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

FORM 10-K

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

For the fiscal year ended December 31, 2006

or

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

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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 o NO x

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

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

Indicate by check mark whether the registrant is 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 o Accelerated filer x Non-accelerated filer o

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

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 Global Market under the symbol DSCO on June 30, 2006, the last business day of the registrant's most recently

completed second fiscal quarter, was approximately $129 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 15, 2007 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 8, 2007, 70,502,930 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

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 2007 definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2006 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 (Exchange Act). The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; implementation of a corrective action and preventive plan to remediate manufacturing issues related to the April 2006 process validation stability failures and, following such remediation, plans with respect to the manufacture and release and stability testing of new process validation batches of Surfaxin®; plans regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Examples of the risks and uncertainties include, but are not limited to:

- the risk that we may not successfully develop and market our products, and even if we do, we may not become profitable;
- risks relating to the progress of our research and development;
- risks relating to significant, time-consuming and costly research and development efforts, including pre-clinical studies, clinical trials and testing, and the risk that clinical trials may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for any products that we may develop independently, with our development partners or in connection with our collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we file or limit such applications to particular indications or apply other label limitations;
- risks that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;
- risks that we will not timely and successfully resolve the Chemistry, Manufacturing and Controls (CMC) and current Good Manufacturing Practices-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other SRTs presently under development, including those identified in connection with our process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- risks that the CMC section of our NDA will not satisfy the FDA;
- risks relating to our own drug manufacturing operations and the drug manufacturing operations of our third-party suppliers and contract manufacturers;
- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and aerosolization systems and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;

- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully manufacture and commercialize products that combine our drug products with innovative aerosolization technologies;
- risks that financial market conditions may change, additional financings could result in equity dilution, or the Company will be unable to maintain the Nasdaq Global Market listing requirements, causing the price of the Company's shares of common stock to decline;
- the risk that we will not be able to raise additional capital or enter into additional strategic alliances and collaboration arrangements (including strategic alliances in support of our aerosol and other Surfactant Replacement Therapies (SRT));
- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- risks relating to our ability to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all;
- the risk that we or our marketing partners will not succeed in developing market awareness of our products;
- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- risks relating to the maintenance, protection and expiry of the patents and licenses related to our SRT and the potential development of competing therapies and/or technologies by other companies;
- risks relating to the impact of securities, product liability, and other litigation or claims that have been and may be brought against the Company and its officers and directors;
- risks relating to reimbursement and health care reform; and
- other risks and uncertainties detailed in "Risk Factors" and in the documents incorporated by reference in this report.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. 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 our forward-looking statements, whether resulting from new information, future events or otherwise.

DISCOVERY LABORATORIES, INC.
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For the Fiscal Year Ended December 31, 2006

PART I

ITEM 1. BUSINESS.

COMPANY OVERVIEW AND BUSINESS STRATEGY

Discovery Laboratories, Inc., which we refer to as "we," "us," or the "Company," is a Delaware corporation with our principal offices located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania. Our telephone number is 215-488-9300 and our website address is www.discoverylabs.com. Our common stock is listed on the Nasdaq Global Market, where our symbol is DSCO.

We are a biotechnology company developing our proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory disorders and 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), Pediatric Intensive Care Unit (PICU), critical care unit and other hospital settings, where there are few or no approved therapies available.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU. We have filed a NDA with the FDA for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, we received an Approvable Letter from the FDA in connection with this NDA. We are also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf™ is our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU, we also believe that our SRT potentially will address a variety of debilitating respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, such as Acute Respiratory Failure (ARF), cystic fibrosis, Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), chronic obstructive pulmonary disorder (COPD), asthma and other debilitating respiratory conditions.

We are implementing a business strategy that includes:

- undertaking actions intended to gain regulatory approval for Surfaxin for the prevention of RDS in premature infants in the United States, including: (i) finalizing and submitting our response to the April 2006 Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA; and (ii) completing analysis and remediation of manufacturing issues related to the April 2006 Surfaxin process validation stability failure;

- continued investment in the development of our SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);

- continued investment in enhancements to our quality systems and SRT manufacturing operations, acquired in December 2005, to produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin and our other SRT product candidates, beginning with Aerosurf, and potentially to develop new and enhanced formulations of Surfaxin and our other SRT product candidates. Our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities and entering into arrangements with outside contract manufacturing organizations for the production of our precision-engineered SRT drug products; and

- seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. We continue to evaluate a variety of potential strategic alternatives including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure that we will enter into any specific actions or transactions.

SURFACTANT TECHNOLOGY

Our precision-engineered surfactant replacement technology was invented at The Scripps Research Institute and was exclusively licensed to Johnson & Johnson, Inc. (Johnson & Johnson) which 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. Numerous studies have established that, of the four known surfactant proteins, surfactant protein B (SP-B) is essential for respiratory function.

Presently, the FDA has approved surfactants as replacement therapy only for premature infants with RDS, a condition in which infants, due to premature birth, have an insufficient amount of their own natural surfactant. The most commonly used of the approved 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 only one approved synthetic surfactant; 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 from minced cow or pig lung using a chemical extraction process. Because of the animal-sourced materials and the chemical extraction processes, there potentially can be significant variation in production lots. 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 likely 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 surfactant has the potential 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 to treat broader populations for RDS and other respiratory diseases, more consistently and less expensively than the animal-derived surfactants and with 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 brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”).

We have demonstrated through research and feasibility studies that we can aerosolize our SRT at the proper particle size and with the fluid dynamics capable of penetrating the deep lung. 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 to be 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 for the Prevention of 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 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).

RDS afflicts approximately 120,000 premature infants in the United States annually, with a global at-risk population in excess of 500,000 infants. Only approximately 75,000 infants are treated annually in the United States with currently-available surfactant products, all of which are animal-derived.

We conducted a Phase 3 pivotal trial (SELECT) for the prevention of RDS in premature infants, which formed the basis of the NDA that we filed with the FDA in April 2004. The SELECT 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 was responsible for monitoring the overall safety of the trial and no major safety issues were identified.

