

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

**FORM 10-K**

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

For the fiscal year ended December 31, 2005

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-26422

**DISCOVERY LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-3171943**

(I.R.S. Employer  
Identification Number)

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

**(215) 488-9300**

(Registrant's telephone number, including area code)

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

**None**

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

**Common Stock, \$.001 par value**  
**Preferred Stock Purchase Rights**

(Title of class)  
\_\_\_\_\_

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. YES  NO

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

Indicate by check mark 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 .

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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, 2005, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$325 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 28, 2006 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 14, 2006, 61,140,942 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 2006 definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2005 fiscal year.

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

## FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. The forward-looking statements include all matters that are not historical facts and include, 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.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties 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 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 materials suppliers and development partners to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies;
- risks relating to our drug manufacturing operations;
- risks relating to the integration of our recently-acquired manufacturing operations into our existing operations;
- risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of our clinical studies,
- risks relating to our ability and the ability of our collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies;
- risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements;
- risks relating to the development of competing therapies and/or technologies by other companies; and
- the other risks and certainties detailed in Item 1A: “Risk Factors” and in the documents incorporated by reference in this report.

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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## PART I

### ITEM 1. BUSINESS.

#### COMPANY OVERVIEW AND BUSINESS STRATEGY

Discovery Laboratories, Inc., which we refer to as “we,” “us,” or the “Company,” has its principal offices located at 2600 Kelly Road, Warrington, Pennsylvania. Our telephone number is 215-488-9300 and our website address is [www.discoverylabs.com](http://www.discoverylabs.com). Our common shares are listed on the Nasdaq National Market, where our symbol is DSCO.

We are a biotechnology company developing our proprietary surfactant technology as 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 closely mimic the essential properties of natural 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 hospital settings, where there are few or no approved therapies available.

Our lead product, Surfaxin<sup>®</sup> (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medicines Evaluation Agency (EMA). The FDA has established April 2006 as its target to complete its review of the Surfaxin new drug application (NDA) and we anticipate that the commercial launch of Surfaxin will occur late in the second quarter of 2006.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. In addition to Surfaxin for RDS, we are presently conducting a Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. We are also preparing to conduct multiple Phase 2 pilot studies with Aerosurf<sup>™</sup>, our proprietary aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failures.

To address the various 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 to treat Acute Respiratory Distress Syndrome (ARDS) in adults, and are also researching and developing aerosol SRT to address Acute Lung Injury (ALI) prophylaxis, chronic obstructive pulmonary disease (COPD), cystic fibrosis, asthma and other debilitating respiratory conditions.

Our goal is to become a fully integrated biotechnology company. We are implementing a long-term business strategy which includes the following:

- In December 2005, we purchased the manufacturing operation of our contract manufacturer, Laureate Pharma, Inc., which is critical to the production of Surfaxin and our SRT clinical programs. We will use this pharmaceutical manufacturing and development facility for the production of Surfaxin, other SRT formulations and aerosol development capabilities. We view our recent acquisition of manufacturing operations as an initial step in our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. Our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products;
- Anticipating the potential approval and commercial launch of Surfaxin for RDS in the United States, we are building a U.S. commercial organization to focus initially on opportunities in the NICU and, as products are developed, to potentially expand to pediatric, critical care and hospital settings;

- We are investing in the development of our aerosol SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology we licensed in December 2005 through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc.; and
- We plan on securing corporate partnerships for international markets for the development and potential commercialization of our SRT pipeline for the NICU, including Surfaxin. We plan on securing corporate partnerships for the development and potential commercialization of our SRT pipeline addressing respiratory conditions affecting young adult and adult patients in the critical care and other hospital settings. We have entered into a corporate partnership with Laboratorios del Dr. Esteve, S.A., primarily for the marketing and sales of Surfaxin and certain of our other SRT products in Southern Europe.

## 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 alveolar 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, due to premature birth, 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 or 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 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 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 exhibited by the animal surfactants such as longer shelf-life, and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

We have demonstrated that our SRT can be aerosolized at the proper particle size and with the fluid dynamics capable of penetrating the deep lung. We have successfully completed a Phase 2a pilot clinical study of our aerosol SRT in neonates and a Phase 1b pilot clinical study in adults with mild to moderate asthma. To date, we have achieved the following important development objectives with our aerosol SRT:

- full retention of the surface-tension lowering properties of a functioning surfactant necessary to restore lung function and maintain patency of the conducting airways;
- full retention of the surfactant composition upon aerosolization;
- drug particle size believed suitable for deposition in the deep-lungs;
- delivery rates to achieve therapeutic dosages in a reasonable time period; and
- reproducible aerosol output.

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.

## **SURFACTANT THERAPY FOR RESPIRATORY MEDICINE**

### **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 26 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).

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.

For RDS, we conducted a Phase 3 pivotal trial, which formed the basis of our NDA 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, blinded 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.

The supportive, multinational, multicenter, prophylaxis, randomized, controlled masked, Phase 3 clinical trial enrolled 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf<sup>®</sup>, 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 Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In December 2005, we purchased the manufacturing operations of Laureate in Totowa, NJ.

Our previously submitted responses to the Approvable Letter were accepted by the FDA as a complete response as of October 5, 2005. Assuming that the corrective actions made to the Surfaxin manufacturing operation in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006.

In October 2004, the EMEA validated our Marketing Authorization Application (MAA), that we had filed previously, for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. We have recently received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA for Surfaxin. We plan to submit a written response to all of the CHMP's outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the CHMP is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006.

The FDA has granted us Orphan Drug Designation for Surfaxin for the prevention of 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. 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 EMEA. 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<sup>®</sup> for the Prevention of Bronchopulmonary Dysplasia*

Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease, is a costly syndrome affecting premature infants. It is associated with surfactant deficiency and the prolonged use of mechanical ventilation and oxygen supplementation. Some premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS. To treat RDS, babies require a surfactant usually within one hour of birth as well as mechanical ventilation to support the babies' respiration. The lack of surfactant and use of mechanical ventilation may cause chronic injury and scarring of the lungs - resulting in BPD. 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 clinical trial that will enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study's objective is to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. The BPD study design provides that premature infants receive a treatment regime of up to 5 Surfaxin doses beginning within the first 3-10 days of life that are in addition to the surfactant they received on day 1 of life for RDS. 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 and its severity. The trial is being conducted at sites throughout the United States, as well as sites in Latin America and Europe. We anticipate the results of this trial to be available in the third quarter of 2006.

In January 2006, the FDA granted us Fast-Track designation for Surfaxin for the treatment and prevention of BPD in premature infants. Designation as a Fast Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years.

In October 2005, the FDA designated Surfaxin as an Orphan Drug for the treatment of BPD in premature infants

#### *Aerosurf™, Aerosolized Surfactant Replacement Therapy in the NICU*

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

Aerosurf is our precision-engineered aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants at risk for respiratory failure. In September 2005, we completed and announced the results of a Phase 2 pilot clinical trial of Aerosurf which was designed to evaluate its feasibility, safety and tolerability for the prevention of RDS in premature infants. The study demonstrated that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated.

In December 2005, we entered into a strategic alliance with Chrysalis for us to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. The alliance united two potentially complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for respiratory failure. We anticipate conducting Phase 2a pilot clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in the second half of 2006.

#### **Products for the Critical Care Unit and other Hospital Settings**

##### *Surfaxin® for Acute Respiratory Distress Syndrome in Adults*

Acute Respiratory Distress Syndrome (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 severe respiratory 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 gastric aspiration, smoke inhalation, near drowning, industrial accidents and other traumas.

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of ARDS in adults. Patients are randomized to either receive our SRT or the current standard of care, which is mechanical ventilation and support therapies. Our SRT 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 our SRT 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 alive and off mechanical ventilation at Day 28. Some of the key secondary endpoints include mortality at the end of Day 28 and safety and tolerability of our SRT and the bronchoscopic lavage procedure. Results of the Phase 2 trial are anticipated to be available at the end of March 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 designation and Orphan Drug designation for our SRT for the treatment of ARDS in adults. The EMEA has granted us Orphan Product designation for our SRT for the treatment of ALI in adults (which in this circumstance is a larger patient population that encompasses ARDS).

#### *Aerosolized Surfactant for Acute Lung Injury and Other Respiratory Indications*

We believe that our proprietary precision-engineered aerosolized SRT may be effective as a preventive measure for patients at risk for respiratory disorders such as ALI, chronic obstructive respiratory disorder (COPD), cystic fibrosis (CF), asthma, and other debilitating respiratory conditions. We anticipate that our aerosol SRT pipeline programs will primarily utilize the aerosol generating technology rights which we acquired in December 2005 through our strategic alliance with Chrysalis. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients at risk for Acute Lung Injury (ALI).

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 ALI annually and there are no currently-approved therapies.

We believe that the successful application of our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology has the potential of producing surfactant-based therapies that may significantly advance the treatment of serious respiratory conditions such as COPD. Given the focus on developing the SRT pipeline for the NICU, we will be assessing the development priority of these programs throughout 2006.

### **STRATEGIC ALLIANCES**

#### **Chrysalis Technologies, a Division of Philip Morris USA Inc.**

In December 2005, we entered into a strategic alliance with Chrysalis Technologies (Chrysalis), a division of Philip Morris USA Inc., to develop and commercialize aerosolized surfactant replacement therapies to address a broad range of serious respiratory conditions, such as ALI, neonatal respiratory failure, COPD, asthma, cystic fibrosis and others. This alliance unites two potentially highly complementary respiratory technologies -- our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung.

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

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

Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for respiratory failure. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI.

#### **Laboratorios del Dr. Esteve, S.A.**

In 1999, we entered into a corporate partnership with Laboratorios del Dr. Esteve, S.A. (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 prevention of RDS in premature infants, the treatment of Meconium Aspiration Syndrome (MAS) in full-term infants and the treatment of 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 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 regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of 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 potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and other SRT that is increased from that provided for in the 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 its 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. We also granted to Esteve rights to additional potential SRT products in our pipeline, and 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 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.

In October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceutici s.p.a. (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution in Italy of Surfaxin.

## 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, United States Patent No. 6,613,734 issued, covering 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, European Patent No. 0590006 was granted covering claims directed to compositions that contain sinapultide for use as a therapeutic surfactant for treating RDS and related conditions. European Patent Nos. 0350506 and 0593094 have also issued 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 respiratory disorders. Our proprietary pulmonary lavage techniques (using surfactant) include lavage via a bronchoscope in adults. Scientific rationale supports the premise that our proprietary lavage technique may provide a clinical benefit to the treatment of ALI and ARDS in adults 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.

#### *Our Patents and Patent Rights*

We have been active in seeking patent protection for our innovations relating to new formulations and methods of manufacturing and delivering sinapultide pulmonary surfactants. Our patent activities have focused particularly on formulation and delivery of aerosolized pulmonary surfactant.

In May of 2005, we filed United States and International patent applications (US 11/130,783 and PCT US/2005/0178184) directed to systems, devices and methods for non-invasive pulmonary delivery of aerosolized surfactant. In August of 2005, we filed additional U.S. and International patent applications (US 11/209,588 and PCT US/2005/0029811) to seek expanded protection of our aerosol delivery system and methods to include non-invasive pulmonary delivery in conjunction with invasive techniques as needed.

In November of 2005, we filed U.S. and International patent applications (US11/274,201 and PCT US/2005/041281), directed to lyophilized formulations of sinapultide pulmonary surfactants and methods of manufacture. In December of 2005, we filed U.S. and International patent applications (US 11/316,308 and PCT US/2005/046862), directed to sinapultide pulmonary surfactant formulations having improved viscosity characteristics, aerosolization capacity and storage stability.

See Item 1A: "Risk Factors - 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**

#### **Manufacturing -- Precision-Engineered Surfactant**

Our precision-engineered surfactant product candidates, including Surfaxin, must be manufactured in a sterile environment and in compliance with current good manufacturing practices (cGMPs) set by the FDA and other relevant worldwide regulatory authorities. We have our manufacturing operation in Totowa, NJ in approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMPs. Our product candidates are manufactured through the combination of raw materials such as 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. Packaging and labeling of commercial product will be performed by a third party vendor.

In December 2005, we purchased, for \$16.0 million, the manufacturing operation of Laureate that are critical to the production of Surfaxin and our SRT clinical programs. We will use this pharmaceutical manufacturing and development facility for the production of Surfaxin, other SRT formulations and aerosol development capabilities. Laureate previously was our contract manufacturer and the Totowa facility was essentially a dedicated Surfaxin operation. Together with Laureate, we have invested in resources, facilities and quality systems to prepare a cGMP-compliant operation for the anticipated FDA approval of Surfaxin. We feel the acquisition provides us with operational control and potentially improved economics for the potential commercial and clinical production of our lead product, Surfaxin, and our pipeline of precision-engineered SRT products. We have entered into a transitional services arrangement with Laureate whereby it is anticipated that Laureate will provide us with certain limited manufacturing-related support services through December 2006.

In January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate, at that time our contract manufacturer of Surfaxin, citing certain observations concerning Laureate's compliance with 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. To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements. Assuming that the corrective actions made to the Surfaxin manufacturing operations in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the commercial launch of Surfaxin will occur late in the second quarter of 2006.

We anticipate that our manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants, the prevention and treatment of BPD and all of our anticipated clinical-scale production requirements for SRT for the treatment of ARDS in adults, and Aerosurf for neonatal respiratory failures.

The lease for our Totowa, NJ, manufacturing operation is through December 2014. In addition to the customary terms and conditions, the lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and, in the earlier years, payment to us of significant early termination amounts. Taking into account this early termination option for our Totowa, NJ, facility, our long-term commercial strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products. We view our recent acquisition of manufacturing operations as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

#### **Manufacturing -- SRT Aerosolization Systems**

In December 2005, we entered into a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc., to develop and commercialize aerosolized surfactant replacement therapies to address a broad range of serious respiratory conditions. The alliance focuses on therapies for hospitalized patients, including those in the NICU, pediatric intensive care unit and the adult intensive care unit, and can be expanded into other hospital applications and ambulatory settings. The product candidates resulting from the alliance will combine our proprietary precision-engineered SRT with Chrysalis' aerosolization device technology.

Chrysalis has developed a proprietary aerosol generation technology that is being designed with the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications. The Chrysalis technology is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery.

The parties are utilizing their respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products.

To manufacture the aerosolization systems we plan on utilizing third-party contract manufacturers, suppliers and assemblers for our planned clinical trials. This includes the assembly of key sub-components that comprise the important parts of the drug-device products such as the aerosol generator, dose packet, disposable delivery parts and patient interface system necessary to administer our SRT in patients in the NICU and ICU. These sub-components will be manufactured by third-party vendors and shipped to one central location for assembly and integration of the aerosolization system. Once assembled, the aerosolization systems will be quality control tested prior to release for clinical trial or commercial use. The SRT drug product will be manufactured at our Totowa, NJ facility and filled in the disposable dose packets at the same location.

## Distribution

Surfaxin requires cold-chain storage and distribution. We have secured an arrangement with ASD Healthcare Inc., a subsidiary of AmerisourceBergen Corporation for the exclusive distribution of 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.

## 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 1A: "Risk Factors- 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 prevention and 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. Curosur<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>, in the United States. There is presently only one approved synthetic surfactant available, Exosurf<sup>®</sup>, 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 recombinant SP-C technology under development by Altana Pharma AG and 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.

Presently, there are no approved therapies for the treatment of BPD. Further, there are no currently approved aerosolized technology therapies to address neonatal respiratory failures in the NICU, where mechanical ventilation represents the current standard of care.

Similarly, there are no drugs currently approved that are specifically indicated for the treatment of ARDS in adults. 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.

## 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 Investigational New Drug (IND) application that the FDA must review before human clinical trials of an investigational drug can commence.

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. An NDA 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 1A: "Risk Factors - Our technology platform is based solely on our proprietary precision-engineered surfactant technology" and "Our ongoing clinical trials may be delayed, or fail, which will harm our business"; and " - The regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products."

The FDA has granted us Fast-Track designation for the indications of ARDS in adults and for the prevention and treatment of BPD in premature infants. Designation as a Fast Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years.

The Office of Orphan Products Development of the FDA has granted Orphan Drug designation for Surfaxin as a treatment for RDS in premature infants, ARDS in adults, MAS in full-term infants, and BPD in premature infants. "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. Additionally, our SRT has received designation as an Orphan Product for ALI (which, in this circumstance, encompasses ARDS) from the EMEA.



## EMPLOYEES

We have approximately 160 full-time employees, primarily employed in the United States, Europe and Latin America. In connection with our manufacturing operation in Totowa, NJ, we have entered into collective bargaining arrangements, expiring December 2009, with respect to certain employee classifications. See Item 1A: "Risk Factors - 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 materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC'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](mailto:ir@DiscoveryLabs.com) or contact the Investor Relations Department 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 1A. RISK FACTORS.**

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.

**We may not successfully develop and market our products, and even if we do, we may not become profitable.**

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, 2005, we have an accumulated deficit of approximately \$202.0 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 technology platform is based solely on our proprietary precision-engineered surfactant technology.**

Our precision-engineered surfactant technology platform is based on the scientific rationale of using 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 technology platform. Any material problems with our technology platform could have a material adverse effect on our business.

**The regulatory approval process for our products is expensive and time-consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products.**

In order to sell Surfaxin or any of our other products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators 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 foreign regulators that the manufacturer of the product maintains good laboratory and manufacturing practices during testing and manufacturing. 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. 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.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). The FDA issued an Approvable Letter to us in February 2005 regarding our NDA. To address the Form 483 inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In October 2005, the FDA accepted our responses to the Approvable Letter as a complete response thereby establishing April 2006 as its target to complete its review of our NDA. Assuming that the corrective actions made to the Surfaxin manufacturing operation in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006. The FDA, however, might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

We have filed an MAA with the EMEA for clearance to market Surfaxin for the prevention of RDS in premature infants in Europe. In February 2006, we received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA. We plan to submit a written response to all of the CHMP's outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006. The EMEA, however, may not complete the review or may reject the MAA.

See also Item 1: "Business - Company Overview and Business Strategy" and Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operation - Plan of Operations."

**If the FDA and foreign regulators do not approve our products, we will not be able to market our products.**

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. The FDA or a foreign regulator 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 or a foreign regulator 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.

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

We submitted an NDA to the FDA for Surfaxin for the prevention of RDS in premature infants. Under the Prescription Drug User Fee Act of 1992, or PDUFA, guidelines, we expect that the FDA will complete its review or otherwise respond to this NDA on or about April 6, 2006. In connection with its review, the FDA may request additional information from us, including data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product.

**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 has notified us that two of our intended indications for our precision-engineered SRT, BPD in premature 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. Designation as a Fast Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years. Fast Track designation does not accelerate clinical trials nor does it mean that the regulatory requirements are less stringent. Our products may cease to qualify for expedited review and our other drug candidates may fail to qualify for Fast Track designation or expedited review.

**Our ongoing clinical trials may be delayed, or fail, which will harm our business.**

Clinical trials generally take two to five years or more to complete. Our first product is not expected to be commercially available in the United States until the second quarter of 2006 at the earliest, and our other product candidates will take longer to commercialize. Like many biotechnology companies, we may suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials. Data obtained from clinical trials 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 and enrollment criteria for the study;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both. Patients may also suffer adverse medical events or side effects that are common to those administered with the surfactant class of drugs such as a decrease in the oxygen level of the blood upon administration.

It is also possible that the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we or any regulator 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 or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials.

In addition to our efforts to commercialize Surfaxin for the prevention of RDS in premature infants, we are currently conducting two clinical trials: a Phase 2 clinical trial to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD in premature infants and a Phase 2 clinical trial to address ARDS in adults. We are preparing to conduct multiple Phase 2 pilot studies with Aerosurf for the potential treatment of premature infants in the NICU suffering from neonatal respiratory failure.

See also Item 1: "Business - Company Overview and Business Strategy" and Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operation - Plan of Operations."

**The manufacture of our products is a highly exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.**

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Manufacturing or quality control problems have already and may again occur at our Totowa facility or our materials suppliers. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

In December 2005, we acquired Laureate's clinical manufacturing facility in Totowa, New Jersey. The facility has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies. With this acquisition, we now maintain a complete manufacturing facility and we will be manufacturing our products. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we expect to invest in additional manufacturing equipment. We may be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards for use in clinical studies. If we do not successfully develop our manufacturing capabilities, it will adversely affect the sales of our products.

**If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.**

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services in order to produce material that meets appropriate standards for commercial distribution and use in clinical trials of our products. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor 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 and vendors, 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 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 working capital will be adequate to satisfy our capital needs into the second half of 2006. 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. 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 also Item 1A: "Risk Factors - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

Furthermore, if the market price of our common stock declines as a result of the dilutive aspects of such potential financings, we could cease to meet the financial requirements to maintain the listing of our securities on The NASDAQ National Market. See Item 1A: "Risk Factors 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 10,962,651 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. In 2005, \$20.2 million was successfully raised under the CEFF in two separate financings over 15 day periods in September and November, respectively. We anticipate using additional portions of the available CEFF during 2006 to support manufacturing, development and commercialization activities associated with our potential U.S. commercial launch of Surfaxin late in the second quarter of 2006.

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 other 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 \$47.6 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.

**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 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. Our collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates is focused on key Southern European markets. Within these countries, Esteve will be responsible for the development and marketing of Surfaxin for a broader portfolio of indications, including the prevention of RDS in premature 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 several indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to EMEA filings.

If we or Esteve 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. 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 collaborators' expertise and dedication of sufficient resources to develop and commercialize our proposed products.

In December, 2005, we entered into a Strategic Alliance Agreement with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Under the agreement, we have exclusive rights to Chrysalis' proprietary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis will assist with the development of certain combination drug-device surfactant products, and provide certain additional consultative services to us in connection with combination drug-device surfactant products, provided that certain terms and conditions are satisfied. Additionally, Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device 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 Item 1A: "Risk Factors - 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 Item 1A: "Risk Factors - 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 develop and 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, Ortho Pharmaceutical and Chrysalis. 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:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how will otherwise become known;
- our competitors will independently develop similar technology; or
- our competitors will independently discover our proprietary information and trade secrets.

**Our limited sales and marketing experience may restrict our success in commercializing our product candidates.**

We have limited experience in marketing or selling pharmaceutical products and have a limited marketing and sales team. 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 expect to rely primarily on our marketing and sales team to market Surfaxin in the United States, if Surfaxin is approved by the FDA. Accordingly, we are further developing our marketing and sales team. Developing a marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process. Recruiting, training and retaining qualified sales personnel is 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. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, we will have difficulty selling, maintaining and increasing the sales of our products.



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. 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 enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates.**

We may 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. Our 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 adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

We may 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.

If we 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.

We have announced our intention to market and sell Surfaxin outside of the United States through one or more marketing partners upon receipt of regulatory 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. As of March 14, 2006, we have employment agreements with eight officers expiring in December 2006. Each employment agreement provides that its term shall automatically be extended for one additional year, unless at least 90 days prior to January 1 either party gives notice that it does not wish to extend the agreement. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. 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, four products are specifically approved for the prevention of RDS in premature infants. There are no approved drugs that are specifically indicated for the prevention and treatment of ALI/ARDS in adults and current therapy consists of general supportive care and mechanical ventilation. See Item 1: "Business – Competition."

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 we acquire companies, products or technologies, we may face risks associated with those acquisitions.**

If we are presented with appropriate opportunities, we intend to acquire or make other investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of these operations and services of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate other companies, products or technologies that we may acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

**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 million per occurrence and \$10 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, 2005, 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 this Item 1A.

Our common stock is listed for quotation on The NASDAQ National Market. During the twelve month period ended December 31, 2005, the price of our common stock has ranged from \$5.05 to \$9.15. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve month period ended December 31, 2005, the average daily trading volume in our common stock was approximately 560,000 shares and the average number of transactions per day was approximately 1,795. 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 Capital 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, 2005, we had 61,021,694 shares of common stock issued and outstanding.

We have a universal shelf registration statement on Form S-3 (File No. 333-128929), filed with the SEC on October 11, 2005, for the proposed offering from time to time of up to \$100 million of our debt or equity securities, of which \$80 million is remaining. We have no immediate plans to sell any securities under this registration statement. However, 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 10,587,651 shares of our common stock that are currently reserved for issuance under the CEFF. See Item 1A: "Risk Factors - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

As of December 31, 2005, up to 10,903,542 shares of our common stock were issuable upon exercise of outstanding options and warrants. 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 1B. UNRESOLVED STAFF COMMENTS.**

There are no material unresolved written comments that were received from the SEC staff 180 days or more before the end of our fiscal year relating to our periodic or current reports under the Securities Exchange Act of 1934.

