	—
Changes in:			
Prepaid expenses, inventory and other current assets	(68,000)	(340,000)	1,255,000
Accounts payable and accrued expenses	3,759,000	1,197,000	1,263,000
Other assets	(23,000)	103,000	(40,000)
Proceeds from research and development collaborative agreements	—	—	1,833,000
Amortization of deferred revenue	(538,000)	(721,000)	(1,055,000)
Net cash used in operating activities	(33,342,000)	(23,461,000)	(13,647,000)
Cash flow from investing activities:			
Purchase of property and equipment	(2,207,000)	(1,514,000)	(661,000)
Restricted cash	(646,000)	—	—
Related party loan payments received	2,000	2,000	2,000
Purchase of marketable securities	(18,483,000)	(284,000)	(8,569,000)
Proceeds from sale or maturity of marketable securities	15,465,000	10,873,000	11,134,000
Net cash (used in) / provided by investing activities	(5,869,000)	9,077,000	1,906,000
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	35,911,000	34,721,000	14,665,000
Proceeds from use of credit facility	3,493,000	986,000	1,450,000
Purchase of treasury stock	(1,765,000)	(1,050,000)	—
Equipment subsequently financed through capital lease	1,928,000	908,000	434,000
Principal payments under capital lease obligation	(514,000)	(259,000)	(66,000)
Net cash provided by financing activities	39,053,000	35,305,000	16,483,000
Net (decrease) / increase in cash and cash equivalents	(158,000)	20,922,000	4,742,000
Cash and cash equivalents - beginning of year	29,422,000	8,500,000	3,758,000
Cash and cash equivalents - end of year	$ 29,264,000	$ 29,422,000	$ 8,500,000
Supplementary disclosure of cash flows information:			
Interest Paid	$ 186,000	$ 167,000	$ 88,000
Noncash transactions:			
Class H warrants issued/revalued	$ (48,000)	$ 50,000	$ (618,000)
Unrealized gain / (loss) on marketable securities	(3,000)	(177,000)	105,000

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 1 - The Company and Basis of Presentation

Discovery Laboratories, Inc. (the "Company") is a biopharmaceutical 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. The Company's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. The Company believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

The Company has received an Approvable Letter from the FDA for Surfaxin^{Ò}, the Company's lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. The Company is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term infants.

Management's Plans and Financings

The Company has incurred substantial losses since inception. The Company funds its operations primarily through the issuance of equity and through strategic alliances. The Company expects to continue to expend substantial amounts for continued product research, development and commercialization activities for the foreseeable future. Management plans to fund its research, development and commercialization activities with the issuance of additional equity and entering into strategic alliances, if possible, that will provide funding for operations, including increased commercialization efforts this year. Continuation of the Company is dependent on its ability to obtain additional financing and, ultimately, on its ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that the Company's efforts ultimately will be successful.

Note 2 - Summary of Significant Accounting Policies

Cash and cash equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Available-for-sale marketable securities

The investments are classified as available for sale and are comprised of shares of high quality fixed income commercial paper and mutual funds. Investments are carried at fair market value. Realized gains and losses are computed using the average cost of securities sold. Any appreciation/depreciation on these investments is recorded as other comprehensive income (loss) in the statements of changes in stockholders' equity until realized.

Property and equipment

Property and equipment is recorded at cost. Depreciation of furniture and equipment is computed using the straight-line method over the estimated useful lives of the assets (five to seven years). Leasehold improvements are amortized over the lower of the (a) term of the lease or (b) useful life of the improvements.

Use of estimates

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

Long-lived assets

Under Statement of Financial Accounting Standards (SFAS) No. 144, the Company is required to recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable from its undiscounted cash flows and measure any impairment loss as the difference between the carrying amount and the fair value of the asset. No impairment was recorded during the years ended December 31, 2004, 2003 and 2002, as management of the Company believes the sum of its future undiscounted cash flows will exceed the carrying amount of the assets.

Research and development

Research and development costs are charged to operations as incurred.

Revenue recognition - research and development collaborative agreements

The Company received nonrefundable fees from companies under license, sublicense, collaboration and research funding agreements. The Company initially records such funds as deferred revenue and recognizes research and development collaborative contract revenue when the amounts are earned, which occurs over a number of years as the Company performs research and development activities. See Note 8 - Corporate Partnerships Agreements for a detailed description of the Company’s revenue recognition methodology under these agreements.

Additionally, the Company has been awarded grants from certain third party organizations to help fund research for the drugs that the Company is currently developing. Once research and development expenditures qualifying under the grant are incurred, grant reports are periodically completed and submitted to the granting agency for review. If approved, the granting agency remits payment to the Company, which is recorded as revenue upon receipt.

Stock-based compensation

The Financial Accounting Standards Board has issued Statement of Financial Accounting Standards (SFAS) No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition to a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on the reported results. The Company continues to account for its stock option plans in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Options Issued to Employees" and, accordingly, recognizes compensation expense for the difference between the fair value of the underlying Common Stock and the exercise price of the option at the date of grant. The effect of applying SFAS No. 148 on pro forma net loss is not necessarily representative of the effects on reported net income or loss for future years due to, among other things, (i) the vesting period of the stock options and (ii) the fair value of additional stock options in future years. Had compensation cost for the Company's stock option plans been determined based upon the fair value of the options at the grant date of awards under the plans consistent with the methodology prescribed under SFAS No. 148, the pro forma net loss for the years ended December 31, 2004, 2003, and 2002 would have been as follows:

	Years Ended December 31,		
	2004	2003	2002
Net Loss as reported	$(46,203,000)	$(24,280,000)	$(17,443,000)
Additional stock-based employee compensation	$ (3,996,000)	$ (3,738,000)	$ (2,264,000)
Pro forma net loss	$(50,199,000)	$(28,018,000)	$(19,707,000)
Pro forma net loss per share	$ (1.09)	$ (0.75)	$ (0.72)

The net loss as reported on the income statement for the year ended December 31, 2004 includes compensation costs for stock-based employee compensation awards of $1,264,000. These costs include a non-cash charge of $483,000 for the modification of options held by a former member of management. These compensation costs also include a non-cash charge related to the vested portion of employee stock options granted and approved by the Company's Board of Directors in December 2003, but were subject to subsequent shareholder approval. These employee options were granted at fair market value on the date of approval by the Board of Directors. These options were expressly subject to the requisite approval of the Company's shareholders for an amendment to the 1998 Plan authorizing an increase in the number of shares of Common Stock issuable under the plan in an amount equal to or greater than the aggregate amount of such options. Approval was obtained at the Company's Annual Meeting of Shareholders for 2004, at which time the fair market value of our Common Stock was greater than the fair market value on the date the options were granted. The difference in fair market value on the date of grant versus the date of subsequent shareholder approval was recorded as unearned portion of compensatory stock options and will be recognized into expense as the options vest. The Company incurred a non-cash charge of $461,000 related to the vesting of such options in 2004.

The weighted average fair value of the options granted were estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	2004	2003	2002
Expected dividend yield	0%	0%	0%
Expected stock price volatility	81%	86%	95%
Risk-free interest rate	3.5%	2.4%	2.5%
Expected option term	3.5 years	3.5 years	3.5 years

In December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment, which establishes standards for transactions in which an entity exchanges its equity instruments for goods or services. See Note 14 - Recently Issued Accounting Standards

Net loss per common share

Net loss per common share is computed pursuant to the provisions of SFAS No. 128, "Earnings per Share", and is based on the weighted average number of common shares outstanding for the periods. For the years ended December 31, 2004, 2003 and 2002, 9,684,000, 8,753,000 and 4,032,000 shares of Common Stock, respectively, were potentially issuable upon the exercise of certain of the Company’s stock options and warrants and were not included in the calculation of net loss per share as the effect would be anti-dilutive.

Reclassification

Certain prior year balances have been reclassified to conform with the current presentation.

Note 3 - Investments

The available-for-sale marketable securities held by the Company at December 31, 2004 consisted of high-quality, corporate bonds with an aggregate cost of $2,737,000 and gross unrealized losses of $3,000 included in accumulated other comprehensive income. As of December 31, 2003, the Company did not hold marketable securities. As of December 31, 2002, the Company had marketable securities with an aggregate cost of $10,475,000 and a net unrealized holding gain of $177,000 included in accumulated other comprehensive income. All available-for-sale marketable securities have a maturity period of less than one year.

Note 4 - Restricted Cash

The Company has cash balances that are restricted as to use and discloses such amounts separately on the Balance Sheet. The primary component of Restricted Cash is a security deposit in the amount of $600,000 in the form of a letter of credit related to the lease agreement dated May 26, 2004 for the Company's office space in Bucks County, Pennsylvania. The letter of credit is secured by cash and is included in the Balance Sheet as "Restricted Cash." Beginning in March 2008, the security deposit and the letter of credit will be reduced to $400,000. That balance will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease in November 2009, the letter of credit will expire.

Note 5 - Note Receivable

Note receivable pertains to a $200,000, 7% per annum mortgagor's note due from an executive of the Company. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly payments of principal and interest over a 360-month period. The principal balance outstanding at December 31, 2004, 2003 and 2002 was approximately $193,000, $195,000 and $197,000, respectively.