We also conducted a supportive, multinational, multicenter, prophylaxis, randomized, controlled masked, Phase 3 clinical trial (STAR) which enrolled 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf®, a porcine (pig) derived surfactant and the leading surfactant used in Europe. The STAR trial demonstrated the overall safety and non-inferiority of Surfaxin to Curosurf.

Data from the SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR trials, as well as a pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*, the Official Journal of the American Academy of Pediatrics and a premier medical journal for pediatric healthcare practitioners.

In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested information primarily focused on the chemistry, manufacturing and controls (CMC) section of the NDA, predominately involving the further tightening of active ingredient and drug product specifications and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our contract manufacturer, Laureate Pharma, Inc. (Laureate) as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. On December 21, 2006, we attended a meeting with the FDA, the purpose of which was to clarify the issues identified by the FDA in the Approvable Letter and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. Following that meeting and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing. This stability data is expected to support our formal response to the Approvable Letter, which we presently anticipate filing in September or October 2007. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants.

In June 2006, we voluntarily withdrew the Marketing Authorization Application (MAA) filed in October 2004 with the European Medicines Agency (EMEA) for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMEA procedure. Our withdrawal of the MAA precluded final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials, which had been the focus of a recent EMEA clinical expert meeting and were expected to be reviewed at a planned Oral Explanation before the Committee for Medicinal Products for Human Use (CHMP) in late June 2006. We plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe.

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 for the Prevention of Bronchopulmonary Dysplasia

BPD, also known as Chronic Lung Disease, is a costly syndrome affecting many 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 prevent and treat RDS, babies require a surfactant usually within the first hours of birth and 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. The cost of treating an infant with BPD in the United States is estimated to approach $250,000. Approximately 100,000 infants are at risk for BPD in the United States and Europe each year.

In October 2006, we announced preliminary results of our recently completed Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD. The BPD Phase 2 clinical trial was a double-blind, controlled trial designed to enroll up to 210 very low birth weight premature infants born at risk for developing BPD. Total enrollment in the trial was 136 premature infants who received either Surfaxin standard dose (175 mg/kg), Surfaxin low dose (90 mg/kg), or a control. The study's objective was to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD but was not powered to determine statistically significant differences in outcomes. Key preliminary findings observed in this Phase 2 BPD trial include: a positive acute pharmacological response to Surfaxin therapy evidenced by a reduction in supplemental oxygen and ventilatory support; a lower incidence of death or BPD in patients receiving the Surfaxin standard dose compared with control (57.8% vs. 65.9%, respectively); a higher survival rate through 36 weeks post-menstrual age in patients receiving the Surfaxin standard dose compared with control (88.9% vs. 84.1%, respectively); a reduction in duration of mechanical ventilation (approximately four less days) and of the need for supplemental oxygen in patients receiving the Surfaxin standard dose compared with control; and Surfaxin therapy was generally safe and well tolerated with generally no differences between the Surfaxin treatment groups and the control group in common complications of prematurity. By chance, infants assigned to the Surfaxin low dose treatment group were significantly sicker, with more pre-existing medical risk factors, such that the data from this treatment group cannot be easily interpreted and no meaningful conclusions can be drawn. We believe that the results suggest that Surfaxin potentially may represent a novel therapeutic option for infants at risk for BPD.

Comprehensive analysis of the data from this trial is ongoing. Following this analysis, in collaboration with our Steering Committee and Investigators, we expect to present the study results to the medical community and submit the data for publication in a peer review journal as well as determine the next development steps for this program.

In June 2006, the FDA granted Orphan Drug designation to Surfaxin for the prevention of BPD in premature infants. The FDA previously designated Surfaxin as an Orphan Drug for the treatment of BPD in premature infants. In January 2006, the FDA granted 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.

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 more than 1 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 insertion of 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 nCPAP intended to treat premature infants at risk for respiratory failure. 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 using a commercially-available aerosolization device (Aeroneb Pro®) 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 to develop and commercialize our aerosolized SRT to address a broad range of serious respiratory conditions. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two highly complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to deliver therapeutics to the deep lung.

Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU with RDS. We are presently collaborating with Chrysalis on the development of a prototype aerosolization system to deliver Aerosurf to patients in the NICU and, if successful, plan to initiate multiple Phase 2 clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in the second half of 2007.

Products for the Critical Care Unit and other Hospital Settings

Surfaxin for Acute Respiratory Distress Syndrome in Adults

ARDS is a life-threatening disorder for which there is no approved therapy. ARDS is characterized by an excess of fluid in the lungs, destruction of surfactants naturally present in lung tissue, and decreased oxygen levels (measured by a decrease in the P/F ratio (PaO2/FiO2), discussed below) in the patient. The disorder is caused by various illnesses and events, including pneumonia, gastric aspiration, near drowning, smoke inhalation, lung contusions (collectively known as Direct ARDS causes) and sepsis (a toxic condition caused by infection), pancreatitis, major surgery, trauma, and severe burns (collectively known as Indirect ARDS causes).

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 30% to 40%.

In March 2006, we announced preliminary results of a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of ARDS in adults. Patients were randomized to receive either our SRT administered in high concentrations and large volumes via a proprietary sequential lavage technique (lung wash), or the current standard of care (SOC), which is mechanical ventilation and other supportive therapies. Surfactant was delivered with a bronchoscope to each of the 19 segments of the lung and was intended to cleanse and remove inflammatory substances and debris from the lung, while leaving sufficient amounts of surfactant behind to help re-establish the lung's capacity to absorb oxygen. The trial was designed to enroll up to 160 patients and was structured in two parts. Total enrollment in the trial was 124 patients. Part A focused on dose escalation and safety and enrolled 22 patients. Part B, which focused on safety and efficacy, included 113 patients, 11 of which were from Part A.