**ITEM 2. PROPERTIES.**

Our principal offices are leased and located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622. 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 lease our research facility in Mountain View, California, where we principally develop aerosolized formulations of our proprietary precision-engineered surfactant. We lease the space for our manufacturing facility in Totowa, New Jersey.

**ITEM 3. LEGAL PROCEEDINGS.**

Other than disputes arising in the ordinary course of our business, we are not aware of any pending or threatened legal actions that would, 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 2005.

## 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 March 2, 2006, the number of stockholders of record of shares of our common stock was 162 and the number of beneficial owners of shares of our common stock was approximately 15,000. As of March 14, 2006, there were 61,140,942 shares of our common stock issued and outstanding.

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

	<u>Low</u>	<u>High</u>
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	\$ 5.05	\$ 8.60
Second Quarter 2005	\$ 5.34	\$ 7.60
Third Quarter 2005	\$ 5.55	\$ 9.15
Fourth Quarter 2005	\$ 5.67	\$ 7.43
First Quarter 2006 (through March 14, 2006)	\$ 6.66	\$ 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, 2005, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 10,834 shares of our common stock at various exercise prices ranging from \$1.50 to \$6.47 per share. We also awarded and issued 30,263 shares of our common stock as restricted stock awards under our Amended and Restated 1998 Stock Incentive Plan that will be held in escrow as vesting terms (100% vesting upon the date that Surfaxin for RDS first becomes widely available, as such date is determined by the Company) are achieved. 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 referred to 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 us with the amount of any such match determined as a percentage of each individual participant's cash contribution. For the quarter ended December 31, 2005, shares issued by us as a discretionary match totaled 10,498 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, 2005, 2004 and 2003 and with respect to the consolidated balance sheets as of December 31, 2005 and 2004 have been derived from audited consolidated financial statements included as part of this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2002 and 2001 and the balance sheet data as of December 31, 2003 and 2002 and 2001 are derived from audited financial statements not included in this Annual Report. The following selected consolidated financial data should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report.

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

	For the year ended December 31,				
	2005	2004	2003	2002	2001
Revenues from collaborative agreements	\$ 134	\$ 1,209	\$ 1,037	\$ 1,782	\$ 1,112
<b>Operating Expenses:</b>					
Research and development	24,137	25,793	19,750	14,347	8,007
General and administrative	18,505	13,322	5,722	5,458	5,067
In-process research and development	16,787	-	-	-	-
Corporate partnership restructuring charges	-	8,126	-	-	-
<b>Total expenses</b>	<b>59,429</b>	<b>47,241</b>	<b>25,472</b>	<b>19,805</b>	<b>13,074</b>
Operating loss	(59,295)	(46,032)	(24,435)	(18,023)	(11,962)
Other income and expense	391	(171)	155	580	816
<b>Net loss</b>	<b>\$ (58,904)</b>	<b>\$ (46,203)</b>	<b>\$ (24,280)</b>	<b>\$ (17,443)</b>	<b>\$ (11,146)</b>
<b>Net loss per common share - basic and diluted</b>	<b>\$ (1.09)</b>	<b>\$ (1.00)</b>	<b>\$ (0.65)</b>	<b>\$ (0.64)</b>	<b>\$ (0.51)</b>
<b>Weighted average number of common shares outstanding</b>	<b>54,094</b>	<b>46,179</b>	<b>37,426</b>	<b>27,351</b>	<b>22,038</b>

Consolidated Balance Sheet Data:  
(in thousands)

	For the year ended December 31,				
	2005	2004	2003	2002	2001
Cash and investments	\$ 50,908	\$ 32,654	\$ 29,422	\$ 19,152	\$ 16,696
Working capital	33,860	24,519	23,061	16,277	16,484
<b>Total assets</b>	<b>56,008</b>	<b>37,637</b>	<b>32,715</b>	<b>21,062</b>	<b>20,065</b>
Long-term obligations, less current portion	3,323	7,583	711	1,706	33
<b>Total stockholder's equity</b>	<b>\$ 34,838</b>	<b>\$ 21,097</b>	<b>\$ 24,303</b>	<b>\$ 14,761</b>	<b>\$ 17,623</b>



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

This item should be read in connection with our Consolidated Financial Statements. See Item 15: "Exhibits and Financial Statement Schedules."

**OVERVIEW**

We are a biotechnology company developing its proprietary surfactant technology as 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 closely mimic the essential properties of natural human lung surfactant. We believe that through this technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the NICU, critical care unit and other hospital settings, where there are few or no approved therapies available.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. Our lead product, Surfaxin<sup>®</sup> (lucinactant), for the prevention of RDS in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. The FDA has established April 2006 as its target to complete its review of the Surfaxin NDA. Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease, in premature infants. We are preparing to conduct multiple Phase 2 pilot studies with Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

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

With the goal of becoming a fully integrated biotechnology company, we are implementing a long-term business strategy which includes:

- continued investment in manufacturing capabilities (including at the manufacturing operations in New Jersey acquired in December 2005) for the production of precision-engineered surfactant drug products to meet anticipated clinical and, if approved, commercial needs in the United States, Europe and other markets. We view our recent acquisition of manufacturing operations as an initial step of our manufacturing strategy for the continued development of our SRT portfolio. Our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products;
- building a specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU;
- investing in development of aerosol SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology we licensed in December 2005 through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc.; and
- securing additional corporate partnerships for international markets outside of the United States for the development and potential commercialization of SRT, including Surfaxin.

Since our inception, we have incurred significant losses and, as of December 31, 2005, we had an accumulated deficit of \$202.0 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities and in 2005 also include significant general and administrative, primarily pre-commercialization, activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and developing manufacturing capabilities (including costs for contract manufacturing and the purchase of our own manufacturing operations in 2005). We expense research and development costs as they are incurred. General and administrative expenses consist primarily of pre-launch commercialization sales and marketing, executive management, financial, business development, 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, debt arrangements and strategic collaborations. As of December 31, 2005, we had: (i) cash and investments of \$50.9 million; (ii) \$47.6 million available under our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), subject to the terms and conditions of the CEFF; (iii) a \$9.0 million capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), of which \$6.4 million has been drawn and, after giving effect to principal payments, \$4.9 million was outstanding; and (iv) a secured revolving credit facility of \$8.5 million with PharmaBio Development Inc. (PharmaBio), of which the entire amount was outstanding. 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, 2005, 2004 and 2003 were \$24.1 million, \$25.8 million, and \$19.8 million, respectively. These costs are charged to operations as incurred and are tracked by category rather than by project. Research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations and other direct clinical trials activities. In 2005, we incurred a non-recurring charge of \$16.8 million associated with the purchase of the manufacturing operations at the Totowa, NJ facility and which we classified as in-process research and development. The one-time charge is not reflected in the following discussion.

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 engineering of 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 (including a research funding and option agreement with The Scripps Research Institute which expired in February 2005).

### Manufacturing Development

Manufacturing development primarily reflects costs incurred to develop current good manufacturing practices (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Manufacturing development activities include external contract manufacturing resources (including expenses associated with technology transfer and significant development costs associated with the implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process at the Totowa, NJ manufacturing facility that we acquired in December 2005), securing our own manufacturing capabilities and expanding the operations to meet production needs for our SRT pipeline, employee costs, depreciation, and expenses for the purchase of raw materials, 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 include 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 each of the foregoing categories for the years ended December 31, 2005, 2004 and 2003:

(Dollars in thousands)

Research and Development Expenses:	Year Ended December 31,		
	2005	2004	2003
Research and pre-clinical operations	\$ 2,211	\$ 2,916	\$ 1,958
Manufacturing development	11,416	7,010	4,268
Unallocated development - clinical and regulatory operations	7,274	8,588	5,966
Direct clinical trial expenses	3,236	7,279	7,558
<b>Total Research and Development Expenses</b>	<b>\$ 24,137</b>	<b>\$ 25,793</b>	<b>\$ 19,750</b>

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 and data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, 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 Operations - Plan of Operations," below. Successful completion of development of our SRT 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 our product candidates 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 supply of raw materials necessary to manufacture Surfaxin;
- Timely resolution of the cGMP-related matters at our manufacturing operation in Totowa, NJ and certain other SRTs presently under development, including matters that were noted by the FDA in its inspectional report on Form FDA-483;
- Successful manufacture of Surfaxin at our operation in Totowa, NJ; and
- Obtaining sales and marketing capabilities and additional manufacturing operations, 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 compatibility with complimentary technologies;
- 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, financial condition and results of operations will be substantially harmed.

## CORPORATE PARTNERSHIP AGREEMENTS

### **Chrysalis Technologies, a Division of Philip Morris USA Inc.**

In December 2005, we entered into a strategic alliance with Chrysalis Technologies (Chrysalis), a division of Philip Morris USA Inc., to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as ALI, neonatal respiratory failure, COPD, asthma, cystic fibrosis and others. The alliance united two highly complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung.

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

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

Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants in the NICU at risk for respiratory failure. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for Acute Lung Injury (ALI).

## **Laboratorios del Dr. Esteve, S.A.**

In 1999, we entered into a strategic alliance with Laboratorios del Dr. Esteve, S.A. (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 prevention of RDS in premature infants, the treatment of MAS in full-term infants and the treatment of 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 December 2004, we reached an agreement with Esteve to restructure our strategic alliance for the development, marketing and sales of our products in Europe and Latin America. This restructured alliance supersedes the existing sublicense and supply agreements we had entered into with Esteve in March 2002. Under the revised alliance, we regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of 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 potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and other SRT that is increased from that provided for in the 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 its 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 alliance, 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. We also granted to Esteve rights to additional potential SRT products in our pipeline, and 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 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.

In October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceutici Spa (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution in Italy of Surfaxin.

## **The Scripps Research Institute**

Our research funding and option agreement with Scripps expired in February 2005. Pursuant to this agreement, we had been 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. We had the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed under the agreement and for which we did not exercise our option to acquire an exclusive license. Payments to Scripps under this agreement were \$400,000, \$600,000 and \$649,000 in 2005, 2004, and 2003, respectively.

## **PLAN OF OPERATIONS**

The Company has incurred substantial losses since inception and expects to continue to expend substantial amounts for continued product research, development, manufacturing and commercialization activities.

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

- (i) increase 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 Item 1A: "Risk Factors - Our technology platform is based solely on our proprietary, precision-engineered surfactant technology;" "Our ongoing clinical trials may be delayed, or fail, which will harm our business;" and "The regulatory approval process for our products is expensive and time-consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products."

Our major research and development projects include:

#### SRT for Neonatal Intensive Care Unit

In order to address 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 have received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. We anticipate potential FDA approval in April 2006 and U.S. commercial launch to occur late in the second quarter of 2006.

We have filed an MAA with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. Activities associated with this regulatory filing are ongoing. We have received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA for Surfaxin<sup>®</sup> for the prevention and rescue treatment of Respiratory Distress Syndrome in premature infants. We plan to submit a written response to all of the CHMP's outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006.

We are currently conducting a double-blind, controlled Phase 2 clinical trial that will enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study's objective is to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. The BPD study design provides that such premature infants receive a treatment regime of up to 5 Surfaxin doses beginning within the first 3-10 days of life that are in addition to the surfactant they received on day 1 of life for RDS. 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 or its severity. We anticipate the results of this trial to be available in the third quarter of 2006. In October 2005, the Office of Orphan Products Development of the FDA granted Orphan Drug designation to Surfaxin for the treatment of BPD in premature infants. We anticipate the results of this trial to be available in the third quarter of 2006.

Aerosurf<sup>™</sup> is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failures. In September 2005, we completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf, which was designed as an open label, multicenter study to evaluate the feasibility, safety and tolerability of Aerosurf delivered via nCPAP for the prevention of RDS in premature infants administered within 30 minutes of birth over a three hour duration. The study showed that it is feasible to deliver Aerosurf via nCPAP and that the treatment was generally safe and well tolerated.

In December 2005, we entered into a strategic alliance with Chrysalis. The alliance united two highly complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. Through this alliance, we gained exclusive rights to their aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants in the NICU at risk for respiratory failure. We anticipate conducting pilot Phase 2 clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in the second half of 2006.

#### SRT for Critical Care and Hospital Indications

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of adults with ARDS. In December 2004, we announced preliminary data from this trial and that we were modifying the trial protocol to allow for increased enrollment of up to 160 patients. Patients are randomized to either receive our SRT or the current standard of care, which is mechanical ventilation and support therapies. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Secondary endpoints include, but are not limited to, safety and tolerability of our SRT and the bronchoscopic lavage procedure, increased oxygenation, decreased ventilatory requirements, mortality at the end of Day 28, number of days in the intensive care unit, and number of days in the hospital. Results of the Phase 2 trial are anticipated to be available in March 2006.

We are also evaluating the development of aerosol formulations of SRT to potentially address ALI, asthma, COPD, and other respiratory conditions. In 2004, we completed a successful Phase 1b clinical trial intended to evaluate the tolerability and lung deposition of our precision-engineered SRT, delivered as an inhaled aerosol to treat patients with mild-persistent asthma (development name DSC-104). In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for Acute Lung Injury (ALI). Given the current focus on developing the SRT pipeline for the NICU, we will be assessing the timing and further prioritization of these programs in 2006.

- (ii) invest in and support our long-term manufacturing strategy for the production of our precision-engineered surfactant drug product including:
  - (a) manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets. We are investing in the further development and expansion of our manufacturing operations in New Jersey (acquired in December 2005).

In October 2003, we entered into a contract manufacturing arrangement with Laureate Pharma, Inc. (Laureate), whereby our Surfaxin manufacturing know-how and dedicated equipment was transferred to their Totowa, NJ operations. Transfer of the Surfaxin manufacturing process was completed in 2004 and, since that time, the Totowa, NJ operations have been predominantly dedicated to Surfaxin and the support of regulatory compliance requirements for our manufacturing operation.

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. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued an inspection report (Form FDA-483) to Laureate, at that time our contract manufacturer of Surfaxin, citing certain observations concerning Laureate's compliance with 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. To address the inspectional observations, we and Laureate implemented improve quality systems and documentation controls believed to support the FDA's regulatory requirements.

In December 2005, we purchased, for \$16.0 million, the manufacturing operation of Laureate that are critical to the production of Surfaxin and our SRT clinical programs. We will use this pharmaceutical manufacturing and development facility for the production of Surfaxin and for the development and enhanced formulations of Surfaxin and the development of aerosol formulations including Aerosurf. Laureate previously was our contract manufacturer and the Totowa facility was essentially a dedicated Surfaxin operation. Together with Laureate, we have invested in resources, facilities and quality systems to prepare a cGMP-compliant operation for the anticipated FDA approval of Surfaxin. We have entered into a transitional services arrangement with Laureate whereby it is anticipated that Laureate will provide us with certain limited manufacturing-related support services through December 2006. See In-Process Research and Development.

Our previously submitted responses to the Approvable Letter were accepted by the FDA as a complete response as of October 5, 2005. This date marks the start of the six month review period during which the FDA expects to complete its review of our NDA for Surfaxin for the prevention of RDS in premature infants. Assuming that the corrective actions made to the Surfaxin manufacturing operations in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006.

We view the recent acquisition of manufacturing operation as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products. We anticipate that our manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants, the prevention and treatment of BPD and all of our anticipated clinical-scale production requirements for SRT for the treatment of ARDS in adults, and Aerosurf for neonatal respiratory diseases;

- (b) securing additional manufacturing capabilities.

The lease for our Totowa, NJ, manufacturing operations is through December 2014. In addition to the customary terms and conditions, the lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and, in the earlier years, payment to us of significant early termination amounts. Taking into account this early termination option for our Totowa, NJ, facility, our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products; and

- (c) manufacture of the aerosolization devices and related componentry for our aerosol SRT products. We plan on utilizing third party contract manufacturers, suppliers and assemblers for our planned clinical trials.

See Item 1A: "Risk Factors - The manufacture of our products is a highly exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer;" and "If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products."

- (iii) build our own specialty pulmonary United States sales, marketing and medical affairs organization to execute the commercial launch of Surfaxin, if approved, in the United States. We anticipate that our Surfaxin NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006. Our sales and marketing force will initially focus on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, which is necessary for the anticipated commercial launch of Surfaxin, is intended to allow us to manage and administer our own commercial operations, establish a strong presence in the NICU and optimize company economics;
- (iv) implement an international partnering strategy for the development and commercialization of our SRT NICU pipeline, including Surfaxin, in international markets outside of the United States; and



- (v) invest in additional general and administrative resources primarily to support our intellectual property portfolios, including building and enforcing our patent and trademark positions, our business development initiatives, financial systems and controls and management information technologies.

We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability. Through December 31, 2005, we had no revenues from any product sales, and had not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2005, we had not generated taxable income. On December 31, 2005, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$187.0 million. 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 \$3.8 million at December 31, 2005. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2009 through 2024.

#### **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, 2005, 2004 and 2003 were \$58.9 million (or \$1.09 per share), \$46.2 million (or \$1.00 per share) and \$24.3 million (or \$0.65 per share), respectively.

In 2005, we purchased the manufacturing operations of Laureate Pharma, Inc. (Laureate) in Totowa, NJ for \$16.0 million and incurred additional related expenses of \$0.8 million. Included in the 2005 net loss is a charge, classified as in-process research & development, of \$16.8 million or \$0.31 per share related to the manufacturing purchase. Included in the 2004 net loss is a charge, classified as corporate partnership restructuring, of \$8.1 million, or \$0.18 per share, associated with the restructuring of strategic collaborations with Quintiles and Esteve.

Excluding these charges, the net loss for the year ended December 31, 2005 and 2004 was \$42.1 million, or \$0.78 per share, and \$38.1 million, or \$0.82 per share, respectively.

## Revenue

Revenue for the years ended December 31, 2005, 2004 and 2003 were \$0.1 million, \$1.2 million and \$1.0 million, respectively. These revenues are primarily associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in Southern Europe. Additionally, 2003 revenues include approximately \$0.3 million related to our Small Business Innovative Research (SBIR) grant to develop Surfaxin for ARDS and the conclusion of this project.

The primary change in revenues from 2003, 2004 and 2005 reflects; (i) the agreements with Esteve as of 2002 whereby Esteve was responsible for providing development funding; (ii) the restructuring of our corporate partnership with Esteve in December 2004 (primarily as it relates to funding of ARDS development costs); and (iii) the extension of the amortization period (based on the anticipated approval timeline for certain world health regulatory authorities) for revenue recognition of the funding previously provided in connection with RDS clinical trial costs.

## Research and Development Expenses

Research and development expenses for the years ended December 31, 2005, 2004 and 2003 were \$24.1 million, \$25.8 million and \$19.8 million, respectively. For a description of expenses and research and development activities see "Management's Discussion and Analysis - Research and Development". For a description of the clinical programs included in research and development see "Management's Discussion and Analysis - Plan of Operations".

The change in research and development expenses for the years ended December 31, 2005, 2004 and 2003 primarily reflects:

- (i) manufacturing development activities to support the production of clinical and commercial drug supply for our SRT programs, including Surfaxin, in conformance with current Good Manufacturing Practices (cGMPs). Expenses related to manufacturing development activities were \$11.4 million, \$7.0 million and \$4.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

The increase in 2005 versus 2004 primarily reflects expenses incurred for the implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process predominantly at Laureate's Totowa, NJ operation (our contract manufacturer at that time) in response to the FDA 483 inspectional observations. Additionally, we made enhancements and improvements to Laureate's Totowa, NJ operations and facility for the production of Surfaxin, SRT formulations and aerosol development capabilities. In December 2005, we purchased the manufacturing operation of Laureate in Totowa, NJ.

The increase in 2004 versus 2003 primarily reflects expenses associated with the transfer and validation of our manufacturing equipment process and know-how to Laureate (completed in 2004) to support the production of clinical and commercial drug supply of Surfaxin in conformance with cGMPs;

- (ii) direct clinical trial and regulatory activities, related to the advancement of our SRT pipeline. Expenses related to these activities were \$3.2 million, \$7.3 million and \$7.6 million for the years ended December 31, 2005, 2004 and 2003, respectively. The decrease in 2005 from 2004 is primarily due to costs in 2004 associated with clinical and regulatory activities for Surfaxin for RDS, principally the NDA filing, a related milestone payment for the license of Surfaxin, and follow-up clinical activity pertaining to the two Phase 3 clinical trials. Expenditures in 2005 primarily reflect regulatory activities associated with Surfaxin for RDS (specifically the U.S. FDA Approvable Letter and the EMEA Marketing Authorization Application) and clinical activities related to the Phase 2 clinical trials for ARDS in adults, BPD in premature infants and Aerosurf for Neonatal Respiratory Failures. Expenses incurred in 2004 and 2003 are primarily related to the clinical and development, regulatory and long-term clinical follow-up activity for the two Phase 3 trials of Surfaxin for RDS in premature infants;
- (iii) clinical and regulatory operations to manage multiple clinical studies related to the advancement of our SRT pipeline. Expenses related to these activities were \$7.3 million, \$8.6 million and \$6.0 million for the years ended December 31, 2005, 2004 and 2003, respectively. The decrease in 2005 versus 2004 is primarily related to the use of external consultants and temporary help associated with the filing of the Surfaxin NDA in 2004. The increase in 2004 versus 2003 is primarily related to the expansion of clinical, regulatory, biostatistics and scientific capabilities to support multiple programs in advancing our SRT pipeline; and
- (iv) research and pre-clinical operations associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and application and engineering of aerosol delivery systems for our SRT pipeline. Expenses related to these activities were \$2.2 million, \$2.9 million and \$2.0 million for the years ended December 31, 2005, 2004 and 2003, respectively. The decrease in 2005 versus 2004 is primarily related to the conclusion of research efforts and funding associated with The Scripps Research Institute agreement, which expired in February 2005. The increase in 2004 versus 2003 is primarily related to building our aerosol technology management and related capabilities in our California operations.

#### **General and Administrative Expenses**

General and administrative expenses for the years ended December 31, 2005, 2004 and 2003 were \$18.5 million, \$13.3 million and \$5.7 million, respectively. General and administrative expenses consist primarily of the costs of pre-launch commercial sales and marketing, executive management, finance and accounting, business and commercial development, legal, facility and other administrative costs.

The increase in general and administrative expenses for the years ended December 31, 2005, 2004 and 2003 primarily reflects:

- (i) pre-launch commercialization activities (in anticipation of the potential approval and launch of Surfaxin for RDS in the second quarter of 2006) related to building our own specialty pulmonary United States commercial organization to focus initially on the commercial and medical promise of its SRT to address respiratory therapies for the Neonatal Intensive Care Unit (NICU). Expenditures are for sales, marketing and medical affairs activities. Expenses for the years ended December 31, 2005, 2004 and 2003 were \$10.1 million, \$5.9 million and \$1.0 million, respectively. A portion of these commercialization expenses were financed by use of the secured, revolving credit facility with PharmaBio in the amounts of \$3.5 million in 2004 and \$1.0 million in 2003; and
- (ii) business administrative expenses were \$8.4 million, \$7.4 million and \$4.7 million for the years ended December 31, 2005, 2004 and 2003, respectively. The increases from 2003 through 2005 primarily include building management and systems for financial and information technology capabilities, business development activities related to potential strategic collaborations, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities expansion activities to accommodate existing and future growth, and corporate governance initiatives to comply with the Sarbanes-Oxley Act.

## **In-Process Research & Development**

In December 2005, we purchased the manufacturing operations of Laureate Pharma, Inc. (Laureate) in Totowa, NJ (our previous contract manufacturer) for \$16.0 million and incurred additional related expenses of \$0.8 million. The pharmaceutical manufacturing and development facility will be used for the production of Surfaxin, SRT formulations and aerosol development capabilities. We believe this acquisition was a logical way to implement the initial step of a long-term manufacturing strategy for the continued development of our SRT portfolio, specifically life cycle management of Surfaxin for new indications, potential formulation enhancements, and expansion of our aerosolized SRT products beginning with Aerosurf™.

The manufacturing facility in Totowa, NJ is located in approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the production of sterile pharmaceuticals in compliance with current Good Manufacturing Practices (cGMP) requirements. There are approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the operations. In October 2003, we and Laureate entered into a contract manufacturing arrangement, whereby our Surfaxin manufacturing know-how and dedicated equipment was transferred to this facility. Transfer of the Surfaxin manufacturing process was completed in 2004 and, since that time, the facility has been predominantly dedicated to Surfaxin and the support of regulatory compliance requirements for our manufacturing operations. In January 2005, as part of the review of the Surfaxin NDA, the FDA issued a Form 483 to Laureate, citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with cGMPs. To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin.