Note 6 - Property and Equipment

Property and equipment as of December 31, 2004 and 2003 was comprised of the following:

	December 31,	
	2004	2003
Equipment [(1)]	$ 3,589,000	$ 2,217,000
Furniture	869,000	314,000
Leasehold improvements	330,000	174,000
Construction in progress	891,000	792,000
Property and equipment before accumulated depreciation	5,679,000	3,497,000
Accumulated depreciation	(1,616,000)	(1,083,000)
Net property and equipment	$ 4,063,000	$ 2,414,000

(1) The equipment balance consists of (i) manufacturing equipment to produce Surfaxin for use in the Company's clinical trials and for anticipated commercial needs; (ii) laboratory equipment for research and development activities, including aerosol development; and (iii) computers and office equipment to support the research, development, administrative and commercialization activities of the Company.

The property and equipment balance as of December 31, 2004 and 2003 includes $3,396,000 and $1,468,000, respectively, of property and equipment subject to a capital lease. The related accumulated depreciation was $546,000 and $194,000 as of December 31, 2004 and 2003, respectively.

The balance of Construction in Progress at December 31, 2003 primarily consisted of manufacturing equipment and related installation and validation costs associated with the transfer of the Company's manufacturing capabilities to its contract manufacturer, Laureate Pharma, Inc. ("Laureate"). This project was completed in 2004 and the assets were transferred from Construction in Progress to Equipment. The balance of Construction in Progress at December 31, 2004 primarily consists of new manufacturing equipment that will ultimately serve as the Company's back-up manufacturing capability.

In addition to the balance in Construction in Progress, the Company had additional construction purchase commitments, yet to be fulfilled, totaling $891,000 as of December 31, 2004. As of December 31, 2003, the Company had $554,000 of construction purchase commitments, yet to be fulfilled, which were subsequently fulfilled in 2004.

Depreciation expense for the years ended December 31, 2004, 2003, and 2002 was $546,000, $331,000, and $252,000, respectively.

Note 7 - Secured Credit Facility and Capital Lease Financing Arrangement

Secured Credit Facility with Quintiles Transnational Corp. ("Quintiles")

The Company entered into a collaboration arrangement with Quintiles, in 2001, to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. In connection with the commercialization agreement, Quintiles extended to the Company a secured, revolving credit facility of up to $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States certain milestones were achieved. The Company was obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services provided by Quintiles. Principal amounts owed by us under the credit facility may have been repaid out of the proceeds of milestone payments to be paid to the Company by Quintiles upon the achievement of certain corporate milestones. Interest was payable quarterly in arrears at a rate of 8% annually. Outstanding principal was due on December 10, 2004.

In November 2004, the Company restructured its business arrangements with Quintiles and terminated the commercialization agreement for Surfaxin in the United States. The existing secured, revolving credit facility remained available to borrow up to $8.5 million. By virtue of the termination of the commercialization agreements, the Company is no longer obligated to use funds advanced under the credit facility for services provided by Quintiles, and Quintiles is no longer obligated to make milestone payments. The original maturity date of December 10, 2004, is now extended until December 31, 2006. The interest rate remains 8% annually and payments are due quarterly in arrears. As of December 31, 2004, $5,929,000 was outstanding under the credit facility, including $3,493,000 used in 2004. Subsequent to December 31, 2004, in February 2005, the Company borrowed the remaining available funds and has an outstanding balance of $8.5 million. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006.

Capital Lease Financing Arrangement with General Electric Capital Corporation (GECC)

Capital lease liabilities for the years ended December 31, 2004 and 2003 are as follows:

	2004	2003
Current		
GECC	$ 828,000	$ 305,000
All Other	26,000	78,000
Capital Leases, Current	854,000	383,000
Long Term		
GECC	1,626,000	658,000
All Other	28,000	52,000
Capital Leases, Long Term	1,654,000	711,000
Total Capital Leases	$ 2,508,000	$ 1,094,000

The Company has a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation (“GECC”). Under this arrangement, the Company purchases capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finances those purchases through this capital lease financing arrangement. The arrangement originally provided for financing up to $1,000,000 with an interest rate of 12.50% per annum. In 2003, the arrangement was expanded to provide, subject to certain conditions, up to an aggregate $4,000,000 in financing for capital purchases with an interest rate of 9.50% per annum for all lab and manufacturing equipment and 10.50% per annum on all other equipment. In 2004, the arrangement was expanded again to provide, subject to certain conditions, up to $6.5 million in addition to the $2.5 million outstanding at that time, for total available financing of up to $9.0 million. Under the terms of the expanded financing arrangement, $5.0 million of the $6.5 million increase is immediately available to the Company with the remaining $1.5 million subject to FDA approval to market the Company’s lead product Surfaxin, for the prevention of RDS in premature infants. The funds may be drawn through September 2005. Laboratory and manufacturing equipment is leased over 48 months with an interest rate equal to 9.39% per annum and all other equipment is leased over 36 months with an interest rate equal to 9.63% per annum. As of December 31, 2004, the Company had used $3,042,000 of the available financing under the line of credit and, after giving effect to principal payments made by the Company, $2,454,000 was outstanding.

Note 8 - Corporate Partnership Agreements

Laboratorios del Dr. Esteve, S.A. (Esteve)

In 1999, the Company entered into a corporate partnership with Esteve to develop, market and sell Surfaxin in portions of Europe. In 2002, the Company significantly expanded its relationship with Esteve by entering into a new collaboration arrangement, which superseded the 1999 agreement, and expanded the territory covered by those original agreements to all of Europe, Central and South America, and Mexico. Esteve was obligated to provide certain commercialization services for Surfaxin for the treatment of RDS in premature infants, MAS in full-term infants and ARDS in adult patients. The Company's exclusive supply agreement with Esteve provided that Esteve would purchase all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for ARDS and make certain milestone payments to the Company upon the attainment of European marketing regulatory approval for Surfaxin. In connection with the 2002 expanded agreement, Esteve purchased 821,862 shares of Common Stock at $4.867 per share for $4.0 million in gross proceeds and paid the Company a non-refundable licensing fee of $500,000. The Company has accounted for the license fees and reimbursement of research and development expenditures associated with the Esteve collaboration as deferred revenue. The balance in deferred revenue of $134,000 at December 31, 2004 relates entirely to the license agreement with Esteve for which the Company will recognize revenue using a straight-line method through the anticipated date of FDA approval for RDS.

In December 2004, the Company and Esteve restructured their corporate partnership for the development, marketing and sales of the Company's products in Europe and Latin America. Under the revised partnership, the Company has regained full commercialization rights in key European markets, Central America and South America for its SRT, including Surfaxin® for RDS in premature infants and ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal and Spain, and now has development and marketing rights to a broader portfolio of the Company's potential SRT products. This restructured partnership supersedes the existing sublicense and supply agreements we had entered into with Esteve in March 2002.

Esteve has also agreed to pay the Company stipulated cash fees upon achieving certain milestones, primarily upon marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In consideration for regaining commercial rights in the 2004 restructured partnership, the Company issued to Esteve 500,000 shares of Common Stock for no cash consideration, valued at $3.5 million. The Company incurred a non-cash charge, including the value of the shares issued and other costs related to the restructuring, of $4.1 million. This charge is a component of Corporate Partnership Restructuring Charges on the Income Statement. The Company also granted to Esteve rights to additional potential SRT products in the Company's pipeline. The Company also agreed to pay to Esteve 10% of cash up-front and milestone fees that the Company may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of our other Surfactant Replacement Therapies in the territory for which the Company had previously granted a license to Esteve. Any such up-front and milestone fees that the Company may pay to Esteve are not to exceed $20 million in the aggregate.

Quintiles Transnational Corp., and PharmaBio Development Inc.

In 2001, the Company entered into a commercialization agreement with Quintiles, and its affiliate, PharmaBio Development Inc. (PharmaBio), to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. Quintiles was obligated to hire and train a dedicated United States sales force that would have been branded in the market as Discovery's. PharmaBio agreed to fund up to $70 million of the sales force costs as well as other sales and marketing costs for commercialization of Surfaxin in the United States for seven years. Additionally, the collaboration allowed for this sales force to be transferred to the Company at the end of the seven year term, with an option for the Company to acquire it sooner. Under the agreement, the Company was to receive 100% of the revenues from sales of Surfaxin and agreed to pay PharmaBio a commission on net sales in the United States of Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants and all "off-label" uses for 10 years following first launch of the product in the United States. PharmaBio also extended to the Company a secured revolving credit facility of up to $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as the Company achieved certain milestones. See Note 7 - Secured Credit Facility and Capital Lease Financing Arrangement.

In November 2004, the Company reached an agreement with Quintiles to restructure its business arrangements and terminate the commercialization agreements for Surfaxin in the United States. The Company now has full commercialization rights for Surfaxin in the United States. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and the Company's obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS to Quintiles has been terminated.

In connection with obtaining full commercialization rights for Surfaxin, the Company issued 850,000 warrants to PharmaBio, Quintiles' strategic investment group, to purchase shares of Common Stock at an exercise price equal to $7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to the Company if exercised equal to approximately $6.0 million. The Company valued the warrants at this fair value on the date of issuance and incurred a non-cash charge of $4.0 million in connection with the issuance. This charge is a component of Corporate Partnership Restructuring Charges on the Income Statement. The existing secured revolving credit facility of $8.5 million with PharmaBio will remain available and the original maturity date of December 10, 2004 is now extended until December 31, 2006. See Note 7 - Secured Credit Facility and Capital Lease Financing Arrangement.

Note 9 - Licensing and Research Funding Agreements

Ortho Pharmaceutical, Inc.

The Company and Ortho Pharmaceutical, Inc. (Ortho Pharmaceutical), a wholly-owned subsidiary of Johnson & Johnson, Inc., are parties to an agreement granting an exclusive license of the Surfaxin technology to the Company in exchange for certain license fees, future milestone payments (aggregating $2,500,000) and royalties. To date, the Company has paid $450,000 for milestones achieved.