The objective of the surfactant lavage was to restore functional surfactant levels in the patients' lungs, thereby improving oxygenation (measured by an increase the P/F ratio), in order to remove critically ill patients from mechanical ventilation sooner. The primary endpoint was the incidence rate of patients alive and off mechanical ventilation at Day 28. Secondary endpoints included all-cause mortality at Day 28, and safety and tolerability of surfactant and the bronchoscopic lavage procedure.

The key preliminary results of this trial included: surfactant lavage exhibited a positive pharmacologic effect manifested as improved oxygenation, demonstrated by an acute increase in the P/F ratio after patients received surfactant lavage; clinically and statistically significant increases were observed in the P/F ratio at 24 hours after surfactant lavage, compared with SOC (59.7%, 53.4%, 22.5% for Dose Groups A and B, and SOC, respectively; p=0.004 and p=0.036, for Dose Groups A and B, respectively, versus SOC); all-cause mortality at Day 28 was 12% and 21% for patients in Dose Group A (n=34) and Dose Group B (n=43), respectively, and 17% for the combined Dose Groups (n=77) versus 14% for patients who received SOC (n=36); for those patients who responded to the surfactant lavage (defined as patients who had an increase in their P/F ratio of greater than 50%; n=36 combined Dose Groups A and B), all-cause mortality at Day 28 was observed to be approximately 8%; the incidence of being alive and off mechanical ventilation at Day 28 was 71% and 72% for patients in Dose Group A (n=34) and Dose Group B (n=43), respectively, and 71% for the combined Dose Groups (n=77) versus 81% for patients who received SOC (n=36); and there were no meaningful differences noted in the clinical outcomes in patients classified as having Direct or Indirect ARDS.

P/F ratio is a measurement of the efficiency of oxygen exchange at the alveolar level, where P (PaO_2) is the partial pressure of oxygen in arterial blood and F (FiO_2) is the fraction of inspired oxygen, defining the amount of supplemental oxygen in excess of normal room air (21% oxygen). A healthy individual with normal lung function has a P/F ratio greater than 425, whereas an acutely ill patient with ARDS has a P/F ratio less than 200. In other words, a low P/F ratio indicates that a patient is very ill and requires very high supplemental oxygen concentrations in order to maintain adequate blood oxygenation (PaO_2).

We plan to submit data from the study for publication in a peer review journal. We also plan to seek potential partners, with which we can apply the scientific and clinical observations generated from this trial to support the design of potential future trials to treat ARDS.

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 Medicinal Product designation for our SRT for the treatment of ALI in adults (which in this circumstance encompasses ARDS).

Surfaxin and Aerosolized SRT for Other Respiratory Indications

We are also evaluating the potential development of our proprietary precision-engineered SRT to address respiratory disorders such as ARF, cystic fibrosis, ALI, COPD, asthma, and other debilitating respiratory conditions. We plan on initiating clinical studies in 2007 for certain of these respiratory disorders.

Research and Development

In addition to our current focus in the areas described above, we continually evaluate our research and development priorities in light of a number of factors, including our cash flow requirements and financial liquidity, the availability of third party funding, advances in technology, the results of ongoing development projects and the potential for development partnerships and collaborations. As a result of such evaluations, we modify and adapt our research and development plans from time to time and anticipate that we will continue to do so. We recorded research and development expenses of $23.7 million, $24.1 million and $25.8 million during the years ended December 31, 2006, 2005 and 2004, respectively.

STRATEGIC ALLIANCES

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as neonatal respiratory failure, ALI, cystic fibrosis, chronic obstructive respiratory disorder, asthma, and others. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to deliver 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. We and Chrysalis are utilizing our respective capabilities and resources to support and fund the design and development of combination 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 aerosolization device platform, disposable dose packets and patient interface. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination 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, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. We are also planning an adult program utilizing the Chrysalis aerosolization technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI and will be assessing the timing for implementation of our adult program in 2007.

Laboratorios del Dr. Esteve, S.A.

In December 2004, we further restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. We had first entered into the alliance in 1999 and had revised it in 2002 to broaden the territory to include all of Europe, Central and South America, and Mexico. Under the revised alliance, we have regained full commercialization rights to our SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults, in key European markets, Central America and South America. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay us a transfer price on sales of Surfaxin and other SRT. 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. We also agreed to pay to Esteve 10% of cash up-front and milestone fees (not to exceed $20 million in the aggregate) 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. 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 Dompé farmaceutici s.p.a. (Dompé), a privately owned Italian company. Under the sublicense agreement, Dompé will be responsible for sales, marketing and distribution of Surfaxin in Italy.

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. We have received an exclusive, worldwide license and 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 license and sublicense give 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 that 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 been granted 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 2009 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.

In January of 2006, we filed U.S. and International patent applications (US 11/326885 and PCT/US06/00308), directed to a surfactant treatment regimen for BPD.

In September of 2006, we filed a U.S. provisional patent application (US 60/845,991) directed to surfactant compositions and methods of promoting mucus clearance and treating pulmonary disorders such as cystic fibrosis.

In November of 2006, we filed foreign national applications in Australia, Canada, Europe and Japan, based on our aforementioned international application (PCT US/2005/0178184) directed to systems, devices and methods for non-invasive pulmonary delivery of aerosolized surfactant.

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, through our strategic alliance with Chrysalis to develop and commercialize aerosol SRT, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to enable the delivery of therapeutics to the deep lung. Our alliance provides for monitoring inventions and seeking patent protection for innovations related to both Chrysalis' aerosolization technology and our surfactant technology. Our license rights to the Chrysalis technology extends to innovations to the aerosolization technology that are made in connection with the alliance. With these proprietary rights, we believe that our aerosol SRT will potentially address a broad range of serious respiratory conditions, such as neonatal respiratory failure, ALI, cystic fibrosis, chronic obstructive respiratory disorder, asthma, and others. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Corporate Partnership Agreements - Chrysalis Technologies, a Division of Philip Morris USA Inc."