In consideration for the \$16.0 million paid to Laureate, we received the following:

- An assignment of the existing lease of the Totowa facility, with a lease term expiring in December 2014. The lease is subject to customary terms and conditions and contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to us.
- Equipment and leasehold improvements related to the Totowa facility.
- The right to employ the majority of the approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and that were employed by Laureate at the operations.

In connection with this transaction, we incurred a non-recurring charge, classified as in-process research & development in accordance with Financial Accounting Standard No. 2 (FAS 2) "Accounting for Research & Development Costs," of \$16.8 million associated with the purchase of the manufacturing operations at the Totowa, NJ facility.

Also, in connection with the acquisition, we borrowed \$2.4 million pursuant to our capital lease financing arrangement with General Electric Capital Corporation (GECC) to support financially the purchase of the manufacturing operations.

## **Corporate Partnership Restructuring Charges**

In 2004, we incurred non-cash charges totaling \$8.1 million related to the restructuring of our corporate partnerships with Quintiles and Esteve. See "Management's Discussion and Analysis - Corporate Partnership Agreements."

In 2001, we entered into a commercialization agreement with Quintiles Transnational Corp. (Quintiles), and its strategic investment group affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the prevention of RDS in premature infants and the treatment of Meconium Aspiration Syndrome (MAS) in full-term infants. In November 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate our 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 prevention of RDS in premature infants and the treatment of MAS to Quintiles has been terminated. In connection with our arrangement to regain full commercialization rights for Surfaxin, we issued a warrant to PharmaBio to purchase 850,000 shares of our common stock at an exercise price equal to \$7.19 per share. The warrant has 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. The warrant was valued at its fair value on the date of issuance and we incurred a non-cash charge equal to \$4.0 million in connection with the issuance. The existing secured revolving credit facility of \$8.5 million with PharmaBio remains available with the original maturity date of December 10, 2004 being extended until December 31, 2006.

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. 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, 2005, 2004 and 2003 were \$391,000, (\$171,000) and \$155,000, respectively.

Interest income for the years ended December 31, 2005, 2004 and 2003 was \$1,345,000, \$392,000 and \$452,000, respectively. The increase is primarily due to higher average cash balances and a general increase in earned market interest rates.

Interest and amortization expense for the years ended December 31, 2005, 2004 and 2003 was \$954,000, \$563,000 and \$297,000, respectively. The increases are primarily due to higher outstanding balances with our credit facility and capital lease financing arrangements and an increase in 2005 in the prime borrowing rate. See "Liquidity and Capital Resources."

### **LIQUIDITY AND CAPITAL RESOURCES**

#### **Working Capital**

Currently, we require cash to fund our working capital needs, to purchase capital assets, and to pay our debt service, including principal, interest and capital lease obligations. We have funded our cash requirements primarily through the issuance of equity securities and the use of credit and capital lease facilities. We plan to fund our future cash requirements through:

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

We believe our current working capital is sufficient to meet planned activities into the second half of 2006, before taking into account any amounts that may be available through the use of the CEFF. We anticipate using additional portions of the available CEFF to support manufacturing, development and commercialization activities in 2006.

We will need additional financing from investors or collaborators to complete research and development, manufacturing, and commercialization of our current product candidates under development, and satisfy debt obligations. Working capital requirements will depend upon numerous factors, including, without limitation, the approval of Surfaxin for RDS in premature infants by the FDA and EMEA, the progress of 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, ability to establish collaborative arrangements with other organizations, the ability to defend and enforce intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

## **Cash, Cash Equivalents and Marketable Securities**

As of December 31, 2005, we had cash, cash equivalents, restricted cash and marketable securities of \$50.9 million, as compared to \$32.7 million as of December 31, 2004. The change from December 31, 2004, is primarily due to aggregate cash outflows in 2005 of \$58.7 million, which consisted of \$42.7 million used in operating and investing activities and \$16.0 million for the purchase of the manufacturing operations of Laureate. These cash outflows were offset by aggregate cash inflows of \$76.9 million, which consisted of: (i) a registered direct public offering of 5,060,000 shares resulting in net proceeds of \$27.4 million; (ii) a registered direct public offering of 3,030,304 shares resulting in net proceeds of \$18.9 million; (iii) a registered direct public offering to our corporate partner, Esteve, resulting in net proceeds of \$4.5 million; (iv) two financings pursuant to the CEFF of 3,510,607 shares resulting in net proceeds of \$20.2 million; (v) \$2.4 million, net of principal payments, which was primarily associated with financing the manufacturing purchase, from the use of the capital lease financing arrangement with GECC; (vi) \$2.6 million accessed under our credit facility from PharmaBio; and (vii) \$0.9 million received from the exercise of stock options and warrants.

## **Committed Equity Financing Facility**

In July 2004, we 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 our ultimate determination, and certain conditions of the facility agreement. 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. 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, 2005, the Class B Investor Warrant had not been exercised in whole or in part.

In November 2005, we entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to us of \$3.2 million from the issuance of 498,552 shares of common stock at an average price of \$6.42, after taking into account the applicable discount rate provided for by the CEFF.

In September 2005, we entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to us of \$17.0 million from the issuance of 3,012,055 shares of common stock at an average price of \$5.64, after taking into account the applicable discount rate provided for by the CEFF.

In December 2004, we entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to us 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.

Subject to the conditions of the CEFF, there is currently \$47.6 million that remains available under the CEFF.

## **Potential Financings under the October 2005 Universal Shelf Registration Statement**

In October 2005, we filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering, from time to time, of up to \$100.0 million of our debt or equity securities. In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to us of \$20.0 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately \$80.0 million of equity or debt securities. There can be no assurance, however, that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our commercial activities, investor perception of our prospects and the general condition of the financial markets, among others.

## Debt Facilities

Payments due under contractual debt obligations at December 31, 2005, including principal and interest, are as follows:

<i>(in thousands)</i>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>Total</u>
Credit facility with Quintiles	\$ 9,300	\$ —	\$ —	\$ —	\$ 9,300
Capital lease obligations - GECC & others	1,214	1,080	487	49	2,830
Note Payable - GECC	763	833	833	438	2,867
Total	<u>\$ 11,277</u>	<u>\$ 1,913</u>	<u>\$ 1,320</u>	<u>\$ 487</u>	<u>\$ 14,997</u>

### *Credit Facility with Quintiles Transnational Corp.*

We entered into a collaboration arrangement with Quintiles Transnational Corp. (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 \$8.5 to \$10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States.

In November 2004, we restructured our business arrangements with Quintiles and terminated our 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, 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. The original maturity date of December 10, 2004, is now extended until December 31, 2006. The interest rate is the greater of 8% or prime rate plus 2% annually and payments are due quarterly in arrears. As of December 31, 2005, \$8.5 million was outstanding under the credit facility and is classified as a current liability. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006.

We have utilized the credit facility for \$2.6 million in 2005, \$3.5 million in 2004 and \$1.0 million in 2003 as a source of working capital. As of December 31, 2005, \$8.5 million was outstanding, due in December 2006, and classified as a current liability.

### *Capital Lease and Note Payable Financing Arrangements with General Electric Capital Corporation*

Capital lease liabilities and note payable as of December 31, 2005 and 2004 are as follows:

<i>(in thousands)</i>	<u>2005</u>	<u>2004</u>
<b>Current</b>		
Capital leases, GECC	\$ 982	\$ 828
Note payable, GECC	560	—
All other	26	26
Capital leases and note payable, current	<u>1,568</u>	<u>854</u>
<b>Long Term</b>		
Capital leases, GECC	1,480	1,626
Note payable, GECC	1,840	—
All other	3	28
Capital leases and note payable, long term	<u>3,323</u>	<u>1,654</u>
Total capital leases and note payable	<u>\$ 4,891</u>	<u>\$ 2,508</u>

Our primary capital lease financing arrangement is with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC). Under this arrangement, we purchase capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through this capital lease financing arrangement. The capital lease is secured by the related assets. Subject to certain conditions, this arrangement provides for financing of up to \$9.0 million, of which \$0.5 million is contingent upon FDA approval of Surfaxin for the prevention of RDS in premature infants. The funds are available through April 2006, subject to certain conditions. Laboratory and manufacturing equipment is financed over 48 months and all other equipment is financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. For portions of the capital lease financing arrangement accessed in 2005, the interest rates ranged from 9.9% to 10.5%.

As of December 31, 2005, we had used \$6.4 million of the available financing under the arrangement and had \$2.6 million remaining available for future use, subject to certain conditions.

Amounts available, used and remaining available for future use as of December 31, 2005 and 2004 are as follows:

<i>(in thousands)</i>	<u>2005</u>	<u>2004</u>
<b>Financing available</b>		
Currently available	\$ 8,500	\$ 7,500
Availability subject to FDA approval	<u>500</u>	<u>1,500</u>
Total	9,000	9,000
<b>Amount used (cumulative)</b>	<u>(6,358)</u>	<u>(3,042)</u>
<b>Amount available for future use</b>	<u>\$ 2,642</u>	<u>\$ 5,958</u>

Included in the amounts above, in December 2005, we borrowed \$2.4 million pursuant to our capital lease financing arrangement to support the purchase of our manufacturing operations in Totowa, NJ. In accordance with the accounting treatment for the manufacturing purchase, the \$2.4 million was classified as a note payable on the balance sheet (of which \$0.6 million is current and \$1.8 million is long-term as of December 31, 2005). The note has an interest rate of 10.3% and is repayable over a 48-month period. The note payable is secured by equipment at the manufacturing facility in Totowa, NJ.

#### **Lease Agreements**

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

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

We lease a 21,000 square foot pharmaceutical manufacturing and development facility in Totowa, NJ that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements. The lease expires in December 2014 with total aggregate payments of \$1.4 million (\$150,000 per year). The lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to us.



We also lease approximately 11,000 square feet of office and laboratory space in Doylestown, Pennsylvania. We maintain the Doylestown facility for the continuation of analytical laboratory activities under a lease that expires in February 2006, subject to a monthly extensions.

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.

If we are successful in commercializing our SRT portfolio, we expect that our needs for additional leased space will increase.

#### **Registered Public Offerings**

In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors. The shares were priced at \$6.60 per share resulting in gross and net proceeds to us of \$20.0 million and \$18.9 million, respectively. This offering was made pursuant to our October 2005 universal shelf registration statement.

In November 2005, we sold 650,000 shares of our common stock to Esteve, at a price per share of \$6.88, for aggregate proceeds of approximately \$4.5 million. This offering was made pursuant to our December 2003 shelf registration statement.

In February 2005, we completed a registered direct public 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 us equal to \$29.1 million and \$27.4 million, respectively. This offering was made pursuant to our December 2003 shelf registration statement.

In April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at \$11.00 per share resulting in our receipt of gross and net proceeds equal to \$24.2 million and \$22.8 million, respectively. This offering was made pursuant to our December 2003 shelf registration statement.

#### **Private Placements**

In June 2003, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$25.9 million. 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. As of December 31, 2005, 909,381 of the Class A Investor Warrants remain unexercised.

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.

#### **Other Financing Transactions - Warrants**

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. In connection with regaining the full United States commercialization rights for Surfaxin, we issued a warrant to PharmaBio to purchase 850,000 shares of our common stock at an exercise price equal to \$7.19 per share. The warrant has 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. As of December 31, 2005, the warrant has not been exercised in whole or in part.

In July 2004, 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. 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, 2005, the Class B Investor Warrant had not been exercised in whole or in part.

### Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our expanded commercial, manufacturing and research and product development activities and repay our indebtedness. Based on our current operating plan, we believe that our currently available resources, including amounts that may be available under our CEFF with Kingsbridge and our capital lease financing arrangement with General Electric Capital Corporation, will be adequate to satisfy our capital needs into 2007. Our future capital requirements will depend on the potential approval of Surfaxin for RDS in premature infants and any resulting revenue generation, 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 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 when needed or on terms acceptable to us, if at all. If we fail to receive additional funding or enter into collaborative ventures, 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 Item 1A: "Risk Factors - 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 contractual debt obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Payments due under contractual debt obligations at December 31, 2005, including principal and interest, are as follows:

<i>(in thousands)</i>	2006	2007	2008	2009	2010	Thereafter	Total
Credit facility (1)	\$ 9,300	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 9,300
Capital lease obligations (1)	1,214	1,080	487	49	—	—	2,830
Note Payable (1)	763	833	833	438	—	—	2,867
Operating lease obligations (2)	1,422	1,452	1,310	1,146	277	600	6,207
Purchase obligations (3)	2,613	233	—	—	—	—	2,846
Employment agreements (3)	2,117	—	—	—	—	—	2,117
<b>Total</b>	<b>\$ 17,429</b>	<b>\$ 3,598</b>	<b>\$ 2,630</b>	<b>\$ 1,633</b>	<b>\$ 277</b>	<b>\$ 600</b>	<b>\$ 26,167</b>

(1) See Item 7: "Management's Discussion and Analysis of Financial Condition and Operations - Liquidity and Capital Resources - Debt Facilities".

(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.

On December 31, 2005, we had employment agreements with seven officers providing for an aggregate annual salary of \$2,117,000. The agreements expire in December 2006. However, on each January 1st thereafter, the term of each agreement automatically extends 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.

**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 the Index to Consolidated Financial Statements on Page F-1 attached hereto.

**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 our 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, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management 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, our management believes that our internal control over financial reporting is effective based on those criteria, as of December 31, 2005.

Our independent registered public accounting firm has audited management's assessment of our internal control over financial reporting, and issued an unqualified opinion dated January 27, 2006 on such assessment and on our internal control over financial reporting, which opinion 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.**

The consolidated financial statements required to be filed in this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements on page F-1 hereof.

Exhibits are listed on the Index to Exhibits at the end of this Annual Report on Form 10-K. The exhibits required to be filed pursuant to Item 601 of Regulation S-K, which are listed on the 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, 2006

By: /s/ Robert J. Capetola

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Name &amp; Title</u>	<u>Date</u>
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. President, Chief Executive Officer and Director	March 16, 2006
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer	March 16, 2006
/s/ Kathleen A. McGowan	Kathleen A. McGowan Controller (Principal Accounting Officer)	March 16, 2006
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Chairman of the Board of Directors	March 16, 2006
/s/ W. Thomas Amick	W. Thomas Amick Director	March 16, 2006
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 16, 2006
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 16, 2006
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 16, 2006



## INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Amended and Restated By-Laws of Discovery.	Incorporated by reference to Exhibit 3.2 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the SEC on March 15, 2004.
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
3.4	Certificate of Amendment to the Certificate of Incorporation of Discovery, dated as of May 28, 2004.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 9, 2004.
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of Discovery, dated as of July 8, 2005.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 8, 2005.
4.1	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	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.
4.4	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.
4.5	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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.6	\$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.
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).
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 13, 2005).	Incorporated by reference to Exhibit 4.1 to Discovery's Registration Statement on Form S-8, as filed with the SEC on August 23, 2005 (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	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.
10.8	* 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.
10.9	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.
10.10	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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.11	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-A, as filed with the SEC on February 6, 2004.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17+	Amended and Restated Sublicense and Collaboration Agreement made as of December 3, 2004, between Discovery and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.28 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.18+	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Discovery and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.29 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.19+	Strategic Alliance Agreement, dated as of December 9, 2005, between Discovery and Philip Morris USA Inc. d/b/a Chrysalis Technologies	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 12, 2005.
10.20	Asset Purchase Agreement, dated as of December 27, 2005, between Discovery and 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 January 3, 2006.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.21	Employment Agreement, dated as of January 1, 2004, between Discovery and Robert J. Capetola, Ph.D.	Incorporated by reference to Exhibit 10.21 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.22	Employment Agreement, dated as of January 1, 2004, between Discovery and John G. Cooper	Incorporated by reference to Exhibit 10.22 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.23	Employment Agreement, dated as of January 1, 2004, between Discovery and David L. Lopez, Esq., CPA	Incorporated by reference to Exhibit 10.23 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.24	Employment Agreement, dated as of May 24, 2004, between Discovery and Mark Osterman	Incorporated by reference to Exhibit 10.24 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.25	Employment Agreement, dated as of January 1, 2004, between Discovery and Christopher J. Schaber, Ph.D.	Incorporated by reference to Exhibit 10.25 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.26	Employment Agreement, dated as of January 1, 2004, between Discovery and Robert Segal, M.D.	Incorporated by reference to Exhibit 10.26 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.27	Employment Agreement, dated as of January 1, 2004, between Discovery and Deni M. Zodda, Ph.D.	Incorporated by reference to Exhibit 10.27 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.28	Employment Agreement, dated as of January 24, 2006, between Discovery and Kathryn Cole.	Filed herewith.
10.29	Assignment of Lease and Termination and Option Agreement, dated as of December 30, 2005, between Laureate Pharma, Inc. and Discovery.	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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
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.

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**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, 2005 and 2004, 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, 2005. 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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, 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, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated January 27, 2006, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

Philadelphia, Pennsylvania

January 27, 2006

**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, 2005, 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, 2005, 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, 2005, 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, 2005 and 2004, 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, 2005 of the Company and our report dated January 27, 2006 expressed an unqualified opinion thereon.

Philadelphia, Pennsylvania  
January 27, 2006

/s/ Ernst & Young LLP



**Consolidated Balance Sheets**  
*(In thousands, except per share data)*

	<u>December 31,</u> <u>2005</u>	<u>December 31,</u> <u>2004</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 47,010	\$ 29,264
Restricted cash	647	646
Investments	3,251	2,744
Note receivable, current portion	3	3
Prepaid expenses and other current assets	557	685
Total Current Assets	51,468	33,342
Property and equipment, net	4,322	4,063
Note receivable, non-current portion	187	190
Other assets	31	42
Total Assets	<u>\$ 56,008</u>	<u>\$ 37,637</u>
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,540	\$ 7,969
Credit facility, current portion	8,500	—
Capitalized leases and note payable, current portion	1,568	854
Total Current Liabilities	17,608	8,823
Credit facility, non-current portion	—	5,929
Capitalized leases and note payable, non-current portion	3,323	1,654
Other liabilities	239	134
Total Liabilities	21,170	16,540
Shareholders' Equity:		
Common stock, \$.001 par value; 180,000 and 80,000 authorized; 61,335 and 48,747 issued, 61,022 and 48,434 outstanding at December 31, 2005 and December 31, 2004, respectively	61	49
Additional paid-in capital	240,028	167,627
Unearned portion of compensatory stock options	(230)	(461)
Accumulated deficit	(201,965)	(143,061)
Treasury stock (at cost; 313 shares of common stock)	(3,054)	(3,054)
Accumulated other comprehensive income	(2)	(3)
Total Shareholders' Equity	34,838	21,097
Total Liabilities & Shareholders' Equity	<u>\$ 56,008</u>	<u>\$ 37,637</u>

See notes to consolidated financial statements

**Consolidated Statements of Operations***(In thousands, except per share data)*

	Year Ended December 31,		
	2005	2004	2003
Revenues:			
Contracts, licensing, milestones and grants	\$ 134	\$ 1,209	\$ 1,037
Expenses:			
Research & development	24,137	25,793	19,750
General & administrative	18,505	13,322	5,722
In-process research & development	16,787	—	—
Corporate partnership restructuring charges	—	8,126	—
Total expenses	<u>59,429</u>	<u>47,241</u>	<u>25,472</u>
Operating Loss	(59,295)	(46,032)	(24,435)
Other income and expenses:			
Interest income, dividends, realized gains, and other income	1,345	404	452
Interest expense	<u>(954)</u>	<u>(575)</u>	<u>(297)</u>
Other income / (expense), net	<u>391</u>	<u>(171)</u>	<u>155</u>
Net Loss	<u>\$ (58,904)</u>	<u>\$ (46,203)</u>	<u>\$ (24,280)</u>
Net loss per common share - basic and diluted	<u>\$ (1.09)</u>	<u>\$ (1.00)</u>	<u>\$ (0.65)</u>
Weighted average number of common shares outstanding - basic and diluted	54,094	46,179	37,426

See notes to consolidated financial statements

**Consolidated Statements of Changes in Stockholders' Equity**  
**For Years Ended December 31, 2005, 2004, and 2003**  
(In thousands)

	Common Stock			Unearned Portion of Compensatory Stock Options	Accumulated Deficit	Treasury Stock		Accumulated Other Comprehensive (Loss)	Total
	Shares	Amount	Additional Paid-in Capital			Shares	Amount		
<b>Balance - January 1, 2003</b>	<b>32,857</b>	<b>\$ 33</b>	<b>\$ 87,463</b>	<b>\$ (95)</b>	<b>\$ (72,578)</b>	<b>(38)</b>	<b>\$ (239)</b>	<b>\$ 177</b>	<b>\$ 14,761</b>
Comprehensive loss:									
Net loss	-	-	-	-	(24,280)	-	-	-	(24,280)
Other comprehensive loss - unrealized losses on investments	-	-	-	-	-	-	-	(177)	(177)
Total comprehensive loss	-	-	-	-	-	-	-	-	(24,457)
Issuance of common stock, stock option exercises	993	1	1,940	-	-	-	-	-	1,941
Issuance of common stock, warrant exercises	3,790	4	6,846	-	-	-	-	-	6,850
Issuance of common stock, 401k employer match	21	-	86	-	-	-	-	-	86
Expense related to stock options	-	-	99	93	-	-	-	-	192
Issuance of common stock, June private financing	4,998	5	25,925	-	-	-	-	-	25,930
Change in value of Class H warrants	-	-	50	-	-	-	-	-	50
Shares tendered for exercise of stock options	-	-	-	-	-	(129)	(1,050)	-	(1,050)
<b>Balance - December 31, 2003</b>	<b>42,659</b>	<b>\$ 43</b>	<b>\$ 122,409</b>	<b>\$ (2)</b>	<b>\$ (96,858)</b>	<b>(167)</b>	<b>\$ (1,289)</b>	<b>-</b>	<b>\$ 24,303</b>
Comprehensive loss:									
Net loss	-	-	-	-	(46,203)	-	-	-	(46,203)
Other comprehensive loss - unrealized losses on investments	-	-	-	-	-	-	-	(3)	(3)
Total comprehensive loss	-	-	-	-	-	-	-	-	(46,206)
Issuance of common stock, stock option exercises	1,271	1	2,500	-	-	-	-	-	2,501
Issuance of common stock, warrant exercises	1,193	1	1,819	-	-	-	-	-	1,820
Issuance of common stock, 401(k) employer match	23	-	196	-	-	-	-	-	196
Expense related to stock options	-	-	1,723	(459)	-	-	-	-	1,264
Issuance of common stock, April financing	2,200	2	22,730	-	-	-	-	-	22,732
Issuance of warrants, October Quintiles restructuring	-	-	3,978	-	-	-	-	-	3,978
Issuance of common stock, December Esteve restructuring	500	1	3,465	-	-	-	-	-	3,466
Issuance of common stock, December draw on CEFF	902	1	7,090	-	-	-	-	-	7,091
Change in value of Class H warrants	-	-	(48)	-	-	-	-	-	(48)
Shares tendered for exercise of stock options	-	-	1,765	-	-	(146)	(1,765)	-	-
<b>Balance - December 31, 2004</b>	<b>48,748</b>	<b>\$ 49</b>	<b>\$ 167,627</b>	<b>\$ (461)</b>	<b>\$ (143,061)</b>	<b>(313)</b>	<b>\$ (3,054)</b>	<b>\$ (3)</b>	<b>\$ 21,097</b>
Comprehensive loss:									
Net loss	-	-	-	-	(58,904)	-	-	-	(58,904)
Other comprehensive loss - unrealized losses on investments	-	-	-	-	-	-	-	1	1
Total comprehensive loss	-	-	-	-	-	-	-	-	(58,903)
Issuance of common stock, stock option exercises	226	-	649	-	-	-	-	-	649
Issuance of common stock, warrant exercises	43	-	250	-	-	-	-	-	250
Issuance of common stock, restricted stock awards	30	-	15	-	-	-	-	-	15
Issuance of common stock, 401(k) employer match	37	-	235	-	-	-	-	-	235
Expense related to stock options	-	-	151	231	-	-	-	-	382
Issuance of common stock, February 2005 financing	5,060	5	27,559	-	-	-	-	-	27,564
Issuance of common stock, December 2005 financing	3,030	3	18,912	-	-	-	-	-	18,915
Issuance of common stock, October 2005 Esteve financing	650	1	4,433	-	-	-	-	-	4,434
Issuance of common stock, 2005 CEFF financings	3,511	3	20,197	-	-	-	-	-	20,200
<b>Balance - December 31, 2005</b>	<b>61,335</b>	<b>\$ 61</b>	<b>\$ 240,028</b>	<b>\$ (230)</b>	<b>\$ (201,965)</b>	<b>(313)</b>	<b>\$ (3,054)</b>	<b>\$ (2)</b>	<b>\$ 34,838</b>

See notes to consolidated financial statements

**Consolidated Statements of Cash Flows**  
*(In thousands)*

Year Ended December 31,

	2005	2004	2003
<b>Cash flow from operating activities:</b>			
Net loss	\$ (58,904)	\$ (46,203)	\$ (24,280)
Adjustments to reconcile net loss to net cash used In operating activities:			
Depreciation and amortization	788	816	416
Realized (gains) losses on marketable securities	—	—	(114)
Non-cash charge for issuance of common stock and warrants related to corporate partnership restructurings	—	7,443	—
Non-cash stock compensation expense	382	1,264	192
Stock issued for 401(k) match	235	196	86
Loss on disposal of fixed assets	16	12	—
Changes in:			
Prepaid expenses and other current assets	128	(68)	(340)
Accounts payable and accrued expenses	(429)	3,759	1,197
Other assets	11	(23)	103
Other liabilities	105	(538)	(721)
Net cash used in operating activities	<u>(57,668)</u>	<u>(33,342)</u>	<u>(23,461)</u>
<b>Cash flow from investing activities:</b>			
Purchase of property and equipment	(1,063)	(2,207)	(1,514)
Restricted cash	(1)	(646)	—
Related party loan payments received	3	2	2
Purchase of marketable securities	(33,340)	(18,483)	(284)
Proceeds from sale or maturity of marketable securities	32,834	15,465	10,873
Net cash (used in) / provided by investing activities	<u>(1,567)</u>	<u>(5,869)</u>	<u>9,077</u>
<b>Cash flow from financing activities:</b>			
Proceeds from issuance of securities, net of expenses	72,027	35,911	34,721
Proceeds from use of credit facility	2,571	3,493	986
Proceeds from note payable for manufacturing purchase	2,400	—	—
Equipment financed through capital lease	916	1,928	908
Principal payments under capital lease obligation	(933)	(514)	(259)
Purchase of treasury stock	—	(1,765)	(1,050)
Net cash provided by financing activities	<u>76,981</u>	<u>39,053</u>	<u>35,306</u>
Net increase / (decrease) in cash and cash equivalents	17,746	(158)	20,922
Cash and cash equivalents - beginning of year	29,264	29,422	8,500
Cash and cash equivalents - end of year	<u>\$ 47,010</u>	<u>\$ 29,264</u>	<u>\$ 29,422</u>
<b>Supplementary disclosure of cash flows information:</b>			
Interest Paid	\$ 860	\$ 186	\$ 167
<b>Noncash transactions:</b>			
Class H warrants issued/revalued	—	\$ (48)	\$ 50
Unrealized gain / (loss) on marketable securities	(1)	(3)	(177)

See notes to consolidated financial statements

**Note 1 - The Company**

Discovery Laboratories, Inc. (the "Company") is a biotechnology company developing its proprietary surfactant technology as 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 this technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the NICU, critical care unit and other hospital settings, where there are few or no approved therapies available.