The Scripps Research Institute

The Company and The Scripps Research Institute (Scripps) were parties to a research funding and option agreement which expired in February 2005. Pursuant to this agreement, the Company was obligated to fund a portion of Scripps' research efforts and thereby had the option to acquire an exclusive worldwide license to the technology developed from the research program during the term of the agreement. Scripps owned all of the technology that it developed pursuant to work performed under the agreement. To the extent the Company did not exercise its option to technology developed under the agreement, the Company had the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed under the agreement. Payments to Scripps under this agreement were $600,000, $649,000 and $572,000 in 2004, 2003, and 2002, respectively.

Note 10 - Stockholders' Equity

2005 Registered Public Offering

Subsequent to December 31, 2004, in February 2005, the Company completed a registered direct offering of 5,060,000 shares of Common Stock. The shares were priced at $5.75 per share resulting in gross and net proceeds to the Company equal to $29.1 million and $27.5 million, respectively.

2004 Committed Equity Financing Facility (CEFF)

In July 2004, the Company entered into a Committed Equity Financing Facility ("CEFF") with Kingsbridge Capital Ltd. ("Kingsbridge"), pursuant to which Kingsbridge has committed to finance up to $75.0 million of capital for newly-issued shares of Common Stock. The exact timing, amount and price of any CEFF financings is subject to the Company's ultimate determination, and certain conditions of the facility agreement. See - Liquidity and Capital Resources "Committed Equity Financing Facility ("CEFF")". In connection with the CEFF, the Company issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of Common Stock at an exercise price equal to $12.0744 per share. The warrant, which expires in January 2010, must be exercised for cash, except in limited circumstances, for total proceeds equal to approximately $4.5 million, if exercised. As of December 31, 2004, the Class B Investor Warrant had not been exercised in whole or in part. In connection with the 2005 Registered Public Offering, the Company entered into a Placement Agent Agreement with SG Cowen & Co. LLC ("SG Cowen") pursuant to which the Company agreed not to access funds under the CEFF for the 90-day period ending May 26, 2005, or in an amount greater than $5 million for an additional 90-day period thereafter.

In December 2004, the Company entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to the Company of $7.2 million from the issuance of 901,742 shares of Common Stock at an average price of $7.98, after taking into account the applicable discount rate provided for by the CEFF. As of December 31, 2004, $67.8 million remained available under the CEFF.

2004 Restructuring of the Corporate Partnership with Esteve

In December 2004, the Company restructured its strategic alliance with Esteve for the development, marketing and sales of our products in Europe and Latin America. Under the revised collaboration, the Company has regained full commercialization rights in key European markets, Central America and South America for its SRT, including Surfaxin for RDS in premature infants and ARDS in adults. The Company granted to Esteve rights to additional potential SRT products in its pipeline. See Note 8 - Corporate Partnership Agreements. In consideration for regaining commercial rights in the restructuring, the Company issued to Esteve 500,000 shares of common stock for no cash consideration, and for accounting purposes, incurred a non-cash charge of $3.5 million, representing the fair market value of the shares on the date of issuance. This charge, including other costs associated with the restructuring, is a component of Corporate Partnership Restructuring Charges on the Income Statement.

2004 Restructuring of Corporate Partnership with Quintiles

In November 2004, the Company agreed with Quintiles to restructure its business arrangements and terminate the commercialization agreements for Surfaxin in the United States. The Company regained full commercialization rights for Surfaxin in the United States. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and the Company’s obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS to Quintiles has been terminated. See Note 8 - Corporate Partnership Agreements. In connection with obtaining full commercialization rights for Surfaxin, the Company issued to Quintiles a warrant to purchase 850,000 shares of Common Stock at an exercise price equal to $7.19 per share. The warrant has a 10-year term and is exercisable for total proceeds equal to approximately $6 million in cash or as an offset to cancel indebtedness of the Company in connection with the existing secured revolving credit facility of $8.5 million. For accounting purposes, the Company incurred a non-cash charge of $4.0 million, representing the fair market value of the warrant on the date of issuance. This charge is a component of Corporate Partnership Restructuring Charges on the Income Statement.

2004 Private Placement

In April 2004, the Company completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in the Company’s receipt of gross and net proceeds equal to $24.2 million and $22.8 million, respectively.

2004 Redemption of Warrants

Pursuant to an equity investment from Quintiles and PharmaBio in December 2001, the Company issued Class G Warrants to purchase 357,143 shares of Common Stock at an exercise price equal to $3.485 per share (subject to adjustment). The Class G Warrants had a 10-year term and the Company was entitled to redeem the Class G Warrants upon the attainment of certain price performance thresholds of the common stock. In February 2004, the price performance criteria was met and the warrants were redeemed. The warrants were cashlessly exercised resulting in the issuance of 249,726 shares of Common Stock.

Pursuant to a credit facility from Quintiles and PharmaBio in December 2001, the Company issued Class H Warrants to purchase 320,000 shares of Common Stock. The Class H Warrants were exercisable at $3.03 per share and were exercisable proportionately only upon availability of the credit facility. The Class H Warrants had a 10-year term and the Company was entitled to redeem the Class H warrants upon the attainment of certain price performance thresholds of the Common Stock. In 2004, the price performance criteria was met and the warrants were redeemed. The Class H Warrants were cashlessly exercised resulting in the issuance of 228,402 shares of Common Stock.

2003 Private Placement

In June 2003, the Company completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately $25.9 million. The Company issued 4,997,882 shares of Common Stock and 999,577 Class A Investor Warrants to purchase shares of Common Stock at an exercise price equal to $6.875 per share. The Class A Investor Warrants have a seven-year term. As of December 31, 2004, approximately 946,000 of the Class A Investor Warrants remain unexercised.

2002 Private Placement

In November 2002, the Company received approximately $11.9 million in net proceeds from the sale of 6,397,517 shares of Common Stock and 2,878,883 Class I Warrants to purchase shares of Common Stock at an exercise price equal to $2.425 per share. In connection with this private placement, the placement agent received fees of approximately $766,000. The Class I Warrants had a five-year term and the Company was entitled to redeem the Class I Warrants upon the attainment of certain price performance thresholds of the Common Stock. In June 2003, the price performance criteria was met and all of the Class I Warrants were redeemed, resulting in 2,506,117 shares of Common Stock issued and proceeds of approximately $4.3 million.

Common shares reserved for future issuance

Common shares reserved for potential future issuance upon exercise of warrants

The chart below details shares of Common Stock reserved for future issuance upon the exercise of warrants.

	Shares Reserved for Issuance upon Exercise of Warrants December 31,			
	2004	2003	Exercise Price	Expiration Date
Quintiles Warrant (2004 business restructuring)	850,000	—	$ 7.19	11/3/2014
Class B Investor Warrants (2004 Kingsbridge CEFF)	375,000	—	$ 12.07	1/6/2010
Class A Investor Warrants (2003)	945,745	954,717	$ 6.88	2/19/2010
Class G Quintiles Warrants (2001)	—	357,143	$ 3.49	12/9/2011
Class H Quintiles Warrants (2001)	—	320,000	$ 3.03	12/9/2011
Class E Investor Warrants (2000)	310,567	549,029	$ 7.38	3/21/2005
Placement Agent (2000)	214,794	348,341	$ 8.11	9/21/2007
Placement Agent Warrants (1999)	—	193,100	$ 0.67	1/1/2010
Placement Agent Warrants (1996)	4,615	41,454	$ 0.64	11/15/2006
Placement Agent Warrants (1996)	138,953	433,670	$ 3.53	11/15/2006
Total	**2,839,674**	**3,197,454**		

Common shares reserved for potential future issuance upon exercise of stock options

The Company's has a Stock Incentive Plan, which includes three equity programs. See Note 11 - Stock Options. The Company had shares reserved for potential future issuance under the Stock Incentive Plan of 7,331,000 and 5,587,000 as of December 31, 2004 and 2003, respectively, for stock options outstanding and stock options available for future grants.

Common shares reserved for potential future issuance under the CEFF

The Company entered into a CEFF with Kingsbridge pursuant to which Kingsbridge has committed to finance up to $75.0 million of capital for newly-issued shares of common stock. See - Liquidity and Capital Resources "Committed Equity Financing Facility (CEFF)". In October 2004, the Company filed a registration statement pursuant to the CEFF, which reserved 15,000,000 shares of common stock for future issuance under the CEFF calculated as the full amount available, $75.0 million, divided by the lowest price per share as determined by the CEFF agreement, $5.00 per share. In December 2004, the Company entered into a financing pursuant to the CEFF resulting in the issuance of 901,742 shares for gross proceeds of $7.2 million. After giving effect to the shares issued in the December CEFF financing, the Company had 14,098,000 shares of Common Stock reserved for issuance under of the CEFF as of December 31, 2004. In connection

Common shares reserved for future issuance under the Shelf Registration Statement

In 2003, the Company filed a shelf registration statement with the SEC for the proposed offering from time to time of up to an aggregate 6,500,000 million shares of Common Stock. In April 2004, the Company completed an underwritten public offering of 2,200,000 million shares of Common Stock pursuant to the shelf registration statement, resulting in gross proceeds of $24.2 million. As of December 31, 2004 and 2003, the Company had 4,300,000 and 6,500,000 shares reserved for issuance under the shelf registration statement.

In February 2005, the Company amended the original shelf registration statement, increasing the shares of Common Stock available by 1,468,592 shares. Also in February 2005, the Company completed a registered direct offering of 5,060,000 shares of Common Stock pursuant to the shelf registration statement, resulting in gross proceeds of $29.1 million. There are currently 708,592 shares of Common Stock reserved for potential future issuance under the shelf registration statement.