See "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 develop and 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 compliance with current general manufacturing practices (cGMPs) established by the FDA and other international regulatory authorities. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients.

Our product candidates are manufactured by combining raw materials, such as sinapultide, which is provided by BACHEM California, Inc., and PolyPeptides Laboratories, Inc., and other active ingredients, including certain lipids that are provided by suppliers such as Genzyme Pharmaceuticals, a division of the Genzyme Corporation and Avanti Polar Lipids.

Our manufacturing facility is located in Totowa, NJ and consists of approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMPs. In December 2005, we purchased these operations from Laureate, our contract manufacturer at that time and entered into a transitional services arrangement under which Laureate agreed to provide us with certain limited manufacturing-related support services through December 2006. In July 2006, we completed transferring the Laureate support activities to our facility and terminated the transitional arrangement with Laureate.

Owning the Totowa operation has provided us with direct operational control and, we believe, potentially improved economics for the production of clinical and potential commercial supply of our lead product, Surfaxin, and our SRT pipeline products. This facility is the only facility in which we produce our drug product. We view our acquisition of the Totowa operations as an initial step of our long-term manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

Prior to our acquisition of the Totowa operations, in connection with its review of our NDA for Surfaxin for the prevention of RDS in premature infants, the FDA, in January 2005, 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, Laureate and we implemented improved quality systems and documentation controls.

In April 2006, we received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested information primarily focused on the CMC section of the NDA and predominately involving the further tightening of active ingredient and drug product specifications and related controls. At the same time, the FDA concluded a re-inspection of the manufacturing facility in Totowa and issued a second Form 483 citing inspectional observations related predominantly to the clarification of procedures, documentation and preventative maintenance.

Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our then contract manufacturer, Laureate, as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues. See “Risk Factors - The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances, our business could suffer.”

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. On December 21, 2006, we attended a meeting with the FDA, the purpose of which was to clarify the issues identified by the FDA in the Approvable Letter and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. Following that meeting and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing. This stability data is expected to support our formal response to the Approvable Letter, which we presently anticipate filing in September or October 2007. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants.

The lease for our Totowa, NJ facility extends through December 2014. In addition to customary lease 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, which may require us to move out of our Totowa, NJ facility as early as December 2009, our long-term manufacturing strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products.

Manufacturing - SRT Aerosolization Systems

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. The alliance focuses initially on therapies for hospitalized patients, including those in the NICU, PICU and ICU, and can be expanded into other hospital applications and ambulatory settings. The resulting product candidates will combine our proprietary precision-engineered SRT with Chrysalis’ aerosolization device technology. “See Management’s Discussion and Analysis of Financial Condition and Results of Operations - Corporate Partnership Agreements - Chrysalis Technologies, a Division of Philip Morris USA Inc.”

To manufacture aerosolization systems for our planned clinical trials, we expect to utilize third-party contract manufacturers, suppliers and assemblers. The manufacturing process will require assembly of the key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, the disposable dose delivery packet and patient interface system necessary to administer our aerosolized SRT in patients in the NICU and ICU. We expect that third-party vendors will manufacture these key device sub-components, and ship them to one central location for assembly and integration into the aerosolization system. Once assembled, critical/product contact components and/or assemblies are packaged and sterilized. Each of the aerosolization systems will be quality-control tested prior to release for use in our clinical trials or, potentially, for commercial use. To complete the combination drug-device product, we plan to manufacture the SRT drug product at our Totowa, NJ facility. See “Risk Factors - The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances, our business could suffer.”

We are planning to have manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential 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 Aerosurf. Our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

Distribution

We are currently manufacturing Surfaxin as a liquid instillate that requires cold-chain storage and distribution. We plan on entering into appropriate distribution arrangements to commercialize Surfaxin, if approved, in the U.S.

Our collaboration with Esteve provides that Esteve has responsibility for distribution of our SRT in Andorra, Greece, Italy, Portugal and Spain. In other parts of the world, we plan to evaluate third-party distribution capabilities prior to commercializing in those regions.

COMPETITION

We are engaged in highly competitive fields of pharmaceutical research and development. 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 “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. Curosurf® is a porcine (pig) lung extract that is marketed in Europe by Chiesi Farmaceutici s.p.a., and in the United States by Dey Laboratories, Inc. Survanta®, marketed by the Ross division of Abbott Laboratories, Inc., is derived from minced cow lung that contains the cow version of surfactant protein B. Forest Laboratories, Inc., markets its calf lung surfactant extract, Infasurf®, in the United States. There is presently only one approved synthetic surfactant available, Exosurf®, marketed by GlaxoSmithKline, plc. However, this product does not contain any surfactant proteins and it is not widely used. The manufacturer of Exosurf has discontinued marketing this product.

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 and 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 normally are conducted 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 clinical trials of a new drug product are completed, the drug sponsor must obtain FDA and foreign regulatory authority marketing approval. After an NDA is submitted, FDA approval generally takes from one to three years. If questions arise during the FDA review process, approval may take significantly longer. 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 we were to obtain regulatory clearances, a marketed product is highly regulated and subject to continual review. A post-approval 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. To market our drug products outside the United States, we also will be subject to foreign regulatory requirements governing human clinical trials and required to obtain foreign marketing approvals. 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 has been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any of our products under development. If we do not obtain the requisite governmental approvals or if we fail to obtain approvals of the scope we request, we or our licensees or marketing partners may be delayed or precluded entirely from marketing our products, or the commercial use of our products may be limited. Such events would have a material adverse effect on our business, financial condition and results of operations. See "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.

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 and the treatment and prevention of BPD in premature infants. Additionally, our SRT has received designation as an Orphan Medicinal Product for ALI (which, in this circumstance, encompasses ARDS) from the EMEA.

EMPLOYEES

We have approximately 100 full-time employees, primarily employed in the United States. In connection with our manufacturing operation in Totowa, NJ, we have entered into collective bargaining arrangements, expiring December 2009, with respect to several employee classifications affecting 16 of our current employees. See “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 through our website our annual, quarterly and current reports, proxy statements and other information filed or furnished pursuant to Section 13(a) or 15(d) the Exchange Act as soon as reasonably practicable after we have filed it electronically with, or furnished it to, the SEC.