The Company's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. The Company's lead product, Surfaxin<sup>®</sup> (lucinactant), for the prevention of RDS in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. The FDA has established April 2006 as its target to complete its review of the Surfaxin NDA. Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease, in premature infants. The Company is preparing to conduct multiple Phase 2 pilot studies with Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

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

With the goal of becoming a fully integrated biotechnology company, the Company's are implementing a long-term business strategy which includes: (i) continued investment in manufacturing capabilities (including at the manufacturing operations in New Jersey acquired by the Company in December 2005) for the production of precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets; (ii) building a specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU; (iii) investing in development of aerosol SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology, rights to which we acquired in December 2005 and are currently developing through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); and (iv) securing additional corporate partnerships for the development and potential commercialization of SRT, including Surfaxin, in Europe and the rest of the world.

**Management's Plans and Financings**

The Company has incurred substantial losses since inception and expects to continue to expend substantial amounts for continued product research, development, manufacturing and commercialization activities. The Company funds its operations primarily through the issuance of equity securities and the use of credit and capital lease facilities. Management plans to fund its research, development, manufacturing and commercialization activities with the issuance of additional equity, debt and entering into strategic alliances, if possible, that will provide funding for operations, including the U.S. commercial launch anticipated late in the second quarter of 2006 of our lead product, Surfaxin. The future 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.

**Business Segments**

The Company currently operates in one business segment, which is the research and development of products focused on Surfactant Replacement Therapies (SRTs) for respiratory diseases. The Company is managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its product candidates. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131, "Disclosure about Segments of an Enterprise and Related Information".

**Note 2 - Summary of Significant Accounting Policies**

**Accounting Principles**

The financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States.

**Consolidation**

The financial statements include all of the accounts of Discovery Laboratories, Inc. and its inactive subsidiary, Acute Therapeutics, Inc.

**Cash, cash equivalents and investments**

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

The investments are classified as available-for-sale and are comprised of shares of high-quality, corporate bonds. 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.

Investments are made pursuant to the Investment Policy approved by the Board of Directors. The policy provides for the purchase of high-quality investments, while ensuring preservation of capital and fulfillment of liquidity needs.

**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. Expenditures for repairs and maintenance are charged to expense as incurred.

**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 "Accounting for the Impairment or Disposal of Long-Lived Assets", 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, 2005, 2004 and 2003, 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 has 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 9 - Corporate Partnership Agreements for a detailed description of the Company's revenue recognition methodology under these agreements.

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

**Stock-based compensation**

The Financial Accounting Standards Board (FASB) 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, 2005, 2004, and 2003 would have been as follows:

(in thousands, except per share data)

	Years Ended December 31,		
	2005	2004	2003
Net Loss as reported	\$ (58,904)	\$ (46,203)	\$ (24,280)
Additional stock-based employee compensation	\$ (14,340)	\$ (3,996)	\$ (3,738)
Pro forma net loss	\$ (73,244)	\$ (50,199)	\$ (28,018)
Pro forma net loss per share	\$ (1.35)	\$ (1.09)	\$ (0.75)

The net loss as reported on the statement of operations for the year ended December 31, 2005 includes compensation costs for stock-based compensation awards of \$397,000. These costs include non-cash charges of \$36,000 for the modification of options held by former members 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 subject to the requisite approval of the Company's shareholders for an increase in the number of shares of Common Stock issuable under the 1998 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 \$231,000 in 2005 and \$461,000 in 2004 related to the vesting of such options.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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,		
	2005	2004	2003
Expected dividend yield	0%	0%	0%
Expected stock price volatility	77%	81%	86%
Risk-free interest rate	4.1%	3.5%	2.4%
Expected option term	3.5 years	3.5 years	3.5 years

In December 2004, the FASB issued Financial Accounting Standards Board Statement No. 123 (revised 2004), "Share-Based Payment" (SFAS 123(R)), which requires stock-based employee compensation to be measured based on the grant-date fair value of the award and the cost to be recognized over the period during which an employee is required to provide service in exchange for the award. SFAS 123(R) eliminates the alternative use of APB No. 25's intrinsic value method of accounting for stock options granted to employees.

The Company adopted the provisions of SFAS No. 123R on January 1, 2006 using the "modified prospective" transition method and the Black-Scholes valuation model to value the stock options. As a result of the provisions of SFAS 123R, the Company expects to incur compensation charges in the range of \$4.0 million to \$6.0 million for the year ending December 31, 2006. However, the estimated compensation charges can be affected by a number of variables, including the Company's stock price and the timing of 2006 employee stock option grants. The Company will recognize compensation cost for stock-based awards issued after December 31, 2005, on a straight-line basis over the requisite service period of the award.

*Board of Directors approved acceleration of the vesting of certain stock options*

On December 27, 2005, pursuant to and in accordance with the recommendation of the Compensation Committee of the Board of Directors of the Company, the Board of Directors approved acceleration of vesting of certain unvested and "out-of-the-money" stock options granted under the 1998 Plan that are held by employees and officers of the Company and that have an exercise price of \$9.02 or greater. Options to purchase approximately 1,050,706 shares of the Company's common stock were accelerated, including options to purchase approximately 948,749 shares of common stock held by employees at or above the level of Vice President.

The Board of Directors decided to accelerate the vesting of these "out-of-the-money" options primarily to minimize certain future compensation expense that the Company would otherwise be required to recognize in its consolidated statements of operations with respect to these options pursuant to SFAS 123(R) which became effective for the Company January 1, 2006. The Company estimates that the aggregate future compensation expense that will be eliminated as a result of the acceleration of the vesting of these options is approximately \$7.2 million, calculated in accordance with SFAS 123(R) (of which approximately \$6.6 million is attributable to options held by employees at or above the level of Vice President).



In connection with the accelerated vesting, holders of accelerated options to purchase an aggregate of 1,018,831 shares of common stock or 97% of the total options subject to vesting acceleration, including each affected employee at or above the level of Director, entered into "lock-up" agreements with the Company to refrain from selling shares acquired upon the exercise of such accelerated options (other than shares needed to cover the exercise price and satisfy withholding taxes) until the date on which the exercise would have been permitted under the option's pre-acceleration vesting terms or, in certain circumstances, the employee's last day of employment or upon a "change in control" (as such term may be defined in any applicable agreement between the individual and the Company), if such last date of employment or "change in control" is earlier.

#### 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, 2005, 2004 and 2003, 10,904,000, 9,684,000 and 8,753,000 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, 2005 and December 31, 2004 consisted of high-quality, corporate bonds with a maturity of greater than three months. All available-for-sale marketable securities have a maturity period of less than one year.

As of December 31, 2005 and 2004, the available-for-sale marketable securities consisted of the following:

<i>(in thousands)</i>	Years Ended December 31,	
	2005	2004
Cost of investment	\$ 3,190	\$ 2,738
Interest earned	66	87
Amortized premium	(3)	(78)
Unrealized loss	(2)	(3)
Fair market value	<u>\$ 3,251</u>	<u>\$ 2,744</u>

#### Note 4 - Restricted Cash

The Company has cash balances that are restricted as to use and discloses such amounts separately on the balance sheets. 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 sheets 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 from Related Party

The 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, 2005 and 2004 was approximately \$190,000 and \$193,000, respectively.

**Note 6 - Property and Equipment**

Property and equipment as of December 31, 2005 and 2004 was comprised of the following:

(in thousands)	December 31,	
	2005	2004
Equipment <sup>(1)</sup>	\$ 4,269	\$ 3,589
Furniture	1,052	869
Leasehold improvements	330	330
Construction-in-progress	1,050	891
Subtotal	6,701	5,679
Accumulated depreciation	(2,379)	(1,616)
Net property and equipment	<u>\$ 4,322</u>	<u>\$ 4,063</u>

<sup>(1)</sup> 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, 2005 and 2004 includes \$3,755,000 and \$3,396,000, respectively, of property and equipment subject to a capital lease. The capitalized leases are secured by the respective assets. The associated accumulated depreciation was \$862,000 and \$546,000 as of December 31, 2005 and 2004, respectively.

The balance of Construction-in-Progress at both December 31, 2005 and December 31, 2004 primarily consists of manufacturing equipment projects for the Company's current manufacturing operations.

In addition to the balance in Construction in Progress, the Company had additional construction purchase commitments, yet to be fulfilled, totaling \$65,000 as of December 31, 2005. As of December 31, 2004, the Company had \$203,000 of construction purchase commitments, yet to be fulfilled, which were subsequently fulfilled in 2005.

Depreciation expense for the years ended December 31, 2005, 2004, and 2003 was \$788,000, \$546,000, and \$331,000, respectively.

**Note 7 - Purchase of Manufacturing Operations - Classified as In-process Research and Development**

In December 2005, the Company purchased the manufacturing operations of Laureate Pharma, Inc. (Laureate) in Totowa, NJ (the Company's then contract manufacturer) for \$16.0 million and incurred additional related expenses of \$0.8 million. The pharmaceutical manufacturing and development facility will be used for the production of Surfaxin, SRT formulations and aerosol development capabilities. The Company believes this acquisition was a logical way to implement a long-term manufacturing strategy for the continued development of the Company's SRT portfolio, specifically life cycle management of Surfaxin for new indications, potential formulation enhancements, and expansion of the Company's aerosol SRT products beginning with Aerosurf™.

The manufacturing facility in Totowa, NJ is located in approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the production of sterile pharmaceuticals in compliance with current Good Manufacturing Practice (cGMP) requirements. There are approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the operations. Discovery and Laureate had previously entered into a contract manufacturing arrangement in October 2003, whereby Discovery's Surfaxin manufacturing know-how and dedicated equipment was transferred to this facility. Transfer of the Surfaxin manufacturing process was completed in 2004 and, since that time, the facility has been predominantly dedicated to Surfaxin and the support of regulatory compliance requirements for Discovery's manufacturing operations. In January 2005, as part of the review of the Surfaxin NDA, the FDA issued a Form 483 to Laureate, citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with cGMPs. To address the inspectional observations, Discovery and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin.

In consideration for the \$16.0 million paid to Laureate, the Company received the following:

- An assignment of the existing lease of the Totowa facility, with a lease term expiring in December 2014. The lease is subject to customary terms and conditions and contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to Discovery.
- Equipment and leasehold improvements related to the Totowa facility.
- The right to employ the majority of the approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and that were employed by Laureate at the operations.

In connection with this transaction, we incurred a non-recurring charge, classified as in-process research & development in accordance with FAS 2 "Accounting for Research & Development Costs", of \$16.8 million associated with the purchase of the manufacturing operations at the Totowa, NJ facility.

Also, in connection with the acquisition, the Company borrowed \$2.4 million pursuant to its capital lease financing arrangement with General Electric Capital Corporation (GECC) to partially finance the purchase of the manufacturing operations. See Note 8 - Debt Facilities.

#### **Note 8 - Debt Facilities**

##### **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 Meconium Aspiration Syndrome (MAS) in full-term infants. In connection with the commercialization agreement, Quintiles extended to the Company a secured, revolving credit facility of \$8.5 to \$10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. 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 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 the greater of 8% or prime rate plus 2% 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 was no longer obligated to use funds advanced under the credit facility for services provided by Quintiles, and Quintiles was 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 is the prime rate plus 2% annually and payments are due quarterly in arrears. As of December 31, 2005, \$8.5 million was outstanding under the credit facility and is classified as a current liability. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006.

## Capital Lease and Note Payable Financing Arrangements

Capital lease liabilities and note payable as of December 31, 2005 and 2004 are as follows:

<i>(in thousands)</i>	<u>2005</u>	<u>2004</u>
Current		
Capital leases, GECC	\$ 982	\$ 828
Note payable, GECC	560	—
All other	26	26
Capital leases and note payable, current	<u>1,568</u>	<u>854</u>
Long Term		
Capital leases, GECC	1,480	1,626
Note payable, GECC	1,840	—
All other	3	28
Capital leases and note payable, long term	<u>3,323</u>	<u>1,654</u>
Total capital leases and note payable	<u>\$ 4,891</u>	<u>\$ 2,508</u>

The Company's primary capital lease financing arrangement is 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 capital lease is secured by the related assets. This arrangement provides for financing of up to \$9.0 million, of which \$0.5 million is contingent upon FDA approval of Surfaxin for the prevention of RDS in premature infants. Subject to certain conditions, the funds are available through April 2006. Laboratory and manufacturing equipment is financed over 48 months and all other equipment is financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. For portions of the capital lease financing arrangement accessed in 2005, the interest rates ranged from 9.9% to 10.5%.

As of December 31, 2005, the Company had used \$6.4 million of the available financing under the arrangement and had \$2.6 million remaining available for future use, subject to certain conditions.

Amounts available, used and remaining available for future use as of December 31, 2005 and 2004 are as follows:

<i>(in thousands)</i>	<u>2005</u>	<u>2004</u>
Financing available		
Currently available	\$ 8,500	\$ 7,500
Availability subject to FDA approval	500	1,500
Total	<u>9,000</u>	<u>9,000</u>
Amount used (cumulative)	<u>(6,358)</u>	<u>(3,042)</u>
Amount available for future use	<u>\$ 2,642</u>	<u>\$ 5,958</u>

Included in the amounts above, in December 2005, the Company borrowed \$2.4 million pursuant to its capital lease financing arrangement associated with the purchase of the manufacturing operations of Laureate in Totowa, NJ. In accordance with the accounting treatment for the manufacturing purchase, the \$2.4 million was classified as a note payable on the balance sheet (of which \$0.6 million is current and \$1.8 million is long-term). The note has an interest rate of 10.3% and is repayable over a 48-month period. The note payable is secured by equipment at the manufacturing facility in Totowa, NJ.

**DISCOVERY LABORATORIES, INC. AND SUBSIDIARY**

Payments due under contractual debt obligations at December 31, 2005, including principal and interest, are as follows:

<i>(in thousands)</i>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>Total</u>
Credit facility with Quintiles	\$ 9,300	\$ —	\$ —	\$ —	\$ 9,300
Capital lease obligations - GECC & others	1,214	1,080	487	49	2,830
Note Payable - GECC	763	833	833	438	2,867
Total	<u>\$ 11,277</u>	<u>\$ 1,913</u>	<u>\$ 1,320</u>	<u>\$ 487</u>	<u>\$ 14,997</u>

**Note 9 - Corporate Partnership Agreements****Chrysalis Technologies, Division of Philip Morris USA Inc. (Chrysalis)**

In December 2005, the Company entered into a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc., to develop and commercialize aerosolized SRT to potentially address a broad range of serious respiratory conditions, such as acute lung injury, neonatal respiratory failure, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others. The intent of the alliance is to unite two potentially highly complementary respiratory technologies - the Company's precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung.

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

The Company's lead program for aerosolized SRT is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for respiratory failure. The Company also plans to develop aerosolized SRT to treat ALI in the hospital.

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

In 1999, we entered into a corporate partnership with Laboratorios del Dr. Esteve, S.A. (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 prevention of RDS in premature infants, the treatment of MAS in full-term infants and the treatment of 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 common stock at \$4.867 per share for \$4.0 million in gross proceeds and paid 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.

## DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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 regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of 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 potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and other SRT that is increased from that provided for in the 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 its 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 October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceutici Spa (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution in Italy of Surfaxin.

License fees and reimbursement of research and development expenditures associated with the Esteve collaboration were recorded as deferred revenue and recognized as revenue when the amounts were earned, which occurs over a number of years as the Company performs research and development activities. For the years ended December 31, 2005, 2004 and 2003, the company recorded revenue related to the Esteve collaboration of \$0.1 million, \$1.2 million and \$0.7 million, respectively.

### **Restructuring of Corporate Partnerships**

#### *2004 Restructuring of Esteve Partnership*

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 statement of operations. 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 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.

#### *2004 Restructuring / Termination of Quintiles Collaboration*

In 2001, we entered into a commercialization agreement with Quintiles Transnational Corp. (Quintiles), and its strategic investment group affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the prevention of RDS in premature infants and the treatment of Meconium Aspiration Syndrome (MAS) in full-term infants.

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 prevention of RDS in premature infants and the treatment of MAS to Quintiles has been terminated.

In connection with our arrangement to regain full commercialization rights for Surfaxin, we issued a warrant to PharmaBio to purchase 850,000 shares of our common stock at an exercise price equal to \$7.19 per share. The warrant has 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. The warrant was valued at its fair value on the date of issuance and we incurred a non-cash charge equal to \$4.0 million in connection with the issuance. The existing secured revolving credit facility of \$8.5 million with PharmaBio remains available with the original maturity date of December 10, 2004 being extended until December 31, 2006.

#### **Note 10 - 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 worldwide license of the proprietary SRT technology, including Surfaxin, 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 had been 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. The Company has exercised its license option with respect to certain inventions developed under the agreement. We had the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed under the agreement and for which we did not exercise our option to acquire an exclusive license. Payments to Scripps under this agreement were \$400,000, \$600,000 and \$649,000 in 2005, 2004, and 2003, respectively.

#### **Note 11 - Stockholders' Equity**

##### **Registered Public Offerings and Private Placements**

In December 2005, the Company completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors. The shares were priced at \$6.60 per share resulting in gross and net proceeds to the Company equal to \$20.0 million and \$18.9 million, respectively. This offering was made pursuant to the Company's October 2005 universal shelf registration statement.

In November 2005, the Company sold 650,000 shares of our common stock to Esteve, at a price per share of \$6.88, for aggregate proceeds of approximately \$4.5 million. This offering was made pursuant to the Company's December 2003 shelf registration statement.

In February 2005, the Company completed a registered direct public 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 \$27.4 million, respectively. This offering was made pursuant to the Company's December 2003 shelf registration statement.

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. This offering was made pursuant to the Company's December 2003 shelf registration statement.

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, 2005, 909,381 of the Class A Investor Warrants remain unexercised.

#### **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. 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 of approximately \$4.5 million, if exercised. As of December 31, 2005, the Class B Investor Warrant had not been exercised in whole or in part.

In November 2005, the Company entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to the Company of \$3.2 million from the issuance of 498,552 shares of common stock at an average price of \$6.42, after taking into account the applicable discount rate provided for by the CEFF.

In September 2005, the Company entered into a financing pursuant to the CEFF resulting in aggregate cash proceeds to the Company of \$17.0 million from the issuance of 3,012,055 shares of common stock at an average price of \$5.64, after taking into account the applicable discount rate provided for by the CEFF.

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.

Subject to the conditions of the CEFF, there is currently \$47.6 million that remains available under the CEFF.

#### **Shares Issued Pursuant to the Restructuring of Corporate Partnerships**

##### *2004 Restructuring of Esteve Partnership*

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. See Note 9 - 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 in 2004, representing the fair market value of the shares on the date of issuance.

##### *2004 Restructuring / Termination of Quintiles Collaboration*

In November 2004, the Company agreed with Quintiles to restructure its business arrangements and terminate the commercialization agreements for Surfaxin in the United States. See Note 9 - 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 \$6.0 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.

#### **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.

In June and July 2003, the Company common stock attained certain price performance thresholds on the Nasdaq SmallCap Market that permitted the Company to redeem (and thereby effectively compel the exercise thereof) three of the Company's 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 the Company in connection with certain private placement financings that occurred in November 2002, October 2001, and April 1999, respectively. These warrants were exercised in June and July 2003, 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 the Company's receipt of aggregate cash proceeds of \$6.1 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.

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		Exercise Price	Expiration Date
	December 31, 2005	2004		
Quintiles Warrant (2004 business restructuring)	850,000	850,000	\$ 7.19	11/3/2014
Class B Investor Warrants (2004 Kingsbridge CEFF)	375,000	375,000	\$ 12.07	1/6/2010
Class A Investor Warrants (2003)	909,381	945,745	\$ 6.88	2/19/2010
Class E Investor Warrants (2000)	—	310,567	\$ 7.38	3/21/2005
Placement Agent (2000)	185,822	214,794	\$ 7.47(1)	9/21/2007
Placement Agent Warrants (1996)	4,615	4,615	\$ 0.54(1)	11/15/2006
Placement Agent Warrants (1996)	138,953	138,953	\$ 2.27(1)	11/15/2006
<b>Total</b>	<b>2,463,771</b>	<b>2,839,674</b>		

(1) Original warrant price adjusted for dilution provision

##### *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 12 - Stock Options. The Company had shares reserved for potential future issuance under the Stock Incentive Plan of 10,074,746 and 7,330,888 as of December 31, 2005 and 2004, respectively, for stock options available and outstanding for future grants. As of December 31, 2005 and 2004, 8,439,771 and 6,844,654 stock options were granted and outstanding, respectively. As of December 31, 2005 and 2004, there were 1,634,975 and 486,234 stock options available for future grants, respectively.

***Potential issuance of common shares under the October 2005 Universal Shelf Registration Statement***

In October 2005, the Company filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering, from time to time, of up to \$100.0 million of our debt or equity securities. In December 2005, the Company completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to the Company of \$20.0 million.

There is currently \$80.0 million remaining on the October 2005 universal shelf registration statement.

***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 Note 11 - "Stockholders' Equity". 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. The Company has entered into three financings pursuant to the CEFF as follows: (i) December 2004 - proceeds of \$7.2 million from the issuance of 901,742 shares; (ii) September 2005 - proceeds of \$17.0 million from the issuance of 3,012,055 shares; and (iii) November 2005 - proceeds of \$3.2 million from the issuance of 498,552 shares. After giving effect to the shares issued in each CEFF financing, the Company had 10,587,651 shares of common stock reserved for issuance under of the CEFF as of December 31, 2005.

***Common shares reserved for future issuance under the December 2003 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, the Company had 4,300,000 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.

In November 2005, Esteve agreed to purchase 650,000 shares of the Company's common stock resulting in gross proceeds of \$4.5 million. Subsequent to this transaction, the remaining 58,592 shares reserved under the shelf registration statement, as amended, were de-registered.