Common shares reserved for potential future issuance under the Company's 401(k) Plan

The Company has a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, the Company allows for periodic discretionary matches as a percentage of each participant's contributions in newly issued shares of Company Stock. The Company match resulted in the issuance of 22,564 and 21,333 shares of common stock for the years ended December 31, 2004 and 2003, respectively. The Company had shares reserved for potential future issuance under the Company's 401(k) Plan of 106,103 and 128,667 for the years ended December 31, 2004 and 2003, respectively.

Treasury stock/Common Stock issued for services

The Company has a stock repurchase program wherein the Company may buy its own shares on the open market and use such shares to settle indebtedness. Such shares are accounted for as treasury stock. During the years ended December 31, 2004, 2003 and 2002, the Company did not repurchase its own shares on the open market.

During the twelve months ended December 31, 2004, certain members of the Company's management and certain consultants, pursuant to terms set forth in the Company's Amended and Restated 1998 Stock Incentive Plan, tendered shares of Common Stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the twelve months ended December 31, 2004, 146,204 shares of our Common Stock were tendered to us by such parties in lieu of cash at a weighted average price of $12.07 per share. These shares are accounted for as treasury stock as follows.

The following chart details shares tendered to the Company in lieu of cash for the exercise of stock options:

	Number of shares received in lieu of cash for the exercise of stock options	Average price Per share
January 2004	97,226	$ 12.44
March 2004	18,497	12.08
May 2004	24,702	11.27
July 2004	5,779	9.30
Total	146,204	$ 12.07

Note 11 - Stock Options

In March 1998, the Company adopted its 1998 Stock Incentive Plan, which includes three equity programs (the "1998 Plan"):

Discretionary Option Grant Program

Under the Discretionary Option Grant Program, options to acquire shares of the Common Stock may be granted to eligible persons who are employees, non-employee directors, consultants and other independent advisors. Options granted under the Discretionary Option Grant Program are granted at no less than one hundred percent (100%) of the fair market value of the common stock on the date of the grant; generally vest over a period of three years; and expire no later than 10 years from the date of the grant, subject to certain conditions. Options granted and outstanding through November 2003 are exercisable immediately upon grant, however, the shares issuable upon the exercise of such options are subject to repurchase by the Company. Any such repurchase rights lapse as the options vest according to their stated terms. All shares of Common Stock issuable upon such non-vested options are subject to restrictions on transferability. Options granted under the 1998 Plan after November 2003 are only exercisable upon vesting.

Stock Issuance Program

Under the Stock Issuance Program, such eligible persons may be issued shares of the Common Stock. The Company has not issued any such shares for the years ended December 31, 2004, 2003 and 2002.

Automatic Option Grant Program

Under the Automatic Option Grant Program, eligible non-employee directors will automatically receive option grants at periodic intervals at an exercise price equal to the fair market value per share on the date of the grant. Such options usually vest upon the first anniversary of the date of the grant and expire no later than 10 years from the date of the grant.

The Company currently has 9,570,000 shares of Common Stock under the 1998 Stock Incentive Plan, of which 7,331,000 remain reserved for issuance over the term of the plan. The 1998 Plan was successively amended at each of the Annual Meetings of Shareholders for the years 2004, 2003, and 2002, to increase the maximum number of shares of Common Stock reserved for issuance over the term of the plan by 3,000,000 shares, 1,420,000 shares, and 1,000,000 shares, respectively. In addition, in 2002, the Board of Directors approved amendments to the 1998 Plan that (i) increased the exercise price of options granted to non-employee directors pursuant to the Automatic Option Grant Program from 60% to 100% of the fair market value per share on the date of the grant and (ii) removed the Plan Administrator's authority to effect the cancellation and regrant of any outstanding options under the Discretionary Option Grant Program.

A summary of the Company's stock option activity and related information is as follows:

	Price Per Share	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Balance at January 1, 2002	$0.0026 - $7.00	4,246,959	$3.15	8.01 years
Options granted	1.26 - 3.65	1,786,000	2.14	
Options exercised	0.0821 - 2.10	(77,925)	0.77	
Options forfeited	.3205 - 7.00	(349,850)	3.34	
Balance at December 31, 2002	0.0026 - 5.375	5,605,184	2.85	7.81 years
Options granted	1.70 - 9.17	1,111,750	6.75	
Options exercised	0.0026 - 4.22	(993,001)	1.95	
Options forfeited	0.1923 - 5.06	(168,611)	2.76	
Balance at December 31, 2003	0.0026 - 9.17	5,555,322	3.80	7.44 years
Options granted	5.92 - 10.60	2,681,250	8.60	
Options exercised	.3205 - 9.17	(1,271,493)	3.41	
Options forfeited	1.42 - 10.60	(120,425)	5.64	
Balance at December 31, 2004	$.0026 - $10.60	6,844,654	$5.69	7.76 years

Options granted and outstanding through November 2003 are exercisable immediately upon grant, however, the shares issuable upon the exercise of such options are subject to repurchase by the Company. Any such repurchase rights lapse as the options vest according to their stated terms. The following table provides detail with regard to options outstanding and exercisable at December 31, 2004:

Price per share	Shares Outstanding	Weighted Average Price per Share	Weighted Average Remaining Contractual Life	Shares Exercisable	Weighted Average Price per Share
$0.0026 - $2.00	749,831	$ 1.59	6.97 years	749,831	$ 1.59
$2.01 - $4.00	1,681,348	$ 2.63	7.01 years	1,681,348	$ 2.63
$4.00 - $6.00	1,052,021	$ 4.69	5.29 years	1,050,021	$ 4.68
$6.01 - $8.00	856,501	$ 6.74	9.45 years	341,488	$ 6.84
$8.01 - $10.00	2,252,953	$ 8.90	8.92 years	1,342,203	$ 8.67
$10.01 - $12.00	252,000	$ 10.12	9.38 years	25,000	$ 10.43
	6,844,654			5,189,891	

The following table provides further detail with regard to options that are exercisable and vested (therefore, not subject to repurchase rights and related restrictions on transferability by the Company) at December 31, 2004:

Price per share	Shares Exercisable	Weighted Average Price per Share	Vested Shares not subject to Repurchase Rights	Weighted Average Price per Share
$0.0026 - $2.00	749,831	$ 1.59	557,085	$ 1.53
$2.01 - $4.00	1,681,348	$ 2.63	854,273	$ 2.52
$4.00 - $6.00	1,050,021	$ 4.68	1,007,689	$ 4.66
$6.01 - $8.00	341,488	$ 6.84	322,720	$ 6.81
$8.01 - $10.00	1,342,203	$ 8.67	1,177,668	$ 8.75
$10.01 - $12.00	25,000	$ 10.43	25,000	$ 10.43
	5,189,891		3,944,435	

Prior to 2002, under the Automatic Option Grant Program, eligible directors automatically received option grants at periodic intervals at an exercise price equal to 60% of fair market value per share on the date of the grant. Since 2002, all stock option grants to non-employee directors pursuant to the Automatic Option Grant Program are required to be at 100% of the fair market value per share on the date of the grant.

The following table pertains to options granted to non-employee directors at less than fair market value prior to 2002 that remain outstanding:

	December 31, 2004	2003	2002
Shares outstanding	200,000	240,000	480,000
Weighted average exercise price	$ 2.11	$ 2.09	$ 2.00
Weighted average fair value	$ 3.52	$ 3.49	$ 3.33

In December 2004, the Board of Directors approved the issuance of options to management to purchase up to 1,148,500 shares of Common Stock at an exercise price of $9.02 per share. Such options are expressly subject to the requisite approval of the Company's shareholders, to be obtained no later than the Company's Annual Meeting of Shareholders for 2005, for an amendment to the 1998 Plan authorizing an increase in the number of shares issuable under the plan in an amount equal to or greater than the aggregate amount of such options and an increase in the total shares authorized for use by the Company. Accordingly, such options are not included in the options outstanding at December 31, 2004. Provided the shareholders of the Company approve such amendment, such options shall vest over a three year period from the date of the grant.

In December 2003, the Board of Directors approved the issuance of options to management to purchase up to 1,464,500 shares of Common Stock at an exercise price of $9.17 per share, the fair market value on the date the Board of Directors approved the grant. Such options were expressly subject to the requisite approval of the Company's shareholders, to be obtained no later than the Company's Annual Meeting of Shareholders for 2004, for an amendment to the 1998 Plan authorizing an increase in the number of shares issuable under the plan in an amount equal to or greater than the aggregate amount of such options. Approval was obtained at the Company's Annual Meeting of Shareholders for 2004, at which time the fair market value of our Common Stock was $9.80, which was greater than the fair market value on the date the options were granted. The difference in fair market value on the date of grant versus the date of subsequent shareholder approval was recorded as unearned portion of compensatory stock options and will be recognized into expense as the options vest. The Company incurred a non-cash charge of $461,000 related to the vesting of such options in 2004.

In December 2002, the Board of Directors approved the issuance of options to management to purchase up to 800,000 shares of Common Stock at an exercise price of $2.75 per share. Such options had been subject to the approval of the Company's shareholders, which was obtained at the time of the Company's Annual Meeting of Shareholders for 2003. Accordingly, such options are now included in the options outstanding at December 31, 2002. Such options shall vest in their entirety upon the fourth anniversary of the date of grant or at such earlier time, if ever, upon the receipt by the Company of a NDA approval by the FDA for Surfaxin for either RDS in premature infants, MAS in full-term infants or ARDS in adults.