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.

You should carefully consider the following risks and any of the other information set forth in this Annual Report on Form 10-K and in the documents incorporated herein by reference, before deciding to invest in shares of our common stock. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. 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. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you may lose all or part of your investment.

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 before 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, 2006, we have an accumulated deficit of approximately million $248.3 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.

Refocusing our business subjects us to risks and uncertainties.

When we received our second Approvable Letter from the FDA in April 2006, we revised our expectations with respect to the timing of potentially gaining approval for Surfaxin for the prevention of RDS in premature infants. Since then, we continue to reassess the business environment, our position within the biotechnology industry and our relative strengths and weaknesses. As a result of this reassessment and as part of our revised overall business strategy, we implemented significant changes to our operations. For example, we reduced the size of our workforce and made changes to senior management. We will consider additional changes to our business as we seek to strengthen financial and operational performance. These changes may disrupt our established organizational culture and systems. In addition, consideration and planning of strategic changes diverts management attention and other resources from day to day operations.

We may fail to realize the benefits that we expect from our cost-savings initiatives.

We have undertaken and expect to continue to undertake cost-savings initiatives. However, we cannot assure you that we will realize anticipated cost savings or any other benefits from these initiatives. Even if we realize the benefits of our cost savings initiatives, any cash savings that we achieve may be offset by other costs, such as costs related to ongoing development activities and pre-clinical and clinical studies. Staff reductions or failure to increase our staff on a timely basis may result in our workforce being at levels below that needed to effectively manage our business and advance our development programs. Our failure to realize the anticipated benefits of our cost-savings initiatives could have a material adverse effect on our business, results of operations and financial condition.

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.

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, in manufacturing the product, we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable testing data are generated by clinical trials of drug products, the FDA or a foreign regulator, such as the EMEA, may not accept or approve an NDA, a MAA or other similar application filed with a foreign regulator. To market our products or conduct clinical trials outside the United States, we also must comply with foreign regulatory requirements governing marketing approval for pharmaceutical products and the conduct of human clinical trials.

Following our meeting with the FDA on December 21, 2006, and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing. This stability data is expected to support our formal response to the Approvable Letter, which we presently anticipate filing in September or October 2007. At that time, the FDA will advise us if it will accept our response to the Approvable Letter as a complete response. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants. Even if the FDA accepts our response as a complete response, the FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

In June 2006 we voluntarily withdrew the MAA that we had filed with the EMEA for Surfaxin for the prevention and rescue treatment of RDS in premature infants. Our withdrawal precluded final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials, which had been the focus of a recent EMEA clinical expert meeting and were expected to be reviewed at a planned Oral Explanation before the CHMP in late June 2006. Although we plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe, we cannot assure you that we will ever file another MAA with the EMEA for Surfaxin for the prevention and rescue of RDS in premature infants, or for any other indication, and if we do file an MAA in the future, that the EMEA will approve such MAA.

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. Without regulatory approval, we will not be able to market our products. Further, even if we were to succeed in gaining regulatory approvals for any of our products, the FDA or a foreign regulator could withdraw any approvals granted 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, or 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.

Receipt of the April 2006 Approvable Letter and the process validation stability failure had the effect of significantly delaying the review of our NDA for Surfaxin for the prevention of RDS in premature infants. See "Business - Surfactant Therapy for Respiratory Medicine - Products for the neonatal intensive care unit - *Surfaxin for the Prevention of Respiratory Distress Syndrome in Premature Infants*." Based on guidance received from the FDA at a meeting held in December 2006, we believe we now have a path to potentially gain approval for Surfaxin for the prevention of RDS in premature infants, and have recently completed manufacture of new process validation batches. We believe that we are on track to file our response to the Approvable Letter in September or October 2007. See "Business - Manufacturing and Distribution - Manufacturing - Precision-Engineered Surfactant." We anticipate providing the FDA information that responds to the CMC issues identified in the Approvable Letter as well as other data that demonstrates that we have remediated our manufacturing issues and are able to manufacture Surfaxin comparable to the Surfaxin drug product used in our statistically significant pivotal Phase 3 trial. Ultimately, the FDA may not accept our responses to the Approvable Letter and 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 affect 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. 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. 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 that 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.

The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also periodically inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We, our contract manufacturers or our materials suppliers may experience manufacturing or quality control problems that could result in product production and shipment delays or a situation where we, our contract manufacturers or our suppliers may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, which is necessary to continue manufacturing our drug products or drug substances. Manufacturing or quality control problems have already and may again occur at our Totowa, NJ facility or may occur at the facilities of a contract manufacturer or our materials suppliers. Such problems, including, for example, our April 2006 process validation stability failure, require potentially complex, time-consuming and costly investigations to determine the root causes of such problems and may also require detailed and time-consuming remediation efforts, which can further delay the regulatory review and approval process. 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, NJ. See "Business - Manufacturing and Distribution - Manufacturing - Precision-Engineered Surfactant. With this acquisition, we are manufacturing our products. We currently own certain specialized manufacturing equipment, employ experienced manufacturing senior executive and managerial personnel, and we plan to continue investing in enhanced quality systems and manufacturing capabilities. However, we may be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards for use in clinical studies or commercialization. If we do not successfully develop our manufacturing capabilities and comply with cGMPs, it will adversely affect the sales of our products.