As of December 31, 2005, the Company had no shares reserved for potential future issuance under this 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 common stock. The Company match resulted in the issuance of 36,750 and 22,564 shares of common stock for the years ended December 31, 2005 and 2004, respectively. The Company had shares reserved for potential future issuance under the Company's 401(k) Plan of 69,353 and 106,103 for the years ended December 31, 2005 and 2004, 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, 2005, 2004 and 2003, 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. For the year ended December 31, 2005, there were no such shares tendered to the Company.

The following chart details shares tendered to the Company in lieu of cash for the exercise of stock options in 2004:

	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
<b>Total</b>	<b>146,204</b>	<b>\$ 12.07</b>

**Note 12 - 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. In 2005, the Company issued 30,263 restricted stock awards to certain employees for no cash consideration. The Company did not issue any such shares for the years ended December 31, 2004 and 2003.

**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 12,570,000 shares of common stock under the 1998 Stock Incentive Plan, of which 10,075,000 remain reserved for issuance over the term of the plan. The 1998 Plan was amended at each of the Annual Meetings of Shareholders for the years 2005, 2004 and 2003 to increase the maximum number of shares of common stock reserved for issuance over the term of the plan by 3,000,000 shares, 3,000,000 shares, and 1,420,000 shares, respectively.

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, 2003	\$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	0.0026 - 10.60	6,844,654	5.69	7.76 years
Options granted	5.15 - 9.02	2,079,000	7.97	
Options exercised	1.46 - 7.22	(225,879)	2.87	
Options forfeited	1.50 - 10.60	(258,004)	7.19	
Balance at December 31, 2005	\$0.0026 - \$10.60	<u>8,439,771</u>	\$6.28	7.31 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, 2005:

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	663,956	\$1.56	5.88 years	663,956	\$1.56
\$2.01 - \$4.00	1,536,846	\$2.63	5.99 years	1,536,846	\$2.63
\$4.01 - \$6.00	1,088,021	\$4.75	4.44 years	1,029,771	\$4.70
\$6.01 - \$8.00	1,642,906	\$6.74	8.95 years	624,147	\$6.76
\$8.01 - \$10.00	3,258,042	\$8.94	8.28 years	3,217,292	\$8.94
\$10.01 - \$10.60	250,000	\$10.12	8.38 years	250,000	\$10.12
	<u>8,439,771</u>			<u>7,322,012</u>	

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, 2005:

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	663,956	\$1.56	663,956	\$1.56
\$2.01 - \$4.00	1,536,846	\$2.63	751,432	\$2.50
\$4.01 - \$6.00	1,029,771	\$4.70	1,029,438	\$4.70
\$6.01 - \$8.00	624,147	\$6.76	620,482	\$6.76
\$8.01 - \$10.00	3,217,292	\$8.94	3,217,292	\$8.94
\$10.01 - \$10.60	250,000	\$10.12	250,000	\$10.12
	<u>7,322,012</u>		<u>6,532,600</u>	

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. Approval was obtained at the Company's Annual Meeting of Shareholders for 2005, at which time the fair market value of our common stock was \$6.28, which was less than the fair market value on the date the options were granted and no additional compensation expense was required to be recognized as a result.

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 \$231,000 and \$461,000 related to the vesting of such options in 2005 and 2004, respectively.

*Board of Directors approved acceleration of the vesting of certain stock options*

On December 27, 2005, pursuant to and in accordance with the recommendation of the Compensation Committee of the Board of Directors of the Company, the Board of Directors approved full acceleration of vesting of certain unvested stock options granted under the Company's Amended and Restated 1998 Stock Incentive Plan that are held by employees and officers of the Company and that have an exercise price of \$9.02 or greater. Options to purchase approximately 1,050,706 shares of the Company's common stock were accelerated, including options to purchase approximately 948,749 shares of common stock held by employees at or above the level of Vice President.

The Board of Directors decided to accelerate the vesting of these "out-of-the-money" options primarily to minimize certain future compensation expense that the Company would otherwise be required to recognize in its consolidated statements of operations with respect to these options pursuant to Financial Accounting Standards Board Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") which became effective for the Company January 1, 2006. The Company estimates that the aggregate future compensation expense that will be eliminated as a result of the acceleration of the vesting of these options is approximately \$7.2 million, calculated in accordance with SFAS 123(R) (of which approximately \$6.6 million is attributable to options held by employees at or above the level of Vice President).

In connection with the accelerated vesting, holders of accelerated options to purchase an aggregate of 1,018,831 shares of common stock or 97% of the total options subject to vesting acceleration, including each affected employee at or above the level of Director, entered into written "lock-up" agreements with the Company to refrain from selling shares acquired upon the exercise of such accelerated options (other than shares needed to cover the exercise price and satisfy withholding taxes) until the date on which the exercise would have been permitted under the option's pre-acceleration vesting terms or, in certain circumstances, the employee's last day of employment or upon a "change in control" (as such term may be defined in any applicable agreement between the individual and the Company), if such last date of employment or "change in control" is earlier.

*Options granted at less than fair market value*

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:

	2005	December 31, 2004	2003
Shares outstanding	200,000	200,000	240,000
Weighted average exercise price	\$ 2.11	\$ 2.11	\$ 2.09
Weighted average fair value	\$ 3.52	\$ 3.52	\$ 3.49

**Note 13 - 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, 2005 was \$255,000, resulting in the issuance of 40,426 shares. The total match for the year ending December 31, 2004 was \$215,000, resulting in the issuance of 25,683 shares.

**Note 14 - Commitments**

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

Payments due under contractual obligations at December 31, 2005 are as follows:

<i>(in thousands)</i>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>Thereafter</u>	<u>Total</u>
Operating lease obligations	\$ 1,422	\$ 1,452	\$ 1,310	\$ 1,146	\$ 277	\$ 600	\$ 6,207
Purchase obligations	2,613	233	—	—	—	—	2,846
Employment agreements	2,117	—	—	—	—	—	2,117
Total	<u>\$ 6,152</u>	<u>\$ 1,685</u>	<u>\$ 1,310</u>	<u>\$ 1,146</u>	<u>\$ 277</u>	<u>\$ 600</u>	<u>\$ 11,170</u>

The Company's operating leases consist primarily of facility leases for the Company's operations in Pennsylvania, New Jersey 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 business administration. The lease expires in February 2010 with total aggregate payments of \$4.6 million.

The Company leases a 21,000 square foot pharmaceutical manufacturing and development facility in Totowa, NJ that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements. The lease expires in December 2014 with total aggregate payments of \$1.4 million (\$150,000 per year). The lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to the Company.

The Company also leases approximately 11,000 square feet of office and laboratory space in Doylestown, PA. The Company maintains the Doylestown facility for the continuation of analytical laboratory activities under a lease that expires in August 2006, subject to monthly extensions.

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, California. 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.

Rent expense under all of these leases for the years ended December 31, 2005, 2004, and 2003 were \$1,367,000, \$752,000 and \$572,000, 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 U.S. commercial launch of Surfaxin late in the second quarter of 2006.

At December 31, 2005, the Company had employment agreements with seven officers providing for an aggregate annual salary equal to \$2,117,000. The agreements expire in December 2006, 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 at the discretion of and 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, benefits continuation and beneficial modifications to the terms of previously granted equity securities.

**DISCOVERY LABORATORIES, INC. AND SUBSIDIARY**

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 15 - Related Party Transactions****Laboratorios del Dr. Esteve, S.A. (Esteve)**

Dr. Antonio Esteve serves as a member of the Company's Board of Directors and is an executive officer of Esteve. The Company has a strategic corporate partnership with Esteve. See Note 9 - Corporate Partnership Agreements.

In November 2005, the Company sold 650,000 shares of our common stock to Esteve, at a price per share of \$6.88, for aggregate proceeds of approximately \$4.5 million. The shares were issued pursuant to a registration statement on Form S-3MEF filed with the SEC on February 17, 2005.

**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, 2005, 2004 and 2003 are as follows:

(in thousands)

	2005	December 31, 2004	2003
Income tax benefit, statutory rates	\$ 20,027	\$ 15,739	\$ 8,255
State taxes on income, net of federal benefit	3,721	2,776	2,015
Research and development tax credit	840	623	441
Other	(47)	(87)	92
Income tax benefit	24,541	19,051	10,803
Valuation allowance	(24,541)	(19,051)	(10,803)
Income tax benefit	\$ —	\$ —	\$ —



DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2005 and 2004, are as follows:

(in thousands)

	December 31,	
	2005	2004
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	\$ 72,725	\$ 55,825
Research and development tax credits	3,818	2,832
Compensation Expense on Stock	680	524
Charitable Contribution Carryforward	16	5
Other Accrued	452	161
Deferred Revenue	—	55
Depreciation	3,025	
Capitalized research and development	3,025	38
<b>Total long-term deferred tax assets</b>	<b>83,741</b>	<b>59,440</b>
Long-term deferred tax liabilities:		
Property and equipment	—	(651)
<b>Net deferred tax assets</b>	<b>83,741</b>	<b>58,789</b>
Less: valuation allowance	(83,741)	(58,789)
	<b>\$ —</b>	<b>\$ —</b>

The Company is in a net deferred tax asset position at December 31, 2005 and 2004 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, 2005 and 2004, the Company had available carryforward net operating losses for Federal tax purposes of \$187.0 million and \$140.7 million, respectively, and a research and development tax credit carryforward of \$3.8 million and \$2.8 million, respectively. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2009 and continuing through 2024. At December 31, 2005, the Company had available carryforward federal and state net operating losses of \$1.8 million and \$22,000, respectively, related to stock based compensation. Additionally, at December 31, 2005 and 2004, the Company had available carryforward losses of approximately \$167.5 million and \$121.9 million, 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, \$5.2 million and \$0.4 million, 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 - Selected Quarterly Financial Data (unaudited)**

The following table contains unaudited statement of operations information for each quarter of 2005 and 2004. The operating results for any quarter are not necessarily indicative of results for any future period.

**2005 Quarters Ended:***(in thousands, except per share data)*

	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	\$ 61	\$ 24	\$ 20	\$ 29	\$ 134
Expenses:					
Research and development	5,120	5,864	5,676	7,477	24,137
General and administrative	4,270	4,095	4,817	5,323	18,505
In-process research & development	—	—	—	16,787	16,787
Corporate partnership restructuring charge	—	—	—	—	—
Total expenses	9,390	9,959	10,493	29,587	59,429
Operating loss	(9,329)	(9,935)	(10,473)	(29,558)	(59,295)
Other expense, net	13	109	67	202	391
Net loss	\$ (9,316)	\$ (9,826)	\$ (10,406)	\$ (29,356)	\$ (58,904)
Net loss per common share - basic and diluted	\$ (0.18)	\$ (0.18)	\$ (0.19)	\$ (0.51)	\$ (1.09)
Weighted average number of common shares outstanding	50,784	53,587	54,476	57,843	54,094

**2004 Quarters Ended:***(in thousands, except per share data)*

	Mar. 31	June 30 <sup>(1)</sup>	Sept. 30	Dec. 31	Total Year
Revenues	\$ 142	\$ 697	\$ 236	\$ 134	\$ 1,209
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
In-process research & development	—	—	—	—	—
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

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

## EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of this 24<sup>th</sup> day of January 2006, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and KATHRYN COLE (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, 2006; provided, however, that commencing on January 1, 2007, 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, Human Resources. 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 Warrington, Pennsylvania; provided, that the Executive acknowledges and agrees that the performance by the Executive of her duties shall, from time-to-time, require travel including, without limitation, overseas travel.

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

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5. Devotion of Time to Company's Business.

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

(b) No Other Employment. During her 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 Sections 8(a) and (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 5(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 5(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 \$180,000, 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 6. 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 sign-on bonus of \$25,000, payable in accordance with and on the date of the Company's regular payroll practices on such date first following the date of commencement of this Agreement. 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 (i) with respect to that period of time beginning with the date of commencement of this Agreement through the date of initiation of Executive's eligibility for participation in Company-sponsored health-related programs, the Company shall bear the costs of Executive's COBRA benefits offered by her predecessor employer; and (ii) 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 her duties and responsibilities under this Agreement and the Company shall reimburse her 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 50,000 shares of Common Stock at an exercise price equal to the fair market value as of the commencement date of this Agreement. Twenty-five percent (25%) of such stock options shall vest upon date of grant and the remainder shall vest in a series of three successive equal annual installments, provided, however that all 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 her options at a time and in a fashion that will entitle her 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 her 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 8(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 her 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 her 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 8(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 8(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 her 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 her 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 8(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 13. 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 11, 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 11, 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 her 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 her 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 12, 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:

Kathryn Cole  
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 16. 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 12, 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 16(a), the provisions of this Section 16 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 16 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 Section 17(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) Omitted.

(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 her 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

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

/s/ Kathryn Cole

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KATHRYN COLE

(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 her 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 her 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 her 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 her benefits under any of such plans or deprive her 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).

**ASSIGNMENT  
OF LEASE  
AND  
TERMINATION AND OPTION AGREEMENT**

THIS ASSIGNMENT OF LEASE AND TERMINATION AND OPTION AGREEMENT (this "Agreement") is made this 30th day of December, 2005, by and between

LAUREATE PHARMA, INC., a Delaware corporation ("Assignor"), and DISCOVERY LABORATORIES, INC., a Delaware corporation ("Assignee").

**BACKGROUND**

Assignor, as tenant, entered into a certain Agreement of Lease with Landlord, dated as of December 3, 2004, as amended by Amendment No. 1 to Lease between Landlord and Assignor (collectively, the "Lease"). Pursuant to the Lease, Tenant is occupying approximately 21,000 rentable square feet in the building located at 700 Union Boulevard, Totowa, New Jersey (the "Premises"), as more particularly described in the Lease, for a term currently expiring on December 3, 2014, unless sooner terminated pursuant to the terms of the Lease and the Termination And Option Agreement (as defined below). The Lease is hereby incorporated herein by this reference, and a copy of the Lease is attached hereto as Exhibit "A".

In connection with the Lease, Assignor and Landlord have entered into a certain Termination and Option Agreement, dated December 3, 2004, as amended by Amendment No.1 to Termination And Option Agreement between Assignor and Landlord, dated the date hereof (collectively, the "Termination and Option Agreement") pursuant to which Landlord is granted certain early termination option upon the payment to Assignor of certain early termination payments and Assignor is granted certain purchase options, as set forth more fully set forth in the Termination and Option Agreement.

Assignor, as seller, and Assignee, as buyer, entered into a certain Asset Purchase Agreement (the "APA Agreement"), pursuant to which Assignor agreed to sell and Buyer agreed to purchase certain assets more particularly described in the Agreement.

Pursuant to the APA Agreement, Assignor agreed to assign to Assignee all of Assignor's right, title and interest in and to the Lease and the Termination and Option Agreement, and Assignee agreed to accept such assignment, on the terms and conditions more fully set forth herein.

Landlord has consented to the assignment of all of Assignor's right, title and interest in and to the Lease and the Termination and Option Agreement, pursuant to that certain Consent to Assignment and Assumption, dated the date hereof between Landlord, Assignor and Assignee.

NOW, THEREFORE, Assignor and Assignee, in consideration of the mutual promises contained herein and in the Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, covenant and agree as follows:

1. Assignment. Effective as of the Effective Date, Assignor hereby conveys, transfers, assigns and sets over unto Assignee all of Assignor's right, title, interest and privilege as tenant in and to (i) the Lease and (ii) the Termination and Option Agreement, including, without limitation, the right to receive all Termination Payments (as defined therein) and the rights to exercise the Purchase Option (as defined therein) in accordance with the terms of the Termination and Option Agreement.

2. Assumption. Effective as of the Effective Date, Assignee hereby accepts the foregoing assignment of the Termination and Option Agreement from Assignor, and Assignee assumes all of the liabilities and obligations of the tenant under (i) the Lease and (ii) the Termination and Option Agreement accruing on and after the Effective Date.

3. Further Assurances. Assignor and Assignee agree to cooperate in good faith in completing the transactions described herein, including executing further instruments of assignment as reasonably necessary.

4. Effective Date. Assignor and Assignee acknowledge that this Agreement shall only be effective on the earliest date (the "Effective Date") when each of the following shall have been accomplished:

(a) Assignor and Assignee shall have executed and delivered this Agreement;

(b) Settlement shall have been completed under the Agreement;

(c) Assignor and Assignee and Landlord shall have executed and delivered the Consent to Assignment and Assumption, in form and substance acceptable to Landlord, Assignor and Assignee in their reasonable discretion.

5. Miscellaneous.

(a) This Agreement and the APA Agreement contains the entire agreement between the parties hereto with respect to the subject matter hereof and may only be amended by an instrument in writing signed by the parties hereto. Neither the making nor the acceptance of this instrument shall enlarge, restrict or otherwise modify the terms of the APA Agreement or constitute a waiver or release by Seller or Buyer of any Liabilities, duties or obligations imposed upon either of them by the terms of the APA Agreement, including, without limitation, the representations and warranties and other provisions that the APA Agreement provides shall survive the Closing Date and the limitations on survival and remedies set forth in the APA Agreement.

(b) This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and assigns;

(c) This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey, without giving effect to any choice of laws provisions which may direct the application of the laws of another jurisdiction; and

(d) This Agreement may be executed in multiple counterparts, each of which shall be an original and all of which together shall constitute but one and the same instrument.

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IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, under seal, the day and year first above written.

ASSIGNOR:

LAUREATE PHARMA, INC.

By: /s/ Christopher J. Davis

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Name: Christopher J. Davis  
Title: Vice President and Treasurer

ASSIGNEE:

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

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

EXHIBIT A

Lease

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AGREEMENT OF LEASE

Dated as of December 3, 2004

between

NORWELL LAND COMPANY, Landlord

and

LAUREATE PHARMA, INC., Tenant

SAFEGUARD SCIENTIFICS, INC., Guarantor

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## AGREEMENT OF LEASE

This LEASE ("Lease") is made and entered into as of December 3, 2004, by and between NORWELL LAND COMPANY, a New York general partnership, having an address at One Stamford Forum Stamford, Connecticut 06901 ("Landlord") and LAUREATE PHARMA, INC. (formerly known as Biopharma Acquisition Company, Inc.), a Delaware corporation, having an address at 800 The Safeguard Building, 435 Devon Park Drive, Wayne, Pennsylvania 19087 ("Tenant").

### WITNESSETH:

For and in consideration of the covenants herein contained and upon the terms and conditions herein set forth, intending to be legally bound hereby, Landlord and Tenant agree as follows:

### ARTICLE I

#### DEFINITIONS

1.1 As used herein, the following terms shall have the following meanings:

(a) "Affiliate" means, with respect to a particular party, a Person or Persons controlling, controlled by or under common control with that party, as well as any officers, directors and majority-owned entities of that party and of its other Affiliates. For the purposes of the foregoing, ownership, directly or indirectly, of 20% or more of the voting stock or other equity interest shall be deemed to constitute control.

(b) "Associated Companies" means any corporation, partnership, limited liability company or other entity or combination thereof which directly or indirectly (a) owns or controls a party, (b) is owned or controlled by a party, or (c) is under common ownership or control with said party; the terms "control" and "controlled" meaning ownership of 20% or more, including ownership by trusts with substantially the same beneficial interests, of the voting and/or equity rights of such corporation, partnership, limited liability company or other entity or combination thereof or the power to direct the management of such corporation, partnership, limited liability company or other entity or combination thereof.

(c) "Base Rent" shall have the meaning specified in Section 4.1 herein.

(d) "Base Year" means (i) for Expenses, the twelve (12) month period ended July 31, 2004, and (ii) for Taxes, the twelve month period ended June 30, 2004.

(e) "Building" shall have the meaning specified in Section 2.1 herein.

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(f) "Commencement Date" shall have the meaning specified in Section 3.1 herein.

(g) "Environmental Law" means all federal, state and local laws related to protection of the environment, natural resources, safety or health or the handling, use, recycle, generation, treatment, storage, transportation or disposal of Hazardous Materials, and any common law cause of action relating to the environment, natural resources, safety, health or the management of or exposure to Hazardous Materials;

(h) "Event of Default" shall have the meaning specified in Section 16.1 herein.

(i) "Expenses" means the actual costs and expenses incurred by Landlord during the Term in providing the services to be provided by Landlord under Section 11.1 herein, but excluding Taxes.

(j) "Expense Statement" means a reasonably detailed statement prepared by Landlord, or at its option, a third party, showing the calculation of Tenant's Expense Payment.

(k) "Fiscal Year" means (i) for Expenses, a twelve (12) month period ending July 31, and (ii) for Taxes, a twelve month period ending June 30.

(l) "Hazardous Materials" shall mean any hazardous, dangerous, explosive, radioactive, infectious or toxic substance, waste or material that is or becomes regulated by any local governmental authority, the State in which the Leased Premises are located (including any agency thereof) or the United States government (including any agency thereof), including, without limitation, asbestos, asbestos containing materials, polychlorinated biphenyls (PCBs), mercury, lead and/or lead-based paint, petroleum and petroleum by-products, chlorofluorocarbons (CFCs), carcinogens, infectious or radioactive biological or medical wastes, mold, yeast or fungi, and/or any material or substance that is now or hereafter: (i) designated as a "hazardous substance" pursuant to Section 311 of the Federal Water Pollution Control Act (33 U.S.C. § 1321) or the regulations promulgated thereunder, (ii) defined as a "hazardous waste" pursuant to Section 1004 of the Federal Resource Conservation and Recovery Act (42 U.S.C. § 6903) or the regulations promulgated thereunder, or (iii) defined as a "hazardous substance" pursuant to Section 101 or 102 of the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. § 9601 and § 9602) or the regulations promulgated thereunder (as each of the foregoing statutes and regulations may be amended from time to time), and/or any items or substances now or hereafter identified by or included within any of the foregoing general classifications.

(m) "Land" shall have the meaning specified in Section 2.1.

- (n) "Leased Premises" shall have the meaning specified in Section 2.1.
- (o) "Master Tenant" means The P.F. Laboratories, Inc., a New Jersey corporation, its successors and assigns.
- (p) "Person" means any natural person, corporation, partnership, proprietorship, association, joint venture, trust or other legal entity.
- (q) "Rent" shall have the meaning specified in Section 4.2.
- (r) "Structural Portions" shall have the meaning specified in Section 9.1.
- (s) "Tax Statement" means an annual statement given to Tenant by Landlord, showing the calculation of Tenant's Tax Payment.
- (t) "Taxes" means the aggregate of all real estate taxes, assessments (special or otherwise), and other charges (including business improvement district charges and payments in lieu of Taxes) of any authority assessed against all or any part of the Building, the Land and other improvements thereon. If the method of taxation is changed so that in lieu of, as an addition to or as a substitute for all or any part of such real estate taxes, assessments or charges, there is assessed any other tax, assessment or charge, including one based on rents received, all such taxes, assessments and charges shall be considered Taxes. Taxes shall not, however, include any franchise, gift, inheritance, estate, sales, transfer, general income or profit tax imposed on Landlord (unless it is considered part of Taxes pursuant to the preceding sentence). If in any year, including the Base Year there is any abatement, exemption or discount of Taxes (or any assessment or rate which comprises Taxes), the abatement, exemption or discount shall not be taken into account, and Taxes shall be determined as if there was no abatement, exemption or discount.
- (u) "Tenant's Expense Payment" means Tenant's Share of the excess of Expenses for any Fiscal Year over Expenses for the Base Year.
- (v) "Tenant's Share" means six (6) percent.
- (w) "Tenant's Tax Payment" means Tenant's Share of the excess of Taxes for any Fiscal Year over Taxes for the Base Year.
- (x) "Tenant's Termination Option" shall have the meaning specified in Section 3.2.
- (y) "Term" shall have the meaning specified in Section 3.1.

## ARTICLE 2

### DESCRIPTION

2.1 Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord the premises (the "Leased Premises"), shown outlined in bold on the diagram attached hereto as Schedule A, which space is located in the building (the "Building") located on the land described in Schedule B (the "Land") having an address at 700 Union Boulevard, Totowa, New Jersey, at the Rent and on the other terms of this Lease. The parties agree that the Leased Premises contains approximately 21,000 square feet of space, and the Building contains approximately 311,000 square feet of space, all as shown on Laureate Sheet 1 and Laureate Sheet 2 taken from drawing PFL-A-1004 manually redated September 28, 2004.

## ARTICLE 3

### TERM

3.1 The term of this Lease (the "Term") shall commence on December 3, 2004 (the "Commencement Date") and shall end on December 3, 2014, unless this Lease shall sooner terminate as provided hereinafter.

3.2 Tenant shall have the option (the "Tenant's Termination Option") upon not less than twelve (12) months' prior written notice to Landlord, to terminate this Lease, effective on a date specified in such notice.