Note 12 - 401(k) Match

The Company has a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, the Company allows for periodic discretionary matches as a percentage of each participant's contributions in newly issued shares of Common Stock. The total match for the year ended December 31, 2004 was $215,000, resulting in the issuance of 25,683 shares. The total match for the year ending December 31, 2003 was $119,000, resulting in the issuance of 25,470 shares.

Note 13 - Commitments

The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Payments due under contractual obligations at December 31, 2004 are as follows:

	2005	2006	2007	2008	2009	Thereafter	Total
Credit facility	$ —	$ 5,929,000	$ —	$ —	$ —	$ —	$ 5,929,000
Capital lease obligations	1,073,000	886,000	747,000	225,000	—	—	2,931,000
Operating lease obligations	1,214,000	1,161,000	1,193,000	1,078,000	957,000	160,000	5,763,000
Purchase obligations	4,947,000	—	—	—	—	—	4,947,000
Employment agreements	2,203,000	—	—			—	2,203,000
Total	$ 9,437,000	$ 7,976,000	$ 1,940,000	$ 1,303,000	$ 957,000	$ 160,000	$ 21,773,000

The Company has a secured revolving credit facility of up to $8,500,000 with Quintiles available for use until December 31, 2006, of which $5,929,000 was outstanding at December 31, 2004. See Note 7 - Secured Credit Facility and Capital Lease Financing Arrangement.

The Company has a capital lease financing arrangement with the General Electric Capital Corporation. The arrangement provides, subject to certain conditions, up to an aggregate $9.0 million in financing for capital purchases. See Note 7 - Secured Credit Facility and Capital Lease Financing Arrangement. As of December 31, 2004, approximately $2.5 million was outstanding under this financing arrangement. Total future payments under the arrangement, including interest, are approximately $2.9 million.

The Company's operating leases consist primarily of facility leases for the Company's operations in Pennsylvania and California.

The Company maintains its headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, sales and marketing, and administration. The lease expires in February 2010 with total aggregate payments of $4.6 million.

The Company also leases approximately 18,000 square feet of office and laboratory space in Doylestown, PA. The Company intends to maintain a portion of the Doylestown facility for the continuation of analytical laboratory activities and sublease the remaining portions to the greatest extend possible. To the extent that subleasing is not possible, the leases will expire according to their terms. The leases expire in March 2005 and August 2005.

The Company leases office and laboratory space in Mountain View, California. The facility is 16,800 square feet and houses the Company's aerosol development operations. The lease expires in June 2008 with total aggregate payments of $804,000.

Prior to the Mountain View facility, the Company leased office and laboratory space in Redwood City, CA. The facility was approximately 5,000 square feet and housed the Company's aerosol development operations. In December 2004, the Company vacated the Redwood City facility and moved to the Mountain View facility. In February 2005, the sublease agreement for the Redwood City facility was terminated.

Payments made under all of these existing leases for the years ended December 31, 2004, 2003, and 2002 were $585,000, $590,000 and $481,000, respectively.

The Company's purchase obligations include commitments entered in the ordinary course of business, primarily commitments to purchase manufacturing equipment and services for the enhancement of the Company's manufacturing capabilities for Surfaxin and sales and marketing services related to the potential launch of Surfaxin in the United States.

At December 31, 2004, the Company had employment agreements with eight officers providing for an aggregate annual salary equal to $2,203,000. The agreements expire in December 2005, however, commencing on January 1, 2006, and on each January 1st thereafter, the term of these agreements shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend the agreement. All of the foregoing agreements provide for the issuance of annual bonuses and the granting of options subject to approval by the Board of Directors. All of the foregoing agreements provide that in the event that the employment of any such officers is terminated without Cause or should any such officers terminate employment for Good Reason, as defined in the respective agreements, including in circumstances of a change of control, such officer shall be entitled to certain cash compensation and benefits continuation.

In addition to the contractual obligations above, the Company has future milestone commitments, aggregating $2,500,000, and royalty obligations to Johnson & Johnson, Inc., and Ortho Pharmaceutical, a wholly-owned subsidiary of Johnson & Johnson, Inc., related to the Company's product licenses. To date, the Company has paid $450,000 for milestones achieved.

Note 14 - Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS No. 123(R)), which replaces SFAS No. 123 and supersedes APB Opinion NO. 25. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 win no longer be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123(R) in the third quarter of 2005. Under SFAS No. 123(R), the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The permitted transition methods include either retrospective or prospective adoption. Under the retrospective option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options at the beginning of the first quarter of adoption of SFAS No. 123F, while the retrospective methods would record compensation expense for all unvested stock options beginning with the first period presented. The Company is currently evaluating the requirements of SFAS No. 123(R) and expects that adoption of SFAS No. 123(R) will have a material impact on the Company's financial position and results of operations. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123(R), and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. See Note 2 - Summary of Significant Accounting Policies - Stock-based Compensation.

Note 15 - Related Party Transactions

Laboratorios del Dr. Esteve, S.A.

Dr. Esteve serves as a member of the Company's Board of Directors and is an executive officer of Esteve. In December 2004, the Company and Laboratorios Esteve restructured their corporate partnership for the development, marketing and sales of Discovery's products in Europe and Latin America. Under the revised collaboration, Discovery has regained full commercialization rights in key European markets, Central America and South America for its SRT, including Surfaxin for RDS in premature infants and ARDS in adults. Laboratorios Esteve will focus on Andorra, Greece, Italy, Portugal and Spain and now has development and marketing rights to a broader portfolio of the Company's potential SRT products. See Note 8 - Corporate Partnership Agreements.

Note 16 - Income Taxes

Since its inception, the Company has never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to the Company's recorded tax benefit for the years ended December 31, 2004, 2003 and 2004 are as follows:

	December 31,		
	2004	2003	2002
Income tax benefit, statutory rates	$ 15,739,000	$ 8,255,000	$ 5,938,000
State taxes on income, net of federal benefit	2,776,000	2,015,000	1,088,000
Research and development tax credit	623,000	441,000	274,000
Other	(87,000)	92,000	(755,000)
Income tax benefit	19,051,000	10,803,000	6,545,000
Valuation allowance	(19,051,000)	(10,803,000)	(6,545,000)
Income tax benefit	$ —	$ —	$ —

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2004 and 2003, are as follows:

	December 31, 2004	2003
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	$ 55,825,000	$ 35,607,000
Research and development tax credits	2,832,000	1,868,000
Compensation Expense on Stock	524,000	—
Charitable Contribution Carryforward	5,000	—
Other Accrued	161,000	70,000
Deferred Revenue	55,000	273,000
Capitalized research and development	38,000	122,000
Total long-term deferred tax assets	59,440,000	37,940,000
Long-term deferred tax liabilities:		
Property and equipment	(651,000)	(272,000)
Net deferred tax assets	58,789,000	37,668,000
Less: valuation allowance	(58,789,000)	(37,668,000)
	$ —	$ —

The Company was in a net deferred tax asset position at December 31, 2004 and 2003 before the consideration of a valuation allowance. Due to the fact that the Company has never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

At December 31, 2004 and 2003, the Company had available carryforward net operating losses for Federal tax purposes of $140,652,000 and $91,585,000, respectively, and a research and development tax credit carryforward of $2,832,000 and $1,868,000, respectively. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2009 and continuing through 2023. At December 31, 2004, the Company had available carryforward federal and state net operating losses of $1,744,000 and $326,000 respectively related to stock based compensation. Additionally, at December 31, 2004 and 2003, the Company had available carryforward losses of approximately $121,876,000 and $82,483,000, respectively, for state tax purposes. The utilization of the Federal net operating loss carryforwards is subject to annual limitations in accordance with Section 382 of the Internal Revenue Code. Certain state carryforward net operating losses are also subject to annual limitations.

Federal and state net operating losses, $5,129,000 and $4,969,000, respectively, relate to stock based compensation, the tax effect of which will result in a credit to equity as opposed to income tax expense to the extent these losses are utilized in the future.

Note 17 - Subsequent Events

On February 24, 2005, the Company completed a registered direct offering of 5,060,000 shares of Common Stock. The shares were priced at $5.75 per share resulting in the Company's receipt of gross and net proceeds equal to $29.1 million and $27.5 million, respectively.

In February 2005, the Company received an Approvable Letter from the FDA for Surfaxin® for the prevention of RDS in premature infants. The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application for Surfaxin and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that the Company must meet primarily involve finalizing labeling and correcting certain manufacturing issues associated with an inspection report (Form FDA-483) from the FDA issued to the Company's contract manufacturer, Laureate. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. Based on the nature of the observations contained in the Approvable Letter, the Company currently anticipates that it will respond to the FDA with a "Class 2" response. A "Class 2" response allows the FDA up to six months following the completion of the labeling and manufacturing issues outlined in the PDUFA letter. Therefore, the Company anticipates that the potential approval of Surfaxin for RDS may occur in the fourth quarter of 2005 or the first quarter of 2006.

In February 2005, the Company borrowed the remaining available funds under the secured credit facility with Quintiles and now has an outstanding balance of $8.5 million. Outstanding principal and accrued interest is due and payable as a balloon payment on December 31, 2006.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 18 - Selected Quarterly Financial Data (unaudited)

The following table contains unaudited statement of operations information for each quarter of 2004 and 2003. The operating results for any quarter are not necessarily indicative of results for any future period.