In connection with the development of aerosol formulations of our SRT, including Aerosurf, we expect to rely on third-party contract manufacturers to manufacture, assemble and integrate the subcomponents of the Chrysalis aerosolization systems to support our clinical studies and potential commercialization of Aerosurf. Certain of these key components must be manufactured in a sterile environment and each of the aerosolization systems must be quality-control tested prior to release and monitored for conformance to designated product specifications. The manufacturer, assembler and integrator must be registered with the FDA and must conduct its manufacturing activities in compliance with cGMP requirements or similar requirements of foreign regulators. We may be unable to identify qualified manufacturers to manufacture the subcomponents or to assemble and integrate the aerosolization systems to our specifications for use in clinical studies or, if approved, commercialization. In addition, the manufacturers and assembler and integrator that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, requirements regulating the manufacture of combination drug device products. If we do not successfully identify and enter into a contractual agreements with aerosolization systems and components manufacturers, it will adversely affect the timeline of our plans for development, including, potentially, initiation of our planned Phase 2 clinical trials, and, if approved, commercialization of Aerosurf.

If the parties we depend on for supplying our active drug substance 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 active drug substances and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards for use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. The manufacturing process for the Aerosurf combination drug-product devices includes the integration of a number of products, many of which are comprised of a large number of subcomponent parts that we expect will be produced by potentially a number of manufacturers. We and our suppliers may not be able to (i) produce our drug substances, drug product or drug product devices or related subcomponent parts 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 suppliers, 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.

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 fail to 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.

If we or Esteve or its sublicensee breach or terminate the strategic alliance agreements that make up our collaboration arrangements or if Esteve or its sublicensee 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 covered products in the territory.
Additionally, if we or Chrysalis breach or terminate the agreements that make up our collaboration arrangements to develop and commercialize SRT to address a broad range of serious repiratory conditions, or if Chrysalis otherwise fails to conduct its development activities in a timely manner or if there is a dispute about our respective obligations under the collaboration, to continue the development of our aerosolized SRT, we may need to seek other partners or we may have to undertake our own development activities without a collaboration arrangement.

Accordingly, if our current collaboration arrangements fail to timely meet our objectives, we may need to enter into additional collaboration agreements and our success 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 the covered products.

We may, in the future, grant to our present or additional collaboration partners rights to license and commercialize our pharmaceutical products. Under these arrangements, our collaboration partners may control key decisions relating to the development and commercialization of the covered products. By granting such rights to our collaboration partners, we would likely limit our flexibility in considering alternatives for the development and commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop, market 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.

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. We have developed operating plans to require that expenditures will only be committed if we have the necessary working capital resources. If we are unable to obtain additional capital when needed, on acceptable terms, we have determined that we have the ability to adjust our expenditures to ensure that our existing capital will allow us to continue operations through at least January 1, 2008. 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 new capital lease arrangements, if available. In some cases, we may elect to develop products on our own instead of entering into collaboration arrangements, which would increase our cash requirements for research and development.

Our equipment lease financing arrangement with GECC expired on October 31, 2006. We continue to engage in discussions with GECC and we are considering alternative arrangements with other financing entities; however, we cannot assure you that our discussions with GECC will continue or that any alternative arrangements will be successfully concluded. Even if we are successful in arranging for property and lease financing arrangements, there is no assurance that such arrangements will be on terms that are favorable to us or sufficient to meet our capital financing needs over the term of the arrangement. If we do not obtain additional capital financing, we may not be able to execute on our business plan, in particular our manufacturing strategy, and be forced to delay or scale back our activities.

We continue to consider multiple strategic alternatives, including, but not limited to potential additional financings as well as potential business alliances, commercial and development partnerships and other similar opportunities, although we cannot assure you that we will enter into any further specific actions or transactions.

If we seek additional financing, such additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to complete any desired financings, we may have to delay, scale back or discontinue certain of our research and development operations, or 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 "Risk Factors: Our Committed Equity Financing Facilities 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 Global Market.

The terms of our indebtedness may impair our ability to conduct our business.

Our capital requirements are funded in part with an $8.5 million loan with PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp. (Quintiles), which is secured by substantially all of our assets and contains a number of covenants and restrictions that, with certain exceptions, restricts our ability to, among other things, incur additional indebtedness, borrow money or issue guarantees, use assets as security in other transactions, and sell assets to other companies. We may not be able to engage in these types of transactions, even if we believe that a specific transaction would be in our best interests. Moreover, our ability to comply with these restrictions could be affected by events outside our control. A breach of any of these restrictions could result in a default under the PharmaBio loan documents. If a default were to occur, PharmaBio would have the right to declare all borrowings to be immediately due and payable. If we are unable to pay when due amounts owing to PharmaBio, whether at maturity or in connection with acceleration of the loan following a default, PharmaBio would have the right to proceed against the collateral securing the indebtedness.

In addition, the aggregate amount of our indebtedness may adversely affect our financial condition, limit our operational and financing flexibility and negatively impact our business. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources-Debt.”

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

The issuance of shares of our common stock under the CEFF and upon exercise of the warrants we issued to Kingsbridge 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% to the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Kingsbridge sells to third parties the shares of our common stock that we issue to Kingsbridge under the CEFF, 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 the CEFF and we may not be able to issue any portion of the shares potentially available for issuance for future financings, subject to the terms and conditions of the CEFF. Kingsbridge has the right under certain circumstances to terminate the CEFF, including in the event of a material adverse event. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any inability on our part to use the CEFF or any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

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 by patients;
- 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;
- changes in the United States or foreign political environment and the passage of laws, including tax, environmental or other laws, affecting the product development business;
- 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 these “Risk Factors.”