## ARTICLE 4

### RENT

4.1 Tenant shall pay to Landlord, in such money of the United States of America as at the time of payment shall be legal tender for the payment of public and private debts, at the place specified in Article 22 hereof for the giving of notices to Landlord hereunder, or at such other place to such agent as Landlord may from time to time designate by notice to Tenant, a base rent in the amount of \$150,000.00 per annum (the "Base Rent"). The Base Rent shall be in addition to and over and above all other payments to be made by Tenant hereunder and shall be paid in advance, in equal monthly installments of \$12,500.00 on the first day of each calendar month. Base Rent for partial months shall be adjusted pro-rata.

4.2 All sums, other than Base Rent, payable by Tenant to Landlord under this Lease are considered additional rent, including without limitation, Tenant's Tax Payments and Tenant's Expense Payments. Base Rent and all additional rent are referred to herein as "Rent". Landlord's delay in rendering, or failure to render, any statement required to be rendered by Landlord for any Rent for any period shall not waive Landlord's right to render a statement or collect that Rent for that or any subsequent

period. The rendering of an incorrect statement shall not waive Landlord's right to render a corrected statement for the period covered by the incorrect statement and collect the correct amount of Rent.

## ARTICLE 5

### TAXES

5.1 If Taxes for any Fiscal Year, all or any part of which falls within the Term, exceed Taxes for the Base Year, Tenant shall pay to Landlord, Tenant's Tax Payment within thirty (30) days following Tenant's receipt of a Tax Statement for that year. At Tenant's request, Landlord shall deliver to Tenant a copy of the relevant bill for Taxes. If Taxes for any Fiscal Year are less than Taxes for the Base Year, Tenant shall not be entitled to any payment or credit.

5.2 Landlord represents and warrants that Taxes for the Base Year were \$429,409, as set forth in detail on Schedule C hereto, that such Taxes were paid on or before the date due and that there is no current appeal regarding the amount of such Taxes.

5.3 If the Commencement Date or the expiration date is a date other than the first or last day of a Fiscal Year, Tenant's Tax Payment for that Fiscal Year shall be apportioned according to the number of days of that Fiscal Year within the Term.

5.4 Tenant shall pay for any taxes assessed on Tenant's personal property.

## ARTICLE 6

### EXPENSES

6.1 If Expenses for any Fiscal year, all or any part of which falls within the Term, exceed Expenses for the Base Year, Tenant shall pay to Landlord, Tenant's Expense Payment within thirty (30) days following Tenant's receipt of the Expense Statement for that year. If Expenses for any such year are less than Expenses for the Base Year, Tenant shall not be entitled to any payment or credit.

6.2 If the Commencement Date or the expiration date is a date other than the first or last day of a Fiscal Year, Tenant's Expense Payment for that Fiscal Year shall be apportioned according to the number of days of that Fiscal Year within the Term.

6.3 Tenant shall have the right, at Tenant's expense, during normal business hours, on notice to Landlord, to examine, at Landlord's office within 150 miles of the Building (or at Landlord's option, the office of Landlord's managing agent or accountant within 150 miles of the Building, Landlord's books and records which are relevant to the determination of the Expenses for any Fiscal Year following the Base Year shown on any Expense Statement, provided (a) the examination is conducted on one or more dates mutually convenient for Landlord and Tenant and concluded within 365

days following Tenant's receipt of the Expense Statement in question (if Landlord has provided Tenant with reasonable access during that period), (b) the person examining Landlord's books and records is not a person who is paid based in whole or in part on the amount of any reduction of the Tenant's Expense Payment resulting from the examination (and, prior to making an examination both Tenant and the person retained by Tenant to make the examination shall certify to Landlord that the person making the examination is not to be paid any sum based in whole or in part on the reduction of the Tenant's Expense Payment), and (c) any information obtained by Tenant or the person examining Landlord's books and records shall be kept confidential, except for disclosure to Tenant's legal counsel and other advisors and any independent person designated to resolve any dispute between Landlord and Tenant relating to a Tenant's Expense Payment or as required by any law.

6.4 Landlord represents and warrants that Expenses for the Base Year, as shown on Schedule C attached hereto, are \$50,300. Tenant agrees that Expenses for the Base Year are not subject to audit.

#### ARTICLE 7

##### LANDLORD'S WORK

7.1 Landlord shall not be obligated to do any work to prepare the Leased Premises for Tenant's occupancy. Tenant accepts the Leased Premises in "as-is, where-is" condition.

#### ARTICLE 8

##### USE; PARKING

8.1 Tenant may use the Leased Premises for the purposes which the Leased Premises or the facility of Laureate Pharma, L.P. in Princeton, New Jersey are presently used by Laureate Pharma L.P., namely microparticle, protein, and monoclonal antibody cell line development, manufacturing, process development, formulation, purification and filling for use as medicine or diagnostics, as well as storage and office operations related to the foregoing activities. Tenant shall not use the facility for (a) penicillin or penicillin-based products, (b) anabolic steroid hormones, or (c) teratogenic compounds identified by the U.S. Food and Drug Administration as Pregnancy category X, as defined in 21 C.F.R. § 201.57(f)(6)(i)(e), or (d) as identified by Landlord in writing, has been shown in publicly available animal reproduction studies, or in investigations or studies or marketing experience to have an adverse effect on fetus consistent with FDA Pregnancy category X described above. Tenant further agrees that it shall not use the facility for the activities set forth in the first sentence of this Section 8.1 to manufacture (i) laxatives, (ii) iodine-based topical microbicides, (iii) cefditoren pivoxil, (iv) theophylline, (v) oxycodone, or (vi) morphine. Finally, Tenant shall not use any part of the Leased Premises as a vivarium.

8.2 Should Tenant desire to introduce new purposes at the Leased Premises, Tenant shall give not less than sixty (60) days prior written notice to Landlord and Landlord shall within thirty (30) days of receipt thereof indicate whether Landlord approves or disapproves of such new purposes, such approval not to be unreasonably withheld, delayed or conditioned. Landlord shall base its decision to grant or withhold such approval on the following factors: competitive threat, security, compliance, economic impact, nature of activities in the balance of the site and any other reasonable factors. If Landlord fails to respond within such thirty (30) day period, Tenant's proposal shall be deemed approved. Tenant shall not use the Leased Premises in any manner so as to constitute a nuisance or cause cancellation of any fire insurance covering the Leased Premises, once Tenant has knowledge that it would cause such cancellation.

8.3 Landlord shall provide Tenant with twelve (12) parking spaces at or near the entrance of the Leased Premises. If Tenant hires additional employees necessitating additional parking spaces, Landlord shall provide up to an additional eight (8) spaces (a) should they become available on the existing blacktopped area because of the removal of trailers presently parked thereon, or (b) should Tenant wish to blacktop, at Tenant's sole cost and expense, land adjacent to the existing parking areas at a location mutually reasonably acceptable to Landlord and Tenant.

8.4 Tenant shall comply with all applicable governmental laws, ordinances, codes, rules and regulations applicable to or regulating Tenant's manner of use of the Leased Premises. Landlord shall comply with all applicable governmental laws, ordinances, codes, rules and regulations applicable to or regulating the condition of the Building and Landlord's manner of use of the balance of the Building.

## ARTICLE 9

### REPAIRS AND MAINTENANCE

9.1 Landlord shall, at Landlord's sole cost and expense, perform all necessary or appropriate maintenance, repairs and replacements to the utility services and Structural Portions of the Building, except for repairs made necessary by the misuse or neglect of Tenant or Tenant's agents. As used herein, the term "Structural Portions" means: the foundation, roof structural supports, structural steel, load bearing walls, loading docks, exterior walls, exterior windows, exterior doors, retaining walls and Building systems.

9.2 Tenant shall, at Tenant's sole cost and expense, keep and maintain the interior portions of the Leased Premises that are not Structural Portions in good condition and repair and make any other repairs to the Leased Premises that may be required due to the misuse or neglect of Tenant, so as to tender the Leased Premises to Landlord at the expiration or earlier termination of this Lease in substantially the same condition as at the Commencement Date except for normal wear and tear.

9.3 Except to the extent caused by Landlord's negligence or willful misconduct, Landlord shall have no liability to Tenant, there shall be no abatement of the

Rent and there shall not be deemed to be any actual or constructive eviction of Tenant arising from Landlord performing any repairs or other work to any portion of the Building (including the Leased Premises or the Building systems). Landlord shall perform such repairs or other work in a manner which minimizes interference with the conduct of Tenant's business in the Leased Premises.

#### ARTICLE 10

##### ALTERATIONS AND IMPROVEMENTS

10.1 Except as provided below, Tenant shall make no changes in or to the Leased Premises of any nature without Landlord's consent, which consent shall not be unreasonably withheld, delayed or conditioned.

10.2 Subject to giving Landlord ten (10) days' prior written notice (with reasonable detail of the proposed change) and to the provisions of this Article 10, Tenant at Tenant's expense may make any changes, which do not adversely affect the Building systems, utility services or plumbing and electrical services, in or to the interior of the Leased Premises.

10.3 Trade fixtures and equipment either owned by Tenant or placed or installed upon or within the Leased Premises by Tenant and all severable improvements shall remain the personal property of Tenant and, unless otherwise agreed to by Landlord, shall be removed by Tenant upon the expiration or earlier termination of this Lease. If Tenant does not remove such personal property at such time, and there is not a prior written agreement with Landlord, Landlord shall have the right either to remove such personal property at Tenant's expense or retain such property in which case title to such property shall automatically pass to Landlord without further action by the parties. At the expiration of the Term or earlier termination of this Lease, Tenant shall repair any damage to the Leased Premises and leave the Leased Premises in substantially the same condition as the Leased Premises was delivered to Tenant on the Commencement Date, ordinary wear and tear and damage by casualty excepted.

10.4 Tenant agrees to indemnify, protect, defend and hold harmless Landlord from and against any and all liability for mechanics' liens or other liens and claims in connection with any construction by Tenant and shall, within thirty (30) days after notice from Landlord, bond or discharge any such liens or claims.

#### ARTICLE 11

##### SERVICES

11.1 Landlord shall furnish the following services and utilities during the Term:

- (a) 24 hour security service with access to the Leased Premises as provided for in Article 20;



- (b) Shipping and receiving dock services;
- (c) Non-hazardous process waste treatment and trash removal, and sanitary waste disposal;
- (d) Ground cleanup and maintenance (outside only);
- (e) Pest control (outside only);
- (f) Fire and alarm services;
- (g) Rescue Squad - fire and first aid;
- (h) Snow and ice removal; and
- (i) Monitoring devices for waste water discharged by Tenant into Master Tenant's treatment facilities.

11.2 Landlord shall have no obligation to provide to Tenant or the Leased Premises any services except as specifically set forth in this Lease. Landlord does not warrant that any Building system or service to be provided by Landlord, or any other systems or services which Landlord may provide (a) shall be adequate for Tenant's particular purposes or (b) shall be free from interruption or reduction. Building systems and services, including access, may be interrupted or reduced by reason of laws or repairs which are, in Landlord's judgment, necessary, in which event such interruption or reduction shall not (i) constitute an actual or constructive eviction, or a disturbance of Tenant's use of the Leased Premises, (ii) except as set forth in the next sentence, entitle Tenant to any compensation or abatement of the Rent, (iii) relieve Tenant from any obligation under this Lease, or (iv) impose any obligation or liability on Landlord. Notwithstanding the foregoing, if any of the services Landlord is obligated to supply under Section 11.1 are interrupted, and the interruption does not result from the negligence or willful misconduct of Tenant, Tenant shall be entitled to an equitable abatement of Rent. The abatement shall begin on the fourth consecutive day of the interruption or when Tenant stops using the Leased Premises because of the interruption, whichever is later, and shall end when the services are restored. During any such interruption, Landlord shall use commercially reasonable efforts to restore such services. Landlord shall maintain the Land, other than the Leased Premises, in a clean, safe and orderly condition.

11.3 Tenant acknowledges and agrees that Landlord shall have no obligation to provide, and Tenant, at Tenant's sole cost and expense, shall be responsible for obtaining the following:

- (a) food services;
- (b) rental of copier or other office equipment;
- (c) telephone, computer and other telecommunications services;
- (d) janitorial and cleaning services;
- (e) mail services;

- (f) window washing;
- (g) cooling;
- (h) heat;
- (i) biohazard and other hazardous waste disposal; and
- (j) boiler maintenance services.

11.4 Landlord and Tenant recognize that the boiler servicing the Leased Space is in adjoining premises of Landlord, and Landlord and Tenant agree to cooperate with each other should Tenant wish to move such boiler to the Leased Space or connect such boiler to Tenant's power source in the Leased Premises. Any such move or connection shall be at Tenant's sole cost and expense. Tenant shall have access to such boiler to maintain and service it.

## ARTICLE 12

### ELECTRICITY, GAS, WATER

12.1 Landlord represents that electricity, gas and water are presently available at and to the Leased Premises, and that there are separate meters for the electricity and gas used in the Leased Premises. Landlord shall have no obligation to provide electricity, gas or water to Tenant or the Leased Premises. Tenant shall, at Tenant's expense (a) arrange for a separate water meter to measure the water used in the Leased Premises, (b) provide electricity, gas and water in the Leased Premises to Landlord, or Landlord's employees, agents or contractors performing any work in the Leased Premises, (c) maintain and promptly make all repairs, ordinary and extraordinary, to all components of the electricity, gas and water systems serving only the Leased Premises, including all meters, and (d) pay, as and when due, for electricity, gas and water used in the Leased Premises. Tenant shall not overload the electrical system serving the Leased Premises. If for any reason separate metering of any of these services cannot be maintained or achieved, Landlord will allocate costs based on usage and bill these costs to Tenant, and Tenant will pay such bill within thirty (30) days.

## ARTICLE 13

### INSURANCE; INDEMNITY

13.1 Landlord shall maintain or cause to be maintained fire and extended coverage insurance in respect of the Building and other improvements on the Land normally covered by such insurance (except for the property Tenant is required to cover with insurance under Section 13.2) for the benefit of Landlord and any other parties Landlord may at any time and from time to time designate, as their interests may appear, but not for the benefit of Tenant. The fire and extended coverage insurance will be in the amounts of the full replacement cost of the Building, provided that such coverage is commercially reasonably available. Landlord shall also maintain or cause to be maintained commercial general liability insurance in an amount not less than \$5,000,000.

Landlord may also maintain any other forms and types of insurance which Landlord shall deem reasonable in respect to the Building and Land. Landlord shall have the right to provide any insurance maintained or caused to be maintained by it under blanket policies.

13.2 Tenant shall maintain the following insurance: (a) comprehensive general public liability insurance in respect of the Leased Premises and the conduct and operation of business therein, with Landlord as an additional insured, with a combined single limit for bodily injury or death and property damage of not less than \$5,000,000, and (b) fire and extended coverage insurance in respect of Tenant's stock in trade, fixtures, furniture, furnishings, removable floor coverings, equipment, and all other property of Tenant in the Leased Premises in any amounts required by any fee mortgagee but not less than 80% of the full insurable value of the property covered and not less than the amount sufficient to avoid the effect of the co-insurance provisions of the applicable policy or policies. Landlord may, after the expiration of the fifth Fiscal Year, require, on one occasion, that the combined single limit for the comprehensive general public liability insurance to be maintained by Tenant be increased so long as the increase is commercially reasonable. Tenant shall deliver to Landlord and to any additional insured certificates for such fully paid-for policies prior to the Commencement Date. Tenant shall procure renewals of such insurance from time to time before the expiration thereof, and Tenant shall deliver to Landlord certificates therefor before the expiration of any existing policy. All such policies shall be issued by companies of recognized responsibility licensed to do business in New Jersey, and all such policies shall contain a provision whereby the same cannot be cancelled unless Landlord and any additional insured(s) are given at least 20 days' prior written notice of such cancellation. Upon request, Tenant will deliver duplicate originals of the actual policies to Landlord.

13.3 Tenant shall not do, permit or suffer to be done any act, matter, thing or failure to act in respect of the Leased Premises or use or occupy the Leased Premises or conduct or operate Tenant's business in any manner objectionable to any insurance company (provided Tenant is on notice of such objection) whereby the fire insurance or any other insurance then in effect in respect to the Land and Building or any part thereof shall become void or suspended or whereby any premiums in respect of insurance maintained by Landlord shall be higher than those which would normally have been in effect for the occupancy contemplated under Article 8. If Tenant breaches the provisions of this Section 13.3, in addition to all other rights and remedies of Landlord hereunder, Tenant shall (a) indemnify Landlord and the fee mortgagees and hold Landlord and the fee mortgagees harmless from and against any loss which would have been covered by insurance which shall have become void or suspended because of such breach by Tenant and (b) pay to Landlord any and all increases or premiums on any insurance.

13.4 Tenant shall indemnify and hold harmless Landlord and its respective directors, officers, agents, employees and invitees from and against any and all losses, claims, damages and liabilities (including without limitation, legal fees and other expenses as such fees and expenses are incurred) that arise out of, or are based upon, any actions, operations or other events occurring (a) in the Building to the extent caused by the acts, omissions or negligence of Tenant or any of its subtenants or licensees or its or

their directors, officers, agents, employees, invitees or contractors, and (b) in the Leased Premises to the extent caused by the acts, omissions or negligence of a third party or force majeure.

13.5 Landlord shall indemnify and hold harmless Tenant, its directors, officers, agents, employees and invitees from and against any and all losses, claims, damages and liabilities (including, without limitation, legal fees and other expenses as such fees and expenses are incurred), that arise out of, or are based upon, any actions, operations or other events occurring (a) in the Building to the extent caused by the acts, omissions or negligence of Landlord, and (b) in the Building (except for the Leased Premises) to the extent caused by the acts, omissions or negligence of a third party or force majeure.

13.6 Each party waives any right of recovery against the other party and releases all claims arising in any manner in its (the "Injured Party's") favor and against the other party for any loss or damage to the Injured Party's property (real or personal) located within or constituting a part of or all of the Building. The parties intend that such waiver and release apply to their respective insurers and act to waive any rights of subrogation that such insurers may have against the other party. This waiver and release apply to the extent the loss or damage is (1) covered by the Injured Party's insurance or (2) would be covered by the insurance the Injured Party is required to carry under this Lease, whichever is greater. The waiver and release also apply to each party's directors, officers, employees, shareholders and agents.

13.7 Notwithstanding anything to the contrary in this Lease, all indemnity obligations of Landlord and Tenant arising under this Lease, and all claims, demands, damages and losses assertable by Landlord and Tenant against the other in any suit or cause of action arising out of or relating to this Lease, the Leased Premises, the Building or the property on which the Building is located, or the use and occupancy thereof, are limited as follows:

(a) by the releases and waivers expressed herein, including, without limitation, the mutual releases and waivers of rights set forth in Section 13.6;

(b) all claims for indemnification and other recoveries shall be limited to direct, proximately caused damages and exclude all consequential and indirect damages, including, but not limited to, business loss or interruption, suffered by the party asserting the claim or seeking the recovery; and

(c) in the event that Landlord and Tenant (or the persons for whom they are liable as expressly set forth herein) are determined to be contributorily responsible for the indemnified injury or loss, each indemnitor's obligation is limited to the indemnitor's equitable share of the losses, costs or expenses to be indemnified against based on the relative culpability of each indemnifying person whose negligence or willful acts or omissions contributed to the injury or loss.

ARTICLE 14

DESTRUCTION BY FIRE OR OTHER CASUALTY

14.1 If the Leased Premises or any part thereof shall be damaged by fire or other casualty, Tenant shall give immediate notice thereof to Landlord and this Lease shall continue in full force and effect except as hereinafter set forth.

14.2 If the Leased Premises are damaged or rendered unusable by fire or other casualty, the damages thereto shall be repaired by Landlord at Landlord's expense and, unless caused by the negligence or willful misconduct of Tenant, with an abatement of rent until the Leased Premises become usable, provided, however, that if the cost of restoration of the Leased Premises shall exceed fifty (50) percent of the replacement value of the Leased Premises and the damage occurs within three (3) years of the expiration of the Term, then either Landlord or Tenant shall have the right to terminate this Lease within ninety (90) days of such casualty. If neither party terminates this Lease within ninety (90) days of such casualty, Landlord shall repair the damages to the Leased Premises at Landlord's expense.

14.3 If at any time during the Term the Building is damaged or rendered unusable by fire or other casualty, and if the Master Tenant ceases all of its manufacturing activities at the Building as a result of such fire or other casualty, Landlord shall have the right to terminate this Lease on ninety (90) days written notice to Tenant if the cost of restoration of the Building shall exceed fifty (50) percent of the replacement value of the Building. If Landlord does not have or does not exercise such right to terminate, the damages to the Leased Premises shall be repaired (with appropriate work to whatever portion of the Building is to remain so that such portion shall have a reasonable exterior appearance) by Landlord at Landlord's expense and, unless caused by the negligence or willful misconduct of Tenant, if the Leased Premises has been damaged, with an equitable abatement of rent until the Leased Premises becomes usable.

14.4 Upon any termination of this Lease pursuant to this Article, Tenant shall forthwith quit, surrender and vacate the Leased Premises without prejudice however, to Landlord's rights and remedies against Tenant under the Lease provisions in effect prior to such termination, and any Rent owing shall be paid up to such date of termination. The Rent shall be proportionately adjusted to the time of the casualty and thenceforth shall cease.

ARTICLE 15

CONDEMNATION

15.1 If as the result of a taking by condemnation or similar legal action of an authority all of the Leased Premises, or so much thereof as renders the Leased Premises wholly unusable by Tenant, is taken, (b) a portion of the Building or the Land is taken, resulting in Tenant no longer having reasonable access to or use of the Leased Premises, (c) all or substantially all of the Building or the Land is taken, or (d) a portion

of the Building is taken resulting in Landlord's determination to demolish the Building, or (e) a portion of the Building is taken resulting in Landlord's determination that it is not commercially feasible for Landlord to continue operating at the Building, the Term shall expire on the date of the vesting of title. In that event, the Rent shall be apportioned as of the date of termination and any Rent paid by Tenant to Landlord for any period after that date shall be promptly refunded by Landlord to Tenant.

15.2 In the event of any such taking of all or any part of the Leased Premises, the Building or the Land, Landlord shall be entitled to receive the entire award. Tenant shall have no claim against Landlord or any authority for the value of the unexpired portion of the award. Tenant may, however, at Tenant's expense, make a separate claim to the appropriate authority for the value of Tenant's property and for moving expenses, provided such claim and award, if any, do not result in a reduction of the award which would otherwise be paid to Landlord.

15.3 If a taking does not result in the termination of this Lease (a) Landlord shall, at Landlord's expense, as soon as practicable, restore that part of the Leased Premises, the Building or the Land not taken, so that the Leased Premises are usable, and (b) from and after the date of the vesting of title, the Rent shall be reduced in the same proportion as the area of the Leased Premises, if any, which was taken.

## ARTICLE 16

### DEFAULT

16.1 Each of the following shall constitute an "Event of Default" by Tenant under this Lease:

- (a) Tenant shall fail to timely pay Rent and shall fail to rectify such non-payment within ten (10) days after Tenant's receipt of notice thereof from Landlord;
- (b) Tenant shall make an assignment for the benefit of creditors;
- (c) Tenant shall file a petition or answer seeking reorganization or arrangement under any of the laws of the United States relating to bankruptcy or any other applicable statute and such petition is not discharged within sixty (60) days thereafter;
- (d) An attachment or execution shall be levied upon Tenant's property or interest under this Lease, and shall not be satisfied or released within sixty (60) days thereafter;
- (e) An involuntary petition in bankruptcy shall be filed against Tenant, or a receiver or trustee for all or any part of the property of Tenant shall be appointed by any court, and such petition shall not be withdrawn,

dismissed or discharged, or such receiver or trustee removed, within ninety (90) days from the filing or appointment thereof; or

(f) Tenant shall default in the performance or observance of any other covenant, agreement, obligation, provision or condition to be kept or performed by Tenant under the provisions of this Lease and such default shall continue for thirty (30) days after Tenant's receipt of notice thereof from Landlord; provided, however, that if the nature of such default is such that more than thirty (30) days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said thirty (30) day period and thereafter proceeds, in good faith, with such cure to completion.

16.2 If one or more of the foregoing Events of Default shall occur, then Landlord may, at Landlord's option, provide Tenant with ten (10) days notice of termination and enter the Leased Premises and again have, repossess and enjoy the same as if this Lease had not been made, and thereupon this Lease shall cease, terminate and be utterly void, without prejudice, however, to the right of Landlord to recover from Tenant all Rent due up to the time of entry.