(in thousands, except per share data)

2004 Quarters Ended:	Mar. 31	June 30 [(1)]	Sept. 30	Dec. 31	Total Year
Revenues from collaborative agreements	$ 142	$ 697	$ 236	$ 134	$ 1,209
Operating Expenses:					
Research and development	6,710	6,373	5,673	7,037	25,793
General and administrative	2,281	3,175	2,908	4,958	13,322
Corporate partnership restructuring charge	—	—	—	8,126	8,126
Total expenses	8,991	9,548	8,581	20,121	47,241
Operating loss	(8,849)	(8,851)	(8,345)	(19,987)	(46,032)
Other expense, net	(23)	(46)	(37)	(65)	(171)
Net loss	$ (8,872)	$ (8,897)	$ (8,382)	$ (20,052)	$ (46,203)
Net loss per common share - basic and diluted	$ (0.20)	$ (0.19)	$ (0.18)	$ (0.42)	$ (1.00)
Weighted average number of common shares outstanding	43,320	46,683	46,988	47,236	46,179

(in thousands, except per share data)

2003 Quarters Ended:	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues from collaborative agreements	$ 393	$ 263	$ 198	$ 183	$ 1,037
Operating Expenses:					
Research and development	3,844	4,011	5,096	6,799	19,750
General and administrative	1,167	1,137	1,375	2,043	5,722
Total expenses	5,011	5,148	6,471	8,842	25,472
Operating loss	(4,618)	(4,885)	(6,273)	(8,659)	(24,435)
Other income and (expense), net	113	36	54	(48)	155
Net loss	$ (4,505)	$ (4,849)	$ (6,219)	$ (8,707)	$ (24,280)
Net loss per common share - basic and diluted	$ (0.14)	$ (0.14)	$ (0.15)	$ (0.21)	$ (0.65)
Weighted average number of common shares outstanding	32,857	33,487	41,084	42,391	37,426

(1) A reclassification has been made to the presentation of operating expenses in the current second quarter of 2004. The expense associated with a milestone payment related to the license of Surfaxin has been reclassifed from general and administrative expenses and is currently reflected in research and development expenses.

EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "Agreement") is made as of this 1st day of January, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and ROBERT J. CAPETOLA, PH.D. (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its President and Chief Executive Officer pursuant to that certain employment agreement dated as of January 1, 2001, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement in its entirety as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's President and Chief Executive Officer. The Executive shall continue to be responsible for the overall management of the Company and all duties customarily associated with his title including, without limitation, activities regarding (i) day-to-day operational affairs; (ii) the development and commercialization of the Company's products; (iii) proposed strategic alliances, joint ventures and other potential collaborations; and (iv) all other appropriate functions for the Company. All of the operating managers of the Company shall report to the Executive. The Executive shall at all times report to, and shall be subject to the policies established by, the Board and any executive committee thereof (the "Executive Committee"). The Executive hereby agrees to immediately resign from any Board position held by him at the expiration or termination of the Term.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement") a copy of which is attached to this Agreement as Exhibit B. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 15 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor.

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $390,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any such increase in Base Salary shall be solely within the discretion of the Company.

(b) Bonuses. During the Term, the Executive:

(i) shall be eligible for such additional year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year; and

(ii) may receive additional incentive bonuses from time to time, at the discretion of the Compensation Committee of the Board, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, the Executive shall be entitled to receive (i) term life insurance on behalf of the Executive's named beneficiaries in the amount of $2,000,000 and (ii) long-term disability insurance (subject to a combined annual premium cap of $18,000 for 2004, which cap shall be increased by 5% for each successive calendar year of the Term), each at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by the Executive in connection with any such life or disability insurance.

(d) Vacations. During the Term, the Executive shall be entitled to 20 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

(f) Company Leased Automobile. In connection with the Executive's employment hereunder, the Executive shall be entitled to the use of a suitable automobile (to be determined in the good faith discretion of the Executive) (the "Company Car") which shall be leased on the Executive's behalf by the Company or, in the Company's sole discretion, the costs therefor shall be reimbursed to the Executive. The total annual costs incurred by the Company in connection with lease payments for such Company Car shall not exceed $10,000; provided, however, that the Company shall be responsible for all other costs in connection with such Company Car (including, without limitation, insurance, maintenance and repairs, governmental and regulatory fees, gasoline, parking and tolls) in connection with the Executive's service to the Company. The Executive acknowledges and agrees that the Company Car shall be for the Executive's exclusive use primarily with respect to Company business. At the Executive's sole expense, the Executive shall maintain a current United States driving license and shall immediately inform the Company's Controller if such license is revoked or suspended. Upon any such revocation or suspension, the Executive will immediately forfeit any and all entitlement to the Company Car. The Executive hereby agrees to at all times comply with the Company's written policies regarding Company automobiles and shall have full responsibility for any fines incurred for motoring offenses in respect of the Company Car whether such fines are incurred in his personal use or in connection with Company activities.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms.

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If (i) the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period or (ii) the Executive terminates his employment for any reason during the Window Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of three (3) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For three years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Cause unless and until there has been delivered to the Executive a copy of a resolution duly adopted by the affirmative vote of not less than three-quarters (3/4) of the entire membership of the Board at a meeting of the Board called and held for such purpose (after reasonable notice is provided to the Executive and the Executive is given an opportunity, together with counsel, to be heard before the Board), finding that, in the good faith opinion of the Board, the Executive has engaged in the conduct described in Section 1(b) hereof, and specifying the particulars of such conduct.

(c) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

Robert J. Capetola, Ph.D.
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

Name: David L. Lopez, Esq., CPA
Title: Senior Vice President and General Counsel

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 36 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; (vi) the failure of the Company to nominate the Executive for election to the Board at any relevant time during the Term; or (vii) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

(k) **"Window Period"** means the 30-day period commencing on the six-month anniversary of a Change of Control.

Exhibit 10.22

EXECUTION COPY

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 1st day of January, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and JOHN G. COOPER (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Executive Vice President and Chief Financial Officer pursuant to that certain employment agreement dated as of December 10, 2001, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's Executive Vice President and Chief Financial Officer. The Executive shall continue to be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Executive Officer.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 12 month period described in the preceding sentence shall be extended to 24 months in the event of any termination of the Executive's employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $240,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. During the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in the amount of Executive's then current annual salary for the Term of this Agreement at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, the Executive shall be entitled to 15 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

John G. Cooper
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

/s/ John G. Cooper

John G. Cooper

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

Exhibit 10.23

EXECUTION COPY

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 1st day of January, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and DAVID L. LOPEZ, ESQ., CPA (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Senior Vice President and General Counsel pursuant to that certain employment agreement dated as of April 20, 2000, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's Senior Vice President and General Counsel. The Executive shall continue to be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Executive Officer.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 12 month period described in the preceding sentence shall be extended to 24 months in the event of any termination of the Executive's employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $230,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. During the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive (i) life insurance on behalf of Executive's named beneficiaries in the amount of Executive's then current annual salary for the Term of this Agreement at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance and (ii) annual payments of up to (A) $7,000 solely to cover the cost of tuition, fees, books and other materials related to professional courses completed at state approved universities and (B) $1,500 solely to cover professional legal and accounting dues, association fees and continuing education costs, each of the foregoing payments shall be subject to documentation in accordance with reasonable policies of the Company.

(d) Vacations. During the Term, the Executive shall be entitled to 15 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

(c) Promissory Note. Notwithstanding any provision to the contrary contained in the Promissory Note dated July 23, 2001, issued by Executive to the Company (the "Note"), during the Effective Period the Note shall be callable by the Company, with respect to the aggregate principal amount then outstanding, together with all interest thereon accrued yet unpaid, upon 365 days prior written notice to Executive.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:
David L. Lopez, Esq.
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

/s/ David L. Lopez

David L. Lopez, Esq., CPA

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 24th day of May 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and MARK OSTERMAN (the "Executive").

WHEREAS, the Company and the Executive desire that Executive be employed by the Company and that the terms and conditions of such employment be defined.

NOW, THEREFORE, in consideration of the employment of Executive by the Company, the Company and the Executive hereby agree as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall serve as the Company's Senior Vice President, Sales and Marketing. The Executive shall be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Executive Officer.

(b) Location of Employment. The Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

4. Proprietary Information and Inventions Agreement. Upon execution of this Agreement, Executive shall execute the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement") a copy of which is attached to this Agreement as Exhibit B. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information

5. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 12 month period described in the preceding sentence shall be extended to 24 months in the event of any termination of the Executive's employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

6. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $230,000, payable in accordance with the Company's regular payroll practices and less all required withholdings, and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. The Company shall pay to Executive a one-time bonus of $25,000 upon the satisfactory completion of 90 days of service. Thereafter, during the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in the amount of Executive's then current annual salary for the Term of this Agreement at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, the Executive shall be entitled to 20 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

(f) Stock Options. The Company, subject to the approval of the Company's Board of Directors and its shareholders, as appropriate, shall grant to Executive non qualified stock options under the Company's Amended and Restated 1998 Stock Incentive Plan (the "Plan") to purchase 200,000 shares of Common Stock at an exercise price equal to the fair market value on the date of grant, which is intended to be as promptly as practicable following the full execution of this Agreement. Such stock options shall vest in a series of three successive equal annual installments, provided, however that such vesting shall be subject to the terms and conditions as set forth in the Plan, except as may be otherwise provided for herein.

7. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

8. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

9. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

10. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

11. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

12. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

13. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

MARK OSTERMAN
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

14. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

15. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes all other prior agreements, written or oral, with respect thereto.

16. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

17. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

18. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

19. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

/s/ Mark Osterman

Mark Osterman

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 1st day of January, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and CHRISTOPHER J. SCHABER, PH.D. (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Executive Vice President and Chief Operating Officer pursuant to that certain employment agreement dated as of June 16, 2001, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's Executive Vice President and Chief Operating Officer. The Executive shall continue to be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Executive Officer.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 12 month period described in the preceding sentence shall be extended to 24 months in the event of any termination of the Executive's employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $250,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. During the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, the Executive shall be entitled to receive term life insurance on behalf of the Executive's named beneficiaries in the amount of $500,000 (subject to an annual premium cap of $1,000 for 2004, which cap shall be increased by 5% for each successive calendar year of the Term), at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by the Executive in connection with any such life insurance.

(d) Vacations. During the Term, the Executive shall be entitled to 15 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

Christopher J. Schaber, Ph.D.
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

/s/ Christopher J. Schaber

Christopher J. Schaber, Ph.D.

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

EXECUTION COPY

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 1st day of January 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and ROBERT SEGAL, MD (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Senior Vice President, Clinical Research and Chief Medical Officer pursuant to that certain employment agreement dated as of June 1, 2000, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's Senior Vice President, Clinical Research and Chief Medical Officer. The Executive shall continue to be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Operating Officer.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement") a copy of which is attached to this Agreement as Exhibit B. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 6 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 6 month period described in the preceding sentence shall be extended to 12 months in the event of any termination of the Executive’s employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $237,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. During the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements.

(d) Vacations. During the Term, the Executive shall be entitled to 15 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to fifty percent (50%) of the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For six months from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

Robert Segal, MD
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney’s fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

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

/s/ Robert Segal
Robert Segal, MD

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 12 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

Exhibit 10.27

EXECUTION COPY

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 1st day of January, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and DENI M. ZODDA, PH.D. (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Senior Vice President, Business Development pursuant to that certain employment agreement dated as of August 14, 2000, by and between the Company and the Executive (the "Employment Agreement"); and

WHEREAS, the Company and the Executive desire to amend and restate the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree to amend and restate the Employment Agreement in its entirety to read as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2005; provided, however, that commencing on January 1, 2006, and on each January 1st thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

(a) Duties. The Executive shall continue to serve as the Company's Senior Vice President, Business Development. The Executive shall continue to be responsible for all duties customarily associated with this title. The Executive shall at all times report directly to the Company's Chief Executive Officer.

(b) Location of Employment. The Executive's principal place of business shall continue to be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Agreement. The Executive has executed the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During his employment with the Company, the Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During his employment with the Company, the Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, the Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants or any other category of compounds which forms the basis of the Company's material products or any material products under development on the Date of Termination, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent the Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of the Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor. Notwithstanding the foregoing, the 12 month period described in the preceding sentence shall be extended to 24 months in the event of any termination of the Executive's employment described in Section 7(c).

(d) Injunctive Relief. In the event that the Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $220,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually at the start of each calendar year for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors.

(b) Bonuses. During the Term, the Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, the Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in the amount of Executive's then current annual salary for the Term of this Agreement at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, the Executive shall be entitled to 15 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

(e) Reimbursement of Business Expenses. The Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. The Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period at least equal to the Highest Annual Bonus.

(b) Options. Notwithstanding any provision to the contrary in the Company's Amended and Restated 1998 Stock Incentive Plan or any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Change of Control Date and, in the case of any Change of Control in which the Company's common stockholders receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) the Executive shall be permitted to exercise his options at a time and in a fashion that will entitle him to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if the Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by the Executive without Good Reason, Death or Disability.

(i) In the event of a termination of the Executive's employment by the Company for Cause, a termination by the Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of the Executive, the Executive shall be entitled to any unpaid compensation accrued through the last day of the Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to the Executive but not yet paid. The Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or disability, notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for one year from the Date of Termination (or, if shorter, until the expiration of their stated terms).

(b) Termination by the Company without Cause or by the Executive for Good Reason. If (x) the Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) the Executive terminates employment with Good Reason, then the Executive shall be entitled to receive the following from the Company:

(i) The amounts set forth in Section 7(a)(i);

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For one year from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(b)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vi) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

(c) Termination in connection with a Change of Control. If the Executive's employment is terminated by the Company other than for Cause or by the Executive for Good Reason during the Effective Period, then the Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Highest Annual Bonus multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to the product of two (2) times the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

(iv) For two years from the Date of Termination, the Company shall either (A) arrange to provide the Executive and his dependents, at the Company's cost (except to the extent such cost was borne by the Executive prior to the Date of Termination), with life, disability, medical and dental coverage, whether insured or not insured, providing substantially similar benefits to those which the Executive and his dependents were receiving immediately prior to the Date of Termination, or (B) in lieu of providing such coverage, pay to the Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for the Executive to purchase equivalent benefits coverage referred to in clause (A); provided, however, that the Company's obligation under this Section 7(c)(iv) shall be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option agreement between the Company and the Executive, all options to acquire Company stock held by the Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms;

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company; and

(vii) The Company will provide out-placement counseling assistance in the form of reimbursement of the reasonable expenses incurred for such assistance within the 12-month period following the Date of Termination. Such reimbursement amount shall not exceed $40,000.

8. Notice of Termination.

(a) Any termination of the Executive's employment by the Company for Cause, or by the Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination, (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of the Executive will not be deemed to be for Good Reason unless the Executive gives the Notice of Termination provided for herein within 12 months after the Executive has actual knowledge of the act or omission of the Company constituting such Good Reason.

9. Mitigation of Damages. The Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by the Executive as the result of self-employment or employment by another employer or otherwise.

10. Excise Tax Gross-Up.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of the Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount such that after payment by the Executive of all taxes, including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Taxes imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For purposes of this Section 10, the Executive shall be deemed to pay federal, state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross Up Payment is to be made, taking into account the maximum reduction in federal income taxes which could be obtained from the deduction of state and local income taxes.

(b) All determinations required to be made under this Section 10, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the receipt of notice from the Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 10, shall be paid by the Company to the Executive within five days of the later of (i) the due date for the payment of any Excise Tax, and (ii) the receipt of the Accounting Firm's determination. If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on the Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment") or Gross-up Payments are made by the Company which should not have been made ("Overpayments"), consistent with the calculations required to be made hereunder. In the event the Executive is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive. In the event the amount of Gross-up Payment exceeds the amount necessary to reimburse the Executive for his Excise Tax, the Accounting Firm shall determine the amount of the Overpayment that has been made and any such Overpayment shall be promptly paid by the Executive (to the extent he has received a refund if the applicable Excise Tax has been paid to the Internal Revenue Service) to or for the benefit of the Company. The Executive shall cooperate, to the extent his expenses are reimbursed by the Company, with any reasonable requests by the Company in connection with any contests or disputes with the Internal Revenue Service in connection with the Excise Tax.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by the Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if the Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

(a) if to the Board or the Company:

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
Attn: David Lopez, Esq.

(b) if to the Executive:

Deni M. Zodda, Ph.D.
The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supercedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by the Executive, and the third by the two so chosen. If both or either of the Company or the Executive fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrators, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, 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 in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 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 in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of the Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Executive with or without Cause.

18. Executive Acknowledgement. The Executive hereby acknowledges that he has read and understands the provisions of this Agreement, that he has been given the opportunity for his legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that he has received a copy of this Agreement.

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

/s/ Deni M. Zodda

Deni M. Zodda, Ph.D.

(a) **"Beneficiary"** means any individual, trust or other entity named by the Executive to receive the payments and benefits payable hereunder in the event of the death of the Executive. The Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. The Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by the Executive, or if no designated Beneficiary survives the Executive, then the payment and benefits provided under this Agreement, if any, will be paid to the Executive's estate, which shall be deemed to be the Executive's Beneficiary.

(b) **"Cause"** means: (i) the Executive's willful and continued neglect of the Executive's duties with the Company (other than as a result of the Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to the Executive by the Company which specifically identifies the manner in which the Company believes that the Executive has neglected his duties; (ii) the final conviction of the Executive of, or an entering of a guilty plea or a plea of no contest by the Executive to, a felony; or (iii) the Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of the Executive shall be considered "willful" unless it is done, or omitted to be done, by the Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board of Directors of the Company (the "Board"), or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by the Executive in good faith and in the best interests of the Company.

(c) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who, as of the date of this Agreement constitute the Board (the "Incumbent Directors") cease for any reason, including without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority thereof; provided, that any person becoming a director of the Company subsequent to the date of this Agreement shall be considered an Incumbent Director if such person's election or nomination for election was approved by a vote of at least two-thirds (2/3) of the Incumbent Directors in an action taken by the Board or a Committee thereof; provided, further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a "person" (as defined in Section 13(d) and 14(d) of the Exchange Act) other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) the Company consummates a sale of all or substantially all of the assets of the Company or the stockholders of the Company approve a plan of complete liquidation of the Company.

(d) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if the Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by the Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(e) **"Code"** means the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder.

(f) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or the Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(g) **"Disability"** means a mental or physical condition that renders the Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give the Executive at least 30 days' written notice that it considers the time period for disability to be running.

(h) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(i) **"Good Reason"** means, unless the Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Executive of any duties inconsistent with the Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a reduction in the Executive's Base Salary by the Company; (iii) the relocation of the Executive's office to a location more than 30 miles from Doylestown, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); (v) following a Change of Control, unless a plan providing a substantially similar compensation or benefit is substituted, (A) the failure by the Company to continue in effect any material fringe benefit or compensation plan, retirement plan, life insurance plan, health and accident plan or disability plan in which the Executive was participating prior to the Change of Control, or (B) the taking of any action by the Company which would adversely affect the Executive's participation in or materially reduce his benefits under any of such plans or deprive him of any material fringe benefit; or (vi) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months).