Our common stock is listed for quotation on The Nasdaq Global Market. During the twelve month period ended December 31, 2006, the price of our common stock has ranged from $1.16 to $8.60. 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, 2006, the average daily trading volume in our common stock was approximately 1,057,000 shares and the average number of transactions per day was approximately 2,500. 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 Nasdaq Global Market. If the common stock were no longer listed on The Nasdaq Global Market, investors might only be able to trade 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. Such an action is currently pending against us and certain of our former and current executive officers. In addition, a related derivative action naming certain of our directors and executive officers is also pending. See “Legal Proceedings.” Even if they or other actions that we may face in the future are ultimately determined to be meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

We expect that we will require significant additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of our common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. As of March 8, 2007, we had 70,502,930 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 375,000 shares of our common stock that are currently reserved for issuance with respect to the Class B Investor Warrant and approximately 8 million shares of our common stock that are currently reserved for issuance under the CEFF, including 490,000 shares reserved for issuance with respect to the Class C Investor Warrant. See “Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of December 31, 2006, 11,268,888shares of our common stock are reserved for issuance pursuant to our Amended and Restated 1998 Stock Option Plan (including 10,690,160 shares underlying outstanding stock options and 59,991 shares underlying unvested restricted stock awards), 6,525,018 shares of our common stock are reserved for issuance upon exercise of outstanding warrants, and 323,956 shares of our common stock are reserved for issuance pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, 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. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

If, during the term of certain of our warrants, we declare or make any dividend or other distribution of our assets to holders of shares of our common stock, by way of return of capital or otherwise (including any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement or other similar transaction), then the exercise price of such warrants may adjust downward and the number of shares of common stock issuable upon exercise of such warrants would increase. As a result, we may be required to issue more shares of common stock than previously anticipated, which could result in further dilution of our existing stockholders.

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, 2006, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 18% of the issued and outstanding shares of our common stock. For the purpose of computing this amount, an affiliated entity includes any entity that is known to us to be the beneficial owner of more than five percent of our issued and outstanding common stock. 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.

Our technology platform is based solely on our proprietary precision-engineered surfactant technology.

Our technology platform is based solely on the scientific rationale of using our precision-engineered surfactant technology 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.

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 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. In addition, 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, even 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 us any protection against competitors.

The patents that we hold also have a limited life. We have licensed a series of patents from Johnson & Johnson and its wholly owned subsidiary, Ortho McNeil Pharmaceutical Inc. (Ortho Pharmaceutical), which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. These 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 enhanced or additional products or processes that will be patentable under patent law and, if we do enhance or develop additional products that we believe are patentable, additional patents may not be issued to us. See also “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 depends upon our ability to operate our business 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 in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities.

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 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 our confidential information to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, such agreements can be difficult and costly to enforce. Although we generally seek to enter into these types of agreements with our consultants, advisors and research collaborators, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. If a dispute were to arise enforcement of our rights could be costly and the result unpredictable. In addition, we also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our employees, consultants, advisors or others.

Despite the protective measures we employ, we still face the risk that:

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

We do not have marketing and sales experience and our lack of experience may restrict our success in marketing and selling our product candidates.

We do not presently have our own expertise in marketing or selling pharmaceutical products. As a result of our manufacturing problems, we discontinued our commercial activities in the second quarter of 2006. To achieve commercial success, we will have to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates. These arrangements could involve developing our own internal marketing and sales capabilities, entering into arrangements with others to market and sell our products, or a combination of the foregoing.

Developing an internal marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process and requires a substantial capital investment. Recruiting, training and retaining qualified sales personnel would be 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 our products. We also may be unable to provide adequate incentive to our sales force. If we were unable to successfully attract, motivate and expand a sales and marketing force, we would have difficulty selling, maintaining and increasing the sales of our products.

We also may be unable to establish satisfactory arrangements with third parties for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates. To obtain the expertise necessary to successfully market and sell Surfaxin, or any other product, will likely require the development of collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our 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.

To market and distribute our products, 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 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.

If we develop an internal sales and marketing expertise, we may also need to enter into 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 such parties fail to perform, it could adversely affect sales of our products. We and 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.

In the event that we receive the necessary regulatory approvals, we intend to market and sell Surfaxin through one or more marketing partners, potentially both in the Unites States and 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 its sublicensees or the resources they may 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, as a result, we may not receive any revenues from it. Also, we may not be able to enter into marketing and sales agreements for Surfaxin on acceptable terms, if at all, 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, Robert J. Capetola, Ph.D., 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 our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

To lower our cost structure and re-align our operations with business priorities, in April 2006, we reduced our staff levels and reorganized our corporate structure. The workforce reduction totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on our commercial infrastructure. Included in the workforce reduction were three senior executives. As a consequence of this reduction in force, our dependence on our remaining management team is increased. If we find it necessary or advisable to hire additional managers, a portion of the expected cost savings from our recent restructuring might not be realized.

In 2006, to retain and provide incentives to certain of our key executives, we entered into amended and new employment agreements with our executive management and other officers that generally provide for such employment terms as a stated term, enhanced severance benefits in the event of a change of control and equity incentives in the form of stock and option grants, as well as non-competition covenants and provide for severance payments that are contingent upon the employee's refraining from competition with us. The favorable terms provided may not be sufficient to retain our management personnel, and the restrictive 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. 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.

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

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

The clinical testing of, marketing and use of our products exposes us to product liability claims if 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 coverage of up to $10 million per occurrence and $10 million in the aggregate. 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 before initiating 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 the availability or cost of insurance generally and 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 payers, which include governmental health administration authorities, managed care providers and private health insurers. Third party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services. Moreover, the current political environment in the United States and abroad may result in the passage of significant legislation that could, among other things, restructure the markets in which we operate and restrict pricing strategies of drug development companies. If, for example price restrictions were placed on the distribution of drugs such as our SRT, we may be forced to curtail development of our pipeline products and this could have a material adverse effect on our business, results of operations and financial condition. Even if we succeed in commercializing our SRT, uncertainties regarding health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities or at prices, that will enable us to achieve profitability.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law could defer a change of our management and thereby 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, before 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.

The failure to prevail in litigation or the costs of litigation, including securities class action and patent claims, could harm our financial performance and business operations.