16.3 If this Lease is terminated pursuant to Section 16.2 or Landlord re-enters or obtains possession of the Leased Premises by summary proceedings or any other legal action (which Landlord may do without further notice and without liability or obligation to Tenant or any occupant of the Leased Premises), all of the following provisions of this Section shall apply (in addition to any other applicable provisions of this Lease):

(a) Tenant (and all other occupants) shall vacate and surrender to Landlord the Leased Premises in accordance with this Lease.

(b) Landlord, at Landlord's option, may (i) relet the Leased Premises, or any portion of the Leased Premises, from time to time, in the name of Landlord, Tenant or otherwise, as determined by Landlord, to any person and on any terms, but Landlord shall have no obligation to relet the Leased Premises, or any portion of the Leased Premises, or to collect any rent (and the failure to relet the Leased Premises, or any portion of the Leased Premises, or to collect any rent shall not impose any liability or obligation on Landlord or relieve Tenant of any obligation or liability under this Lease), and (ii) make any changes to the Leased Premises as Landlord, in Landlord's judgment, considers advisable or necessary in connection with a reletting, without imposing any liability or obligation on Landlord or relieving Tenant of any obligation or liability under this Lease.

(c) Tenant shall pay Landlord all Rent payable to the date on which this Lease is terminated or Landlord re-enters or obtains possession of the Leased Premises.

(d) Tenant shall also pay to Landlord, as damages, any deficiency between (i) the aggregate Rent for the period which otherwise would have constituted the

unexpired portion of the Term (conclusively presuming the additional rent for each year thereof to be the same as was payable for the year immediately preceding the termination, re-entry or obtaining of possession) and any expenses incurred by Landlord in connection with the termination, reentry or obtaining of possession, and the reletting of the Leased Premises, including all repossession costs, brokerage commissions, reasonable attorneys' fees and disbursements, alteration costs and other expenses of preparing the Leased Premises for reletting and (ii) the rents, if any, applicable to that period collected under any reletting of any portion of the Leased Premises. Tenant shall pay any deficiency in monthly installments on the days specified in this Lease for payment of installments of the Base Rent, and Landlord shall be entitled to recover from Tenant each monthly deficiency as the same arises. No suit to collect the deficiency for any month shall prejudice Landlord's right to collect the deficiency for any subsequent month. Tenant shall not be entitled to any rents payable (whether or not collected) under any reletting, whether or not those rents exceed the Rent.

(e) Landlord may recover from Tenant, and Tenant shall pay Landlord, on request, in lieu of any further deficiency pursuant to paragraph (d) of this Section (as liquidated damages) the amount by which (i) the unpaid Rent for the period which otherwise would have constituted the unexpired portion of the Term (conclusively presuming the additional rent for each year thereof to be the same as was payable for the year immediately preceding the termination, re-entry or obtaining of possession) exceeds (ii) the then fair and reasonable rental value of the Leased Premises, including the additional rent for the same period, both discounted to present value at the annual rate of interest publicly announced by JPMorgan Chase Bank, New York, New York (or any successor thereto) as its "base rate" on the date of the Event of Default in question, or such other term as may be used by JPMorgan Chase Bank from time to time for that rate (and if no longer publicly announced, then a similar rate selected by Landlord). If, before presentation of proof of liquidated damages, Landlord relets the Leased Premises or any portion of the Leased Premises for any period pursuant to a bona fide lease with an unrelated third party, the net rents payable in connection with the reletting shall be considered to be the fair and reasonable rental value for the Leased Premises or the portion of the Leased Premises relet during the term of the reletting. If Landlord relets the Leased Premises, or any portion of the Leased Premises, together with other space in the Building, the rents collected under the reletting and the expenses of the reletting shall be equitably apportioned for the purposes of this Section.

(f) Nothing contained in this Lease shall be considered to limit or preclude the recovery by Landlord from Tenant of the maximum amount allowed to be obtained as damages or otherwise by any Law, except as provided in Section 16.6 below.

16.4 If Tenant fails to pay, when due, for any repairs or improvements to the Leased Premises made by Tenant (to the extent that such repairs were the responsibility of Tenant hereunder), or if Tenant fails to pay any of the charges that Tenant is obligated to pay by the terms of this Lease, or if Tenant fails to make repairs that are Tenant's responsibility as herein provided, then in addition to all other remedies provided by this Lease, Landlord may, but is not obligated to, upon Tenant's failure to



cure such default within thirty (30) days after Tenant's receipt of notice from Landlord that specifies the particular Event of Default complained of, pay any such charges and make such repairs, and the amount or amounts so paid or expended therefore shall become due and payable immediately upon demand by Landlord; and if Tenant shall not repay any such amount or amounts upon demand, said amount or amounts shall be added to, and become a part of, the Rent to be paid by Tenant.

16.5 The various rights and remedies given to or reserved by Landlord by this Lease, or allowed by law, shall be cumulative, and no delay or omission to exercise any of their rights shall be construed as a waiver of any default or Event of Default or acquiescence therein. No waiver by Landlord of any provision of this Lease shall be deemed for any purpose to be a waiver of any breach of any other provision hereof, nor of any continuing or subsequent breach of the same provision.

16.6 Notwithstanding anything to the contrary in this Lease, Landlord shall use commercially reasonable efforts to mitigate Landlord's damages (including, but not limited to, reletting the Leased Premises) following the occurrence of an Event of Default, provided that Landlord shall not be obligated to relet the Leased Premises prior to reletting any other available comparable space in the Building or to relet the Leased Premises for less than its then fair market rental value.

16.7 UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS) ARISING IN CONNECTION WITH THE DEFAULT OR BREACH OF ANY WARRANTIES OR OBLIGATION OF THE OTHER PARTY TO THIS TRANSACTION, OR ANY RELATED TRANSACTIONS, OR ANY DOCUMENTS OR SCHEDULES RELATED THERETO.

## ARTICLE 17

### ASSIGNMENT AND SUBLETTING

17.1 Except as provided in this Article, Tenant shall not, without Landlord's consent (a) assign (by operation of law or otherwise), encumber or otherwise transfer this Lease or any interest in this Lease, or (b) sublet or permit others to occupy all or any part of the Leased Premises. The transfer, redemption or issuance (by one or more transactions, including by way of merger or consolidation) of ownership interests of Tenant, or any direct or indirect parent of Tenant which results in fifty-one (51) percent or more of the ownership interests of that person being held by persons who did not hold 51% ownership interests on the Commencement Date, shall be considered an assignment of this Lease which requires Landlord's consent. Landlord's consent to an assignment, subletting or occupancy shall not relieve Tenant from any liability under this Lease or from obtaining Landlord's consent to any further assignment, subletting or occupancy.

17.2 If Tenant desires to sublet all or part of the Leased Premises or assign this Lease, Tenant shall give Landlord notice of Tenant's desire, accompanied by (i) a

reasonably detailed description of the proposed assignee or subtenant and its principals, the nature of its business and its proposed use of the Leased Premises, and (ii) current financial information with respect to the proposed assignee or subtenant, including its most recent financial statements (and Tenant shall promptly deliver to Landlord such additional information as Landlord reasonably requests). Landlord's consent to the proposed assignment or sublease shall not be unreasonably withheld, conditioned or delayed, if:

- (a) there is then no uncured Event of Default by Tenant under this Lease;
- (b) the proposed assignee or subtenant shall use the Leased Premises for the permitted uses under this Lease, and for no other purpose;
- (c) the proposed assignee or subtenant is not engaged in the research, development, manufacturing or sale of products for the treatment of pain, provided that such products compete with products being researched, developed, manufactured or sold by Master Tenant or an Affiliate of Master Tenant;
- (d) if so requested by Landlord, the proposed assignee or subtenant agrees in writing to comply with the terms of that certain Employee Leasing Agreement dated as of the date hereof between The P.F. Laboratories, Inc. and Tenant and that certain collective bargaining agreement between The P.F. Laboratories, Inc. and Local 825, International Chemical Workers Union Council of the United Food & Commercial Workers International Union (the "CBA"); and
- (e) Tenant reimburses Landlord for any reasonable costs that Landlord incurs in connection with the assignment or sublease, including reasonable attorneys' fees and disbursements.

If approved by Landlord, Tenant shall provide a copy of the assignment or sublease, as applicable, to Landlord, promptly after the same is executed.

17.3 Tenant shall be responsible for any act or omission of any assignee or subtenant (or anyone claiming through any assignee or subtenant) which violates this Lease, and that violation shall be considered a violation by Tenant.

17.4 Tenant shall pay Landlord, within 15 days following payment to Tenant, 100% of (a) all sums and other consideration in connection with an assignment, after Tenant recovers therefrom all reasonable costs incurred by Tenant in connection with that assignment which have been paid or are then due and payable and (b) the excess, if any, of the rents, additional charges or other consideration in connection with a sublease over the Rent allocable to the subleased premises (which Rent shall be allocated equally throughout the Leased Premises) accruing during the term of that sublease after Tenant recovers therefrom all reasonable costs incurred by Tenant in connection with that sublease which have been paid or are then due and payable.

17.5 Tenant may, without Landlord's consent and without complying with Section 17.1, assign this Lease or sublet all or any part of the Leased Premises to any Affiliate of Tenant, provided that (a) the conditions in paragraphs (a) through (d) of Section 17.2 are complied with and, (b) Landlord is given an executed original of all related documents, including an original assignment (with an assumption signed by the assignee) or sublease, and proof reasonably satisfactory to Landlord of the requisite control.

## ARTICLE 18

### ENVIRONMENTAL MATTERS

18.1 Tenant shall conduct its operations and other activities at the Leased Premises in compliance with all applicable laws, including Environmental Laws. Tenant further agrees to use, handle, generate, store and dispose of Hazardous Materials in compliance with Environmental Laws.

18.2 Tenant shall indemnify, protect, defend and save Landlord, its directors, officers, agents, employees and invitees harmless from and against any and all claims, liability, damages, fines, penalties, losses, costs and expenses (including reasonable attorneys' fees) related to, arising out of, or directly or indirectly attributable to, violations of or noncompliance with or obligations under Environmental Laws caused by or due to the actions, omissions or obligations of the Tenant, its directors, officers, agents, employees and invitees or the presence, use, generation, storage, release or disposal of Hazardous Materials in, on, under or about the Leased Premises, but only if and to the extent that such Hazardous Materials were brought to or generated at the Leased Premises by Tenant, its directors, officers, agents, employees and invitees during the Term or otherwise used, stored, released or disposed of by the Tenant, its directors, officers, agents, employees and invitees during the Term. Tenant shall upon execution hereof, and within ten days of any new materials being introduced, furnish Landlord with a complete set of "Material Safety Data Sheets" for all materials used in the Leased Premises.

18.3 To the extent solely arising or occurring on or after the Commencement Date, Landlord shall indemnify, protect, defend and save Tenant, its directors, officers, agents, employees and invitees harmless from and against any and all claims, liability, damages, fines, penalties, losses, costs and expenses (including reasonable attorneys' fees) related to, arising out of, or directly or indirectly attributable to, violations of or noncompliance with or obligations under Environmental Laws caused by or due to the actions, omissions or obligations of the Landlord, its directors, officers, agents, employees and invitees or the presence, use, generation, storage, release or disposal of Hazardous Materials in, on, under or about the Building or the Land, except to the extent that such Hazardous Materials were brought to or generated at the Building or the Land by Tenant, its directors, officers, agents, employees and invitees during the Term or otherwise used, stored, released or disposed of by Tenant its directors, officers, agents, employees and invitees during the Term. This section shall not apply to any

environmental conditions existing in, on, under or about the Building or the Land on or before the Commencement Date.

18.4 Tenant agrees to cooperate on any and all Hazardous Materials claims brought against the Master Tenant or the Landlord, and the Master Tenant or the Landlord, as the case may be, shall prevail in the event that any dispute with respect thereto occurs.

#### ARTICLE 19

##### SUBORDINATION

19.1 Landlord represents and warrants that there are no mortgages encumbering the Land or the Building, and Tenant agrees that this Lease shall be subject and subordinate to any first mortgage placed on the fee by Landlord and to all ground or underlying leases which may now or hereafter affect such leases or the real property of which the Leased Premises are a part and to all renewals, modifications, consolidations, replacements and extensions of any such underlying leases and mortgages provided that Tenant receives a non-disturbance agreement in commercially reasonable form and substance from the holder of any such future mortgage or underlying lease. Tenant acknowledges that it has received from Landlord a copy of Commitment for Title Insurance No. S040569 dated July 23, 2004, issued by Commonwealth Land Title Insurance Company. Landlord represents and warrants that it has paid third quarter taxes for 2004, even though such taxes are shown as unpaid on the aforesaid title commitment.

#### ARTICLE 20

##### ACCESS TO LEASED PREMISES

20.1 Landlord shall have the right of access to the Leased Premises (i) for the limited purpose of examination and inspection, making repairs, alterations or improvements to the extent required or permitted herein, or exercising any of the rights of Landlord under this Lease and (ii) to show it to prospective purchasers and mortgagees or to prospective tenants. Any such visit by Landlord shall be made at reasonable times during Tenant's normal business hours upon reasonable prior notice to Tenant. Any such visit shall be conducted in a manner as to minimize disruptions to the operation of the Tenant.

20.2 Tenant shall have the right of access to the Land and the portion of the Building not constituting the Leased Premises for the limited purpose of making repairs or improvements to any mechanical or other physical systems at the Land and the Building that are used, in whole or in part, by the Tenant in the conduct of its activities at the Leased Premises. Tenant agrees that all such access may be supervised by Landlord, with the cost of such supervision to be paid by Tenant, and that any CBA work must be done by leased or CBA employees.

ARTICLE 21

HOLDING OVER

21.1 If Tenant shall, after the expiration of the Term of this Lease or any renewal or extension thereof, continue to occupy or remain in the Leased Premises without a written agreement having been entered into, any such holding over shall be deemed at sufferance but otherwise subject to all of the terms, conditions and covenants of this Lease to the extent they remain applicable, except that the Base Rent shall be increased to \$25,000 per month for the first three (3) months, and \$37,500 per month thereafter.

ARTICLE 22

NOTICE

22.1 Whenever this Lease calls for any request, notice, consent, approval or demand to be given or served on either party to this Lease, such request, notice, consent, approval or demand shall be in writing, shall specifically reference the date of this Lease, the name of the original Landlord, the name of the current Landlord and the address of the Leased Premises and shall be delivered (a) personally or (b) by "next day" courier service, addressed as follows:

To Landlord: Norwell Land Company  
One Stamford Forum  
Stamford, Connecticut 06901

Attn: General Counsel

with copy to: H. Hedley Stothers, Jr.  
Chadbourne & Parke LLP  
30 Rockefeller Plaza  
New York, NY 10112

To Tenant: Laureate Pharma, Inc.  
700 Union Boulevard  
Totowa, New Jersey 07512

Attn: Christopher J. Davis

with copy to: Safeguard Scientifics, Inc.  
800 The Safeguard Building  
435 Devon Park Drive  
Wayne, Pennsylvania 19087

Attn: Christopher J. Davis

or elsewhere, as the respective parties may from time to time designate in writing. All notices shall be deemed given when received.

#### ARTICLE 23

##### APPLICABLE LAW AND CONSTRUCTION OF PROVISIONS

23.1 This Lease shall be governed by and construed under the laws of the State of New Jersey. The captions used in this Lease are for convenience only and do not in any way modify, limit or amplify the terms and provisions hereof. The language in all parts of this Lease shall in all cases be construed according to its fair meaning and not strictly for or against either Landlord or Tenant, and the construction of this Lease and any of its various provisions shall be unaffected by any argument or claim, whether or not justified, that it has been prepared, wholly or in substantial part, by or on behalf of either Landlord or Tenant.

#### ARTICLE 24

##### SEVERABILITY

24.1 Any provision of this Lease that proves to be invalid, void or illegal shall in no way affect, impair, or invalidate any other provision(s) hereof, and such other provision(s) shall remain in full force and effect.

#### ARTICLE 25

##### AUTHORITY

25.1 Each individual executing this Lease hereby represents and warrants that (a) the entity on whose behalf such individual is executing this Lease is duly formed and validly existing, (b) the entity on whose behalf such individual is executing this Lease has full right and authority to enter into this Lease, and (c) such individual is duly authorized to execute this Lease on behalf of such entity.

#### ARTICLE 26

##### RELATIONSHIP OF PARTIES

26.1 The relationship between Landlord and Tenant created hereunder shall be that of Landlord and Tenant and nothing shall be construed as creating any joint venture or partnership.

ARTICLE 27

TRANSFER; RELEASE OF LANDLORD

27.1 In the event of a transfer or lease of the Building the transferor or Landlord shall be and hereby is relieved of all obligations and liabilities of Landlord under this Lease accruing after the effective date of the transfer or lease, provided the transferee or tenant has assumed Landlord's obligations and liabilities under this Lease effective from and after the effective date of the transfer or lease.

ARTICLE 28

COUNTERPARTS

28.1 This Lease may be executed in multiple counterparts, all of which shall constitute one and the same Lease.

ARTICLE 29

SUCCESSORS

29.1 This Lease shall bind and inure to the benefit of the parties hereto, their respective successors, permitted assigns, heirs, executors and administrators, subject to the provisions herein.

ARTICLE 30

ENTIRE AGREEMENT

30.1 This Lease contains the entire agreement between the parties hereto relating to the Leased Premises, and supersedes all prior agreements, and shall not be modified in any manner except by an instrument in writing executed by the parties or their respective successors in interest.

ARTICLE 31

WAIVER OF JURY TRIAL

31.1 LANDLORD AND TENANT HEREBY WAIVE TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER AGAINST THE OTHER ON ANY MATTER ARISING OUT OF THIS LEASE.

ARTICLE 32

QUIET POSSESSION

32.1 Landlord warrants and agrees that Tenant, on paying the Rent and on keeping, observing, and performing all other terms, conditions, and provisions herein contained on the part of Tenant to be kept, observed, and performed, shall, during the Term peaceably and quietly have, hold and enjoy the exclusive use of the Leased Premises without hindrance, disturbance or ejection from anyone.

*[Signature Page Follows]*



ARTICLE 32

QUIET POSSESSION

32.1 Landlord warrants and agrees that Tenant, on paying the Rent and on keeping, observing, and performing all other terms, conditions, and provisions herein contained on the part of Tenant to be kept, observed, and performed, shall, during the Term peaceably and quietly have, hold and enjoy the exclusive use of the Leased Premises without hindrance, disturbance or ejection from anyone.

*[Signature Page Follows]*

[Signature Page to Agreement of Lease]

LANDLORD:

NORWELL LAND COMPANY

By: Connecticut Avenue Realty Co., Inc.,  
its managing general partner

By: Howard R. Udell  
Name: HOWARD R. UDELL  
Title: VICE PRESIDENT and Assistant  
Secretary

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## AMENDMENT NO. 1 TO AGREEMENT OF LEASE

This AMENDMENT NO. 1 TO AGREEMENT OF LEASE ("Amendment") is made and entered into as of December 30, 2005 by NORWELL LAND COMPANY, a New York general partnership ("Landlord") and LAUREATE PHARMA, INC. (formerly known as Biopharma Acquisition Company, Inc.), a Delaware corporation ("Tenant").

### WITNESSETH:

WHEREAS, Landlord and Tenant entered into that certain Agreement of Lease, dated as of December 3, 2004 (the "Agreement");

WHEREAS, Tenant and Discovery Laboratories, Inc. ("Assignee") are parties to that certain Asset Purchase Agreement, dated as of December 27, 2005 (the "Asset Purchase Agreement"), pursuant to which, among other things, Tenant will assign the Agreement to Assignee and Assignee will assume Tenant's obligations under the Agreement, and it is a condition to the consummation of the transaction contemplated by the Asset Purchase Agreement that Landlord consent to the assignment of the Agreement (the "Landlord Consent"); and

WHEREAS, Landlord and Tenant desire to enter into this Amendment to amend certain portions of the Agreement.

NOW, THEREFORE, in consideration of the mutual premises and promises set forth herein, the parties hereto intending to be legally bound, hereby agree and provide as follows:

1. Capitalized Terms. Capitalized terms used herein and not defined shall have the meaning ascribed to them in the Agreement.
2. Amendment to Section 17.2. If Landlord delivers the Landlord Consent, then, from and after the Effective Date of the Landlord Consent, Section 17.2 of the Agreement shall, without further act or deed, be amended and restated in its entirety as follows:

"17.2 If Tenant desires to sublet all or part of the Leased Premises or assign this Lease, Tenant shall give Landlord notice of Tenant's desire, accompanied by (i) a reasonably detailed description of the proposed assignee or subtenant and its principals, the nature of its business and its proposed use of the Leased Premises, and (ii) current financial information with respect to the proposed assignee or subtenant, including most recent financial statements (and Tenant shall promptly deliver to Landlord such additional information as Landlord reasonably requests). Landlord's consent to the proposed assignment or sublease shall not be unreasonably withheld, conditioned or delayed if:

- (a) there is then no uncured Event of Default by Tenant under the Lease;
  - (b) the proposed assignee or subtenant shall use the Leased Premises for the permitted uses under the Lease, and for no other purpose;
  - (c) the proposed assignee or subtenant is not engaged in the research, development, manufacturing or sale of products for the treatment of pain, provided that such products compete with products being researched, developed, manufactured or sold by Master Tenant or an Affiliate of Master Tenant; and
-

- (d) Tenant reimburses Landlord for any reasonable costs that Landlord incurs in connection with the assignment or sublease, including reasonable attorneys' fees and disbursements.

If approved by Landlord, Tenant shall provide a copy of the assignment or sublease, as applicable, to Landlord, promptly after the same is executed."

3. Amendment to Section 22.1. If Landlord delivers the Landlord Consent, then, from and after the Effective Date of the Landlord Consent, Section 22.1 of the Agreement shall, without further act or deed, be amended by deleting the notice addresses of Tenant in their entirety and substituting therefor the following:

To Tenant: Discovery Laboratories, Inc.  
700 Union Boulevard  
Totowa, New Jersey 07512

Attn: Jerry Orehostky, Vice President

Withcopy to: Discovery Laboratories, Inc.  
2600 Kelly Road  
Warrington, Pennsylvania 18976-3646

Attn: David L. Lopez, SVP and General Counsel

4. Effect of Amendment. This Amendment shall be effective as of the date hereof. Except as amended herein, the Agreement shall remain in full force and effect. To the extent of any conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall control. From the date hereof, any reference to the Agreement shall be a reference to the Agreement as amended by this Amendment.
5. Counterparts. This Amendment may be executed in one or more counterparts (including by facsimile), each of which shall be deemed an original, and all such counterparts shall constitute a single instrument.

[SIGNATURE PAGE FOLLOWS]

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EXHIBIT B

Termination and Option Agreement

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Execution Copy

## TERMINATION AND OPTION AGREEMENT

This TERMINATION AND OPTION AGREEMENT ("Agreement") is made and entered into as of December 3, 2004 by NORWELL LAND COMPANY, a New York general partnership ("Landlord") and LAUREATE PHARMA, INC. (formerly known as Biopharma Acquisition Company, Inc.), a Delaware corporation ("Tenant").

W I T N E S S E T H :

For and in consideration of the covenants herein set forth, and intending to be legally bound hereby, Landlord and Tenant hereto agree as follows:

## ARTICLE 1

## DEFINITIONS

1.1 "Closing Date" shall have the meaning specified in Section 3.4.

1.2 "FMV" shall have the meaning specified in Section 3.1.

1.3 "Historical Revenue" shall mean the revenue realized by Tenant from its operations at the Leased Premises during the twelve calendar month period immediately preceding the Termination Notice Date, which shall equal the sum of (i) the revenues received during such period from Persons which are not Affiliates of Tenant, or from Affiliates of Tenant pursuant to arm's length transactions with Tenant, plus (ii) the value of the services that Tenant has performed during such period for its internal purposes, or for any of its Affiliates with which it deals other than on an arm's length basis, which shall be calculated on the basis of the standard hourly rates charged by the Tenant to third Persons applicable for the personnel by whom such services are performed.

1.4 "Landlord's Termination Option" shall have the meaning specified in Section 2.1

1.5 "Lease" means the Agreement of Lease of even date herewith between Landlord and Tenant.

1.6 "Person" means any natural person, corporation, partnership, proprietorship, association, joint venture, trust or other legal entity.

1.7 "Projected Revenue" shall mean the revenue projected to be realized by Tenant from its operations at the Leased Premises during the twelve calendar month period immediately succeeding the Termination Notice Date, which shall equal the sum of (i) the revenues expected to be received during such period from Persons which are not Affiliates of Tenant, or from Affiliates of Tenant pursuant to arm's length transactions with Tenant, in each case pursuant to binding commitments to purchase goods or services in existence on the Termination Notice Date, plus (ii) subject to adjustment pursuant to Section 2.1(d), the value of the services that Tenant expects to perform during such period for its internal purposes, or for any of its Affiliates with which it deals other than on an arm's length basis, which shall be calculated on the basis of the standard hourly rates charged by the Tenant to third Persons applicable for the personnel by whom such services are performed.