Exhibit 10.28

EXECUTION COPY

AMENDED AND RESTATED
SUBLICENSE AND COLLABORATION AGREEMENT

between

DISCOVERY LABORATORIES, INC.

and

LABORATORIOS DEL DR. ESTEVE, S.A.

Concerning Sinapultide

December 3, 2004

AMENDED AND RESTATED
SUBLICENSE AND COLLABORATION AGREEMENT

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

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

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

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

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

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

ARTICLE 1
DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 2
GRANT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

ARTICLE 3
GRANT BACK

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

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

ARTICLE 4
CONSIDERATION

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

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

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

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

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

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

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

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.

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

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

ARTICLE 5
SCOPE OF THE COLLABORATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 5.3 Regulatory Approvals. (a) Subject to the completion of requisite clinical investigations by the Licensor, Licensor shall prepare and submit to the EMEA a MAA within 6 months of the date of acceptance of filing of the applicable NDA by the FDA and shall use its diligent efforts to obtain and maintain all EMEA Marketing Regulatory Approvals for the term of this Agreement, all at the cost and expense of Licensor, except as may otherwise be provided for in Section 5.2. When filing for MAA, Licensor shall designate, as appropriate, Licensee or such Licensee's Affiliates or permitted sublicensees and/or partners designated by Licensee as its distributors or local representatives for the Licensed Products in the Licensed Territory. Licensor shall, upon the granting of each Marketing Regulatory Approval obtained by Licensor, promptly supply Licensee with a copy of such approval.

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

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

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

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

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

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

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.

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

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

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

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

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

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.

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

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

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

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

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

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

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

ARTICLE 6
GOVERNANCE AND COMMITTEE STRUCTURE

Section 6.1 Steering Committee. (a) Licensee and Licensor shall jointly form an oversight committee (the "Steering Committee") that shall (i) manage the overall strategic relationship and the strategic marketing and sales activities for Licensed Products in the Licensed Territory, (ii) to review and approve the pre- and post-launch Marketing Plans as well as any other matters required for the sales and promotion of Licensed Products in the Licensed Territory (including, without limitation, the strategic decision-making authority to authorize sublicensing, co-promotion or co-marketing and the tactical decision to approve a recommended sublicensing, co-promotion or co-marketing partner in the Licensed Territory), except to the extent that certain matters are solely the responsibility of a single party under this Agreement; (iii) to advise, provide input and determine strategy for future clinical and/or marketing studies; (iv) have overall responsibility for the success of such matters as established by this Agreement, and (v) be charged with promptly resolving disputes of the parties, if any, subject to Section 15.4.

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

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

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

Section 6.2 Development Committee. (a) Licensee and Licensor shall jointly form a development committee (the "Development Committee") to oversee the Development of Licensed Products within the Licensed Territory. The Development Committee shall have functional responsibility for the success of the matters related to the Development of the Licensed Products in the Licensed Territory and related medical and regulatory activities as established by this Agreement, including without limitation: (i) to determine and oversee the overall strategy for all such activities for Licensed Products in the Licensed Territory; (ii) to plan and coordinate the parties' efforts hereunder related to all such activities for Licensed Products in the Licensed Territory; and (iii) to facilitate the flow of information among the parties, including coordinating all such activities with manufacturing schedules and distribution.

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

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

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

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

Section 6.3 Commercialization Committee. (a) Licensee and Licensor shall jointly form a commercialization committee (the "Commercialization Committee") to oversee the commercialization of Licensed Products within the Licensed Territory. The Commercialization Committee shall have functional responsibility for the success of the matters related to commercialization of the Licensed Products in the Licensed Territory as established by this Agreement, including without limitation: (i) the overall Commercialization strategy to assure consistency with Licensor's global branding strategy; (ii) planning and coordinating commercialization activities; (iii) submitting Marketing Plans to the Steering Committee for its review and approval, (iv) facilitating the flow of appropriate commercial information among the parties, including coordinating commercialization activities with manufacturing schedules and distribution and (v) recommending to the Steering Committee sublicensees, co-promoters and/or co-marketers for the Licensed Products as set forth under Section 2.3 hereinabove.

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

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

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

Section 6.4 General Committee Procedures. (a) Each party shall be responsible for all of its own expenses of participating in any committee or any working group. If a representative of either of the parties hereto is unable to attend a meeting, such party may designate an alternate to attend such meeting in place of the absent representative.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 8
TERMINATION

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

(a) Immediately terminate this Agreement; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 9
INFRINGEMENT

Section 9.1. Notice. (a) In the event that Licensee believes that there is an infringement of the Licensed Rights by a third party hereto selling material quantities of products in the Licensed Territory in competition with Licensee's sale of Licensed Products hereunder, Licensee shall promptly provide Licensor with written notice that such infringement is occurring. In the event that Licensee believes that such infringement is to Licensee's substantial detriment, Licensee shall provide Licensor with reasonable evidence of the infringement.

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

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

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

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

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

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

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

ARTICLE 10
NON-USE OF NAMES

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

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

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 12
INDEMNIFICATION

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

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

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

ARTICLE 13
TRADEMARK MATTERS; PATENT MARKING

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

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

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

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

ARTICLE 14
PATENT PROSECUTION AND MAINTENANCE

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

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

ARTICLE 15
GENERAL

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

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

In the case of Licensor: Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976
Attention: Robert J. Capetola, Ph.D,
Chief Executive Officer

With a copy to: Dickstein Shapiro Morin & Oshinsky
1177 Avenue of the Americas, 41st Floor
New York, NY 10036-2714
Attn: Ira L. Kotel
Facsimile: (212) 997-9880

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

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

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

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

Section 15.4 Dispute Resolution.

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

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

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

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

Section 15.6. Registration. Licensee shall take all reasonable and necessary steps to register this Agreement in any country where such is required to permit the transfer of funds and/or payment of royalties to Licensor hereunder or is otherwise required by the government or law of such country to effectuate or carry out this Agreement. Notwithstanding anything contained herein, Licensee shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, Licensee shall not be relieved of its obligation to make any payment due to Licensor hereunder at Licensor's address specified in Article 15.2 hereof, where such payment is blocked due to any failure to register this Agreement.

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

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

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

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

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

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

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

LABORATORIOS DEL DR. ESTEVE, S.A.

By: /s/ Antonio Esteve

Name:
Title:

AMENDED AND RESTATED SUPPLY AGREEMENT

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

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

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

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

ARTICLE I
DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE II
PURCHASE AND SALE OF PRODUCTS

Section 2.1. Purchase and Sale; Delivery; Acceptance or Rejection. (a) Seller agrees to sell to Buyer such quantities of Licensed Products, manufactured in conformity with cGMP and meeting the Specifications, as Buyer may order in accordance with the terms and conditions of this Agreement. Subject to the provisions of Section 7.2 hereof, so long as this Agreement shall remain in effect, Buyer agrees, for itself and its Affiliates and sublicensees, to satisfy solely through the purchase of Licensed Products from Seller under this Agreement one hundred percent (100%) of Buyer's and its Affiliates' and sublicensees' requirements for Licensed Products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

2.3 Reports, Reconciliation and Audit, Transfer Price Payments.

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

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

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

(d)Reconciliation and Audit.

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

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

ARTICLE III
PRODUCTION OF PRODUCTS

Section 3.1. Manufacturing of Licensed Products.

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

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

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

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

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

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

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

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

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

ARTICLE IV
QUANTITY FORECASTS; ORDERS

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

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

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

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

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

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

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

ARTICLE V
CERTAIN OBLIGATIONS OF BUYER

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

ARTICLE VI
REGULATORY MATTERS

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

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

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

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

ARTICLE VII
TERMINATION; RIGHTS AND OBLIGATIONS UPON TERMINATION

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

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

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

ARTICLE VIII
WARRANTIES; REPLACEMENT OF PRODUCTS; INSURANCE

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

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

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

ARTICLE IX
MISCELLANEOUS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE X
BASIS OF BARGAIN

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

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

LABORATORIOS DEL DR. ESTEVE, S.A.

By: /s/ Antonio Esteve

Name:
Title:

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-110412 and Form S-8 No. 333-116268) pertaining to the Amended and Restated 1988 Stock Incentive Plan of Discovery Laboratories, Inc. and in the Registration Statements (Form S-3 No. 333-101666, Form S-3 No. 333-35206, Form S-3 No. 333-86105, Form S-3 No. 333-72614, Form S-3 No. 333-82596, Form S-3 No. 107836, Form S-3 No. 333-111360, Form S-3 No. 333-118595, Form S-3 No. 333-121297 and Form S-3 No. 333-122887) of Discovery Laboratories, Inc. and in the related Prospectuses of our reports dated March 11, 2005, with respect to the consolidated financial statements of Discovery Laboratories, Inc., Discovery Laboratories, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

March 11, 2005
Philadelphia, Pennsylvania

Exhibit 31.1

CERTIFICATIONS

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Robert J. Capetola, certify that:

1. I have reviewed this Annual Report on Form 10-K of Discovery Laboratories, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2005

/s/ Robert J. Capetola

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

Exhibit 31.2

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, John G. Cooper, certify that:

1. I have reviewed this Annual Report on Form 10-K of Discovery Laboratories, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2005

/s/John G. Cooper

John G. Cooper
Chief Financial Officer

Exhibit 32.1

CERTIFICATION UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned certifies that this periodic report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this periodic report fairly presents, in all material respects, the financial condition and results of operations of the issuer.

Date: March 16, 2005

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

Name: /s/ John G. Cooper
Name: John G. Cooper
Title: Executive Vice President, Chief Financial Officer

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

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.