We are potentially susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws, as well as derivative actions. In particular, in early May 2006, four shareholder class actions and two derivative actions were filed in the United States District Court for the Eastern District of Pennsylvania naming as defendants the Company and certain of its current and former executive officers and directors. In the class actions, following dismissal without prejudice on November 1, 2006 of a Consolidated Amended Complaint, plaintiffs filed a Second Consolidated Amended Complaint on November 30, 2006 and on December 22, 2006, defendants filed a Motion to Dismiss the Second Consolidated Amended Complaint. The court has yet to rule on defendants' motion. In the derivative actions, which name our Chief Executive Officer, Robert J. Capetola, our former Chief Operating Officer, Christopher J. Schaber, and four of our five non-employee directors, plaintiffs filed a Consolidated Amended Complaint on December 29, 2006. Defendants filed a Motion to Dismiss on January 26, 2007. The court granted defendants' motion to dismiss on March 15, 2007. See "Legal Proceedings."

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

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

In addition, as The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending, we cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our patents or patent applications for our product candidates may give rise to a declaration of interference by the United States Patent and Trademark Office, or to administrative proceedings in foreign patent offices, or that our activities lead to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking substantial damages or seeking to enjoin us from conducting research and development activities.

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 Exchange Act.

ITEM 2. PROPERTIES.

For our principal offices, we lease 39,594 square feet of office space located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622 at an annual rent of approximately $922,000 per year. We do not own any real property. The term of this lease expires in February 2010, subject to a right to extend for an additional period of 5 years.

We lease 21,000 square feet of space for our manufacturing facility in Totowa, NJ at an annual rent of $150,000 per year. The term of this lease expires in December 2014, subject to an early termination right in the landlord, first beginning in December 2009, exercisable upon two years' prior notice and, in the earlier years, payment of significant early termination amounts.

We lease approximately 5,600 square feet of space in Doylestown, Pennsylvania for our analytical laboratory. The term of this lease expires in August 2007 and thereafter is extendable on a month-to-month basis.

We lease 16,800 square feet at our research facility in Mountain View, California, at an annual rent of approximately $275,000 per year. We use this facility principally to develop aerosolized and other formulations of our proprietary precision-engineered surfactant. The term of this lease expires in June 2008.

ITEM 3. LEGAL PROCEEDINGS.

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased the Company's publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by the Company. The amended complaint had been filed on November 30, 2006 against the Company, its Chief Executive Officer, Robert J. Capetola, and its former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief.

In each of May and June 2006, a shareholder derivative complaint was filed in the United States District Court for the Eastern District of Pennsylvania against certain of our directors and executive officers. In July 2006, these actions were consolidated under the caption "In re:Discovery Laboratories Derivative Litigation." The consolidated actions were initially subject to a stipulation agreement between the parties deferring defendants' obligation to respond to the complaints until after the filing of defendants' answer or a dispositive ruling on defendants' Motion to Dismiss the class actions, described above. Nevertheless, in response to an order issued by the court on November 28, 2006, plaintiffs filed a Consolidated Amended Complaint on December 29, 2006, naming as defendants our Chief Executive Officer, Robert J. Capetola, and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, all directors of the Company, and Christopher J. Schaber, our former Chief Operating Officer. To cure a jurisdictional defect, Mr. McDade was dismissed from the action on January 29, 2007. The Consolidated Amended Complaint alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, which were alleged to have occurred between 2005 and April 2006. The plaintiffs generally seek an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. Defendants filed a Motion to Dismiss on January 26, 2007, plaintiffs filed opposition papers on February 13, 2007 and defendants filed a motion for leave to file a reply memorandum, with an accompanying reply memorandum, on February 16, 2007.

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

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

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 2006.

PART II

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

Certain of the information required by Item 5(a) (performance graph) 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.

Our common stock is traded on the Nasdaq Global Market under the symbol “DSCO.” As of March 2, 2007, the number of stockholders of record of shares of our common stock was 142 and the number of beneficial owners of shares of our common stock was approximately 14,000. As of March 7, 2007, there were 70,502,930 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.

	Low	High
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	$ 6.66	$ 8.60
Second Quarter 2006	$ 1.16	$ 7.40
Third Quarter 2006	$ 1.47	$ 2.40
Fourth Quarter 2006	$ 2.00	$ 3.18
First Quarter 2007 (through March 7, 2007)	$ 1.90	$ 2.90

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

During the twelve months ended December 31, 2006, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options.

There were no stock repurchases in the twelve months ended December 31, 2006.

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, 2006, 2005 and 2004 and with respect to the Consolidated Balance Sheets as of December 31, 2006 and 2005 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, 2003 and 2002 and the balance sheet data as of December 31, 2004 and 2003 and 2002 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,				
	2006	**2005**	**2004**	**2003**	**2002**
Revenues from collaborative agreements	$ -	$ 134	$ 1,209	$ 1,037	$ 1,782
Operating Expenses:					
Research and development	23,716	24,137	25,793	19,750	14,347
General and administrative	18,386	18,505	13,322	5,722	5,458
Restructuring charges	4,805	-	8,126	-	-
In-process research and development	-	16,787	-	-	-
Total expenses	46,907	59,429	47,241	25,472	19,805
Operating loss	(46,907)	(59,295)	(46,032)	(24,435)	(18,023)
Other income and (expense)	574	391	(171)	155	580
Net loss	$ (46,333)	$ (58,904)	$ (46, 203)	$ (24,280)	$ (17,443)
Net loss per common share - basic and diluted	$ (0.74)	$ (1.09)	$ (1.00)	$ (0.65)	$ (0.64)
Weighted average number of common shares outstanding	62,767	54,094	46,179	37,426	27,351

Consolidated Balance Sheet Data:
(in thousands)

	For the year ended December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
Cash and investments	$ 27,002	$ 50,908	$ 32,654	$ 29,422	$ 19,152
Working capital	19,599	33,860	24,519	23,061	16,277
Total assets	34,400	56,008	37,637	32,715	21,062
Long-term obligations, less current potion	12,110	3,562	7,583	711	1,706
Total stockholder’s equity	$ 14,322	$ 34,838	$ 21,097	$ 24,303	$ 14,761

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 "Exhibits and Financial Statement Schedules."

OVERVIEW

We are a biotechnology company developing our proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory disorders and 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), Pediatric Intensive Care Unit (PICU), critical care