- 1.8 "Purchase Option" shall have the meaning specified in Section 3.1.
- 1.9 "Termination Date" shall have the meaning specified in Section 2.1.
- 1.10 "Termination Notice" shall have the meaning specified in Section 2.1.
- 1.11 "Termination Notice Date" shall have the meaning specified in Section 2.1.
- 1.12 "Termination Payment" shall have the meaning specified in Section 2.1.
- 1.13 "Viable" shall have the meaning specified in Section 2.1(c).

1.14 All capitalized terms used and not defined herein shall have the meanings given to such terms in the Lease.

ARTICLE 2

TERMINATION OPTIONS

2.1 If the Master Tenant ceases or has made a decision to cease all its manufacturing activities at the Building and has so advised Landlord in writing, Landlord shall have the option (the "Landlord's Termination Option") at any time thereafter, on notice (the "Termination Notice") to Tenant as hereinafter provided, to terminate the Lease effective on a date (the "Termination Date") specified in the Termination Notice; provided that the Termination Date may not be earlier than the later of (a) two years after the date of the Termination Notice and (b) the fifth anniversary of the Commencement Date. The date on which the Tenant receives the Termination Notice is referred to herein as the "Termination Notice Date"; provided, however, that if a Termination Notice is delivered prior to the third anniversary of the Commencement Date, for all purposes of this Agreement, such Termination Notice shall be deemed to have been delivered on such third anniversary. If Landlord exercises such option, Tenant has timely vacated the Leased Premises on or before the Termination Date, and Tenant has not exercised the Purchase Option, Landlord shall pay to Tenant, within sixty (60) days after the Termination Date, a payment (the "Termination Payment") in an amount as follows:

(a) If Tenant's activities at the Leased Premises are Viable as of the Termination Notice Date, the amount of the Termination Payment shall be as follows:

<u>Termination Date</u>	<u>Amount of Payment</u>
On or after December 3, 2009 and through December 3, 2010	\$8,000,000
On or after December 3, 2010 and through December 3, 2011	\$6,000,000
On or after December 3, 2011 and through December 3, 2012	\$4,000,000
On or after December 3, 2012 and through December 3, 2013	\$2,000,000
On or after December 3, 2013 and through December 3, 2014	\$0

(b) If Tenant's activities at the Leased Premises are not Viable as of the Termination Notice Date, the amount of the Termination Payment shall be an amount equal to all actual, reasonable and customary costs to relocate and reestablish Tenant's operations at the



Leased Premises for which Tenant has presented Landlord reasonable supporting documentation including evidence that any relocated equipment will be actively used in a continuing business operated by Tenant.

(c) Tenant's activities at the Leased Premises will be deemed to be "Viable" if either Historical Revenue or Projected Revenue is greater than or equal to \$3,000,000. Tenant shall deliver Tenant's calculation of whether its activities at the Leased Premises are Viable (the "Final Viability Data") within thirty (30) days after the Termination Notice Date.

(d) The Final Viability Data shall become final and binding upon Landlord and Tenant unless, within fifteen (15) days following the submittal thereof to Landlord, Landlord notifies Tenant of its objection thereto in writing (the "Objection Notice"). If Landlord so notifies Tenant of its objection to the Final Viability Data, Landlord and Tenant shall negotiate in good faith to resolve any differences. If, within fifteen (15) days following the receipt of the Objection Notice by Landlord, any of such differences have not been resolved, Landlord and Tenant shall submit the dispute to an independent auditor reasonably acceptable to both parties. In the event the parties cannot agree upon an independent auditor within fifteen (15) days, either of the parties upon written notice to the other party hereto may request such appointment by a court having jurisdiction. Such independent auditor's opinion thereon and the resulting Final Viability Data shall be final, binding, and not subject to any appeal. The fees and expenses of such independent auditor in connection with any such resolution shall be paid one-half by Landlord and one-half by Tenant. Landlord's obligation to pay the Termination Payment shall be postponed to the date that is two (2) business days after the final determination rendered by such independent auditor.

(e) If Landlord exercises Landlord's termination right provided for in Article 14.3 of the Lease, Landlord shall pay the Termination Payment to Tenant, provided, however, that (i) the Termination Date shall be deemed to be the termination date of the Lease stated in Landlord's notice of termination given pursuant to said Article 14.3, and (ii) the Termination Payment shall be net of any insurance recoveries paid to Tenant or its Affiliates in connection with the fire or other casualty. Except as otherwise expressly contemplated by Article 13 of the Lease and as described below, Tenant shall not have any obligation to obtain insurance coverage or otherwise mitigate its damages resulting from a fire or other casualty. Tenant agrees to use commercially reasonable efforts to exercise its rights under insurance carried by it from which recoveries may be obtained in connection with any fire or other casualty giving rise to Landlord's right to terminate the Lease, the parties hereby agreeing that such efforts shall not include the obligation to litigate to obtain a recovery from an insurance carrier.

### ARTICLE 3

#### PURCHASE OPTION

3.1 In the event that Landlord exercises the Landlord's Termination Option and the Termination Date is on or before December 3, 2013, Tenant shall have the option to purchase (the "Purchase Option") all of Landlord's right, title and interest in the Building and the Building systems, the Land, the other improvements thereon and appurtenances thereto (collectively, the "Option Property").

3.2 If Tenant exercises the Purchase Option, the purchase price shall be paid on the Closing Date, by electronic wire transfer of immediately available funds pursuant to

wiring instructions given to Tenant at least two (2) business days prior to the Closing Date. The purchase price shall equal the fair market value of the Option Property ("FMV") as of the Termination Date, as determined by Landlord and Tenant within thirty (30) days of Landlord's exercise of Landlord's Termination Option or, in the absence of agreement, as provided in Section 3.9 below.

3.3 If Tenant elects to exercise the Purchase Option, Tenant must give notice of such exercise to Landlord within the later of (i) one hundred twenty (120) days after the date on which Tenant receives the Termination Notice and (ii) thirty (30) days after the date on which the purchase price for the Option Property is determined. Delivery of an exercise notice by Tenant shall vitiate the obligation of Landlord to make any payment under Section 2.1 unless Landlord defaults in closing.

3.4 If Tenant exercises the Purchase Option, the closing of the purchase shall take place on the Termination Date or such earlier date on which the parties may agree (the "Closing Date"). Tenant's notice of exercise shall be accompanied by a deposit, on account of the purchase price, equal to 10% thereof.

3.5 (a) If Landlord defaults in its obligation to sell the Option Property in accordance with the terms hereof following Tenant's exercise of the Purchase Option, Tenant's sole remedy against Landlord by reason thereof shall be (i) to bring an action seeking specific performance of Landlord's obligation to sell the Option Property as herein provided, the parties acknowledging that specific performance is an appropriate remedy under the circumstances, or (ii) to terminate this Agreement and receive the return of its deposit together with the interest thereon, and Landlord shall have the obligation to pay to Tenant the Termination Payment under Section 2.1.

(b) If Tenant defaults in its obligation to purchase the Option Property in accordance with the terms hereof (i) the Purchase Option shall thereupon expire without any further notice from Landlord and be of no further force or effect, (ii) Landlord's sole remedy against Tenant by reason thereof shall be to retain any deposit together with interest thereon as liquidated damages, the parties acknowledging that actual damages would be difficult or impossible to ascertain, and (iii) the Lease shall expire and terminate in accordance with Article 2 and Landlord shall have no obligation to make any payment under Section 2.1.

3.6 Landlord, on the Closing Date, shall convey good and marketable fee simple title to the Option Property to Tenant (or to its designee, provided Tenant so requests at least three (3) business days prior to the Closing Date) by special warranty deed, and bill of sale in the case of equipment, subject only to the Lease, the rights of subtenants under the Lease and to those matters shown on Schedule A hereto and to any lien or encumbrance created or caused by Tenant or created by Landlord at the request of Tenant (collectively, "Permitted Encumbrances"). Transfer taxes shall be divided equally. Landlord and Tenant each agrees to indemnify and hold harmless from and against any loss or liability including, but not limited to reasonable attorney's fees, resulting from a failure to pay any tax for which it is responsible. Landlord and Tenant shall each complete such tax filings as may be required and shall furnish such other documentation as may be reasonably required to consummate the sale.

3.7 Landlord shall be obligated to cure any title defects other than Permitted Encumbrances, by the use of sales proceeds for such purpose or otherwise, on or prior to the Closing Date. In the event Landlord is unable to cure such defects, Tenant shall have the option, but not the obligation to waive any such defects and purchase the Option Property subject to such

title defects without abatement of the purchase price. In the event that a condemnation of a material part of the Option Property occurs between the exercise of the Purchase Option and the Closing Date, Tenant shall have the option to rescind its exercise of the Purchase Option, and in such event the Purchase Option shall expire and be of no further force and effect and the Lease shall remain in full force and effect. The Purchase Option is coupled with the Lease and is non-transferable, except (1) to the assignee under a permitted assignment by Tenant of its interest under the Lease or (2) as provided in the last sentence of this Section 3.7. If the Purchase Option shall not have otherwise expired it shall expire and be of no further force and effect upon the expiration or earlier termination of the Lease. At the closing of the purchase, Tenant may designate a Person other than Tenant to take title to the Option Property.

3.8 The FMV is to be considered as of the Termination Date. The Building is to be considered as already occupied by a purchaser and suitable for the use of the purchaser (but consideration not to be given to the rental amount being paid under the Lease), and shall be determined by agreement of Landlord and Tenant as hereinabove provided, or in the absence of agreement, by the appraisal procedure in Section 3.9 below.

3.9 Either party may initiate the appraisal process by giving written notice to that effect to the other party and shall in such notice appoint a disinterested person of recognized competence in real estate appraisals as appraiser on its behalf. Within fifteen (15) days thereafter, the other party shall by written notice to the original party appoint a second disinterested person of recognized competence in real estate appraisals as appraiser on its behalf. Within thirty (30) days thereafter the parties shall simultaneously exchange appraisals and, if the greater appraisal is less than 10% greater than the lesser appraisal, the determined figure shall be the average of the two appraisals. If not, the appraisers thus appointed shall appoint a third disinterested person of recognized competence in real estate appraisals, such third appraiser shall prepare a third appraisal within thirty (30) days of appointment, and the determined figure shall be the average of the third appraiser's determination and the next closest appraisal; provided, however, that if the two appraisers appointed by the parties shall be unable to agree, within fifteen (15) days after the appointment of the second appraiser, upon the appointment of a third appraiser, they shall give written notice of such failure to agree to the parties, and, if the parties fail to agree upon the selection of such third appraiser within fifteen (15) days after the appraisers appointed by the parties give notice as aforesaid, then within ten (10) days thereafter, either of the parties upon written notice to the other party hereto may request such appointment by a court having jurisdiction. Landlord and Tenant shall each be entitled to present evidence and argument to the appraisers. In the event any appraiser selected in accordance with this Section 3.9 shall be unable or unwilling to act, because of death, sickness or other cause, a replacement for such appraiser shall be appointed within fifteen (15) days after such event in the same manner, and by the same party as provided in this Section 3.9 for the appointment of the original appraiser so unable or unwilling to act. Each party shall pay the fees and expenses of the appraiser appointed by such party and one-half of the other expenses (including the fees and expenses of the third appraiser) properly incurred hereunder.

#### ARTICLE 4

#### NOTICE

4.1 All notices that are required or permitted hereunder shall be in writing and shall be delivered (a) personally or (b) by "next day" courier service, addressed as follows:

To Landlord:

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Norwell Land Company  
One Stamford Forum  
Stamford, Connecticut 06901

Attn: General Counsel

To Tenant:

Laureate Pharma, Inc.  
700 Union Boulevard  
Totowa, New Jersey 07512

Attn: Christopher J. Davis

with a copy to:

Safeguard Scientifics, Inc.  
800 The Safeguard Building  
435 Devon Park Drive  
Wayne, Pennsylvania 19087

Attn: Christopher J. Davis

or elsewhere, as the respective parties may from time to time designate in writing. All notices shall be deemed given when received.

#### ARTICLE 5

##### APPLICABLE LAW AND CONSTRUCTION OF PROVISIONS

This Agreement shall be governed by and construed under the laws of the State of New Jersey. The captions used in this Agreement are for convenience only and do not in any way modify, limit or amplify the terms and provisions hereof. The language in all parts of this Agreement shall in all cases be construed according to its fair meaning and not strictly for or against either Landlord or Tenant, and the construction of this Agreement and any of its various provisions shall be unaffected by any argument or claim, whether or not justified, that it has been prepared, wholly or in substantial part, by or on behalf of either Landlord or Tenant.

#### ARTICLE 6

##### SEVERABILITY

Any provision of this Agreement that proves to be invalid, void or illegal shall in no way affect, impair, or invalidate any other provision(s) hereof, and such other provision(s) shall remain in full force and effect.

#### ARTICLE 7

##### AUTHORITY

Each individual executing this Agreement hereby represents and warrants that (a) the entity on whose behalf such individual is executing this Agreement is duly formed and validly

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existing, (b) the entity on whose behalf such individual is executing this Agreement has full right and authority to enter into this Agreement, and (c) such individual is duly authorized to execute this Agreement on behalf of such entity.

ARTICLE 8

COUNTERPARTS

This Agreement may be executed in multiple counterparts, all of which shall constitute one and the same Agreement.

ARTICLE 9

SUCCESSORS

This Agreement shall bind and inure to the benefit of the parties hereto, their respective successors, permitted assignees of the Lease, heirs, executors and administrators, subject to the provisions herein.

ARTICLE 10

WAIVER OF JURY TRIAL

**LANDLORD AND TENANT HEREBY WAIVE TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER**

**AGAINST THE OTHER ON ANY MATTER ARISING OUT OF THIS AGREEMENT.**

**ARTICLE 11**

**TIME OF THE ESSENCE**

**TIME SHALL BE OF THE ESSENCE WITH RESPECT TO ALL DATES  
AND TIME PERIODS IN THIS AGREEMENT.**

**ARTICLE 12**

**MEMORANDUM OF OPTION**

Landlord and Tenant shall enter into a short form of this Agreement for the purpose of recording the same, and shall, at Tenant's expense, record the same. The short form agreed upon by the parties is attached as Exhibit A and shall be executed contemporaneously with the execution of this Agreement.

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*[Signature Page to Termination and Option Agreement]*

IN WITNESS WHEREOF, Landlord and Tenant have executed this Agreement the day and year first above written.

TENANT:

LAUREATE PHARMA, INC.

By:  \_\_\_\_\_

Name: Christopher J. Davis

Title: Vice President & Treasurer

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[Signature Page to Termination and Option Agreement]

LANDLORD:

NORWELL LAND COMPANY

By: Connecticut Avenue Realty Co., Inc., its  
managing general partner

By: Howard R. Udell  
Name: HOWARD R. UDELL  
Title: VICE PRESIDENT and Assistant Secretary



Schedule A

Existing Matters That are Permitted Encumbrances

1. Taxes, charges and assessments: (subject to apportionment at closing)
  2. Subject to Right-of-Way Grant to The East Jersey Water Company, now known as Passaic Valley Water Commission as set forth in Deed Book V-16, page 15.
  3. Subject to Easement, Right of Way and Reservation as set forth in Deed Book Y-74, page 572.
  4. Rights of others in and to any streets, roads, avenues, lanes, highways and/or paths crossing or abutting the premises in question.
  5. Rights of others in and to any brooks, streams, drains, ditches and/or water courses abutting or crossing through the premises in question.
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Exhibit A

Short Form of Memorandum of Option

This Memorandum of Termination and Option Agreement ("Memorandum"), dated as of December 3, 2004, evidences that a Termination and Option Agreement ("Agreement"), dated as of December 3, 2004, was made and entered into by and between Norwell Land Company, a New York general partnership ("Landlord") and Laureate Pharma, Inc., a Delaware corporation ("Tenant").

The Agreement provides in part that Landlord grants to Tenant an option to purchase the property located at 700 Union Boulevard in Totowa, New Jersey (the "Property") under certain terms and conditions set forth more fully in the Agreement. The Property is further described in Exhibit A attached hereto. The option price payable by Tenant to Landlord for the Property is more particularly set forth in the Agreement. The term of the option granted by Landlord to Tenant commences on December 3, 2004 and expires if Landlord has not exercised the Landlord's Termination Option (as such term is defined in the Agreement) such that the Termination Date (as such term is defined in the Agreement) is on or before December 3, 2013. The Agreement contains no right to extend the term of the option.

The parties have executed this Memorandum as of the day and year first above written.

TENANT:

LAUREATE PHARMA, INC.

By: \_\_\_\_\_

Name:

Title:

LANDLORD:

NORWELL LAND COMPANY

By: Connecticut Avenue Realty Co., Inc., its  
managing general partner

By: \_\_\_\_\_

Name:

Title:

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Acknowledgment

State of \_\_\_\_\_ )  
 ) ss.  
County of \_\_\_\_\_ )

On this \_\_\_\_ day of \_\_\_\_\_ in the year 2004 before me,  
\_\_\_\_\_, a Notary Public of said State, duly commissioned and sworn,  
personally appeared \_\_\_\_\_, personally known to me (or proved  
to me on the basis of satisfactory evidence) to be the person who executed the within instrument  
as president (or secretary) or on behalf of the corporation therein and acknowledged to me that  
such corporation executed the same.

In Witness Whereof, I have hereunto set my hand and affixed by official seal the  
day and year in this certificate first above written.

\_\_\_\_\_  
Notary Public

[Notarial Stamp]

Acknowledgment

State of \_\_\_\_\_ )  
 ) ss.  
County of \_\_\_\_\_ )

On this \_\_\_\_ day of \_\_\_\_\_ in the year 2004 before me,  
\_\_\_\_\_, a Notary Public of said State, duly commissioned and sworn,  
personally appeared \_\_\_\_\_, personally known to me (or proved  
to me on the basis of satisfactory evidence) to be the person who executed the within instrument  
as president (or secretary) or on behalf of the corporation therein and acknowledged to me that  
such corporation executed the same.

In Witness Whereof, I have hereunto set my hand and affixed by official seal the  
day and year in this certificate first above written.

\_\_\_\_\_  
Notary Public

[Notarial Stamp]

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Exhibit A  
to  
Memorandum of Termination and Option Agreement

Property Description

BEGINNING at a point lying in the southeasterly right of way line of Union Boulevard, 75 feet in width, where the same is intersected by the southwesterly right of way line of King Road, 50 feet in width and running from the beginning point herein described, thence

1. South 46 degrees 14 minutes 10 seconds East along the southwesterly right of way line of King Road, 800 feet to a point; thence
  2. South 43 degrees 45 minutes 50 seconds West, 1126.50 feet to a point; thence
  3. North 44 degrees 30 minutes 00 seconds West, 800.37 feet to the aforementioned southeasterly right of way line of Union Boulevard; thence
  4. North 43 degrees 45 minutes 50 seconds East along the southeasterly right of way line of Union Boulevard, 1102.25 feet to the point and place of BEGINNING.
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**AMENDMENT NO. 1 TO TERMINATION AND OPTION AGREEMENT**

This AMENDMENT NO. 1 TO TERMINATION AND OPTION AGREEMENT ("Amendment") is made and entered into as of December 30, 2005 by NORWELL LAND COMPANY, a New York general partnership ("Landlord") and LAUREATE PHARMA, INC. (formerly known as Biopharma Acquisition Company, Inc.), a Delaware corporation ("Tenant").

WITNESSETH:

WHEREAS, Landlord and Tenant entered into that certain Termination and Option Agreement, dated as of December 3, 2004 (the "Agreement"); and

WHEREAS, Landlord and Tenant desire to enter into this Amendment to amend certain portions of the Agreement.

NOW, THEREFORE, in consideration of the mutual premises and promises set forth herein, the parties hereto intending to be legally bound, hereby agree and provide as follows:

1. Capitalized Terms. Capitalized terms used herein and not defined shall have the meaning ascribed to them in the Agreement.

2. Amendment to Section 1.3. Section 1.3 of the Agreement is hereby amended and restated in its entirety as follows:

"1.3 "Historical Cost of Goods Sold (HCOGS)" shall mean 150% of the cost of goods sold incurred at the Leased Premises, excluding material costs and idle plant costs, by Tenant under United States generally accepted accounting principals ("GAAP") for products approved by the FDA plus product produced for clinical trial supplies from its operations at the Leased Premises during the twelve calendar month period immediately preceding the Termination Notice Date."

3. Amendment to Section 1.7. Section 1.7 of the Agreement is hereby amended and restated in its entirety as follows:

"1.7 "Projected Cost of Goods Sold (PCOGS)" shall mean 150% of the cost of goods sold projected to be incurred at the Leased Premises, excluding material costs and idle plant costs, by Tenant under GAAP for products approved by the FDA plus product produced for clinical trial supplies from its operations at the Leased Premises during the twelve calendar month period immediately succeeding the Termination Notice Date."

4. Amendment to Section 2.1(b). Section 2.1(b) of the Agreement is hereby amended and restated in its entirety as follows:

"2.1(b) If Tenant's activities at the Leased Premises are not Viable as of the Termination Notice Date, the amount of the Termination Payment shall be an amount equal to all actual, reasonable and customary costs to relocate and reestablish Tenant's operations at the Leased Premises for which Tenant has presented Landlord reasonable supporting documentation including evidence that any relocated equipment will be actively used by Tenant to produce product approved by the FDA plus product produced for clinical trial supplies. Notwithstanding the foregoing, the Termination Payment under this Section 2.1(b) shall in no event exceed the maximum Termination Payment that would be due and payable under Section 2.1(a) if Tenant's activities were deemed Viable under Section 2.1(c)."

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5. Amendment to Section 2.1(c). Section 2.1(c) of the Agreement is hereby amended and restated in its entirety as follows:

"2.1(c) Tenant's activities at the Leased Premises will be deemed to be "Viable" if either HCOGS or PCOGS is greater than or equal to \$3,000,000. Tenant shall deliver Tenant's calculation of whether its activities at the Leased Premises are Viable (the "Final Viability Data") within thirty (30) days after the Termination Notice Date."

6. Effect of Amendment. This Amendment shall be effective as of the date hereof. Except as amended herein, the Agreement shall remain in full force and effect. To the extent of any conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall control. From the date hereof, any reference to the Agreement shall be a reference to the Agreement as amended by this Amendment.

7. Counterparts. This Amendment may be executed in one or more counterparts (including by facsimile), each of which shall be deemed an original, and all such counterparts shall constitute a single instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment the day and year first above written.

TENANT:

LAUREATE PHARMA, INC.

By: \_\_\_\_\_ /s/ Christopher J. Davis

Name: Christopher J. Davis  
Title: Vice President and Treasurer

LANDLORD:

NORWELL LAND COMPANY

By: Connecticut Avenue Realty Co., Inc., its managing general partner

By: \_\_\_\_\_ /s/ Howard R. Udell

Name: Howard R. Udell  
Title: VP and Assistant Secretary

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Annual Report (Form 10-K) of Discovery Laboratories, Inc. of our report dated January 27, 2006, with respect to the consolidated financial statements of Discovery Laboratories, Inc., included in the 2005 Annual Report to Shareholders of Discovery Laboratories, Inc.

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 No. 333-86105, Form S-3 No. 333-35206, Form S-3 No. 333-72614, Form S-3 No. 333-82596, Form S-3 No. 333-101666, Form S-3 No. 333-107836, Form S-3 No. 333-118595, Form S-3 No. 333-121297 and Form S-3 No. 333-128929) of Discovery Laboratories, Inc. and in the related Prospectuses,

(2) Registration Statements (Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-110412, Form S-8 No. 333-116268 and Form S-8 No. 333-127790) pertaining to the Amended and Restated 1988 Stock Incentive Plan of Discovery Laboratories, Inc.;

of our report dated January 27, 2006, with respect to the consolidated financial statements of Discovery Laboratories, Inc. incorporated herein by reference, and our report dated January 27, 2006, with respect to 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) of Discovery Laboratories, Inc.

/s/ Ernst & Young LLP

March 13, 2006  
Philadelphia, Pennsylvania



## CERTIFICATIONS

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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2006

By: /s/ Robert J. Capetola

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

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## CERTIFICATIONS

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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2006

By: /s/ John G. Cooper

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John G. Cooper  
Executive Vice President, Chief Financial Officer

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CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2006

/s/ Robert J. Capetola

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

/s/ John G. Cooper

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John G. Cooper  
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 SEC or its staff upon request.

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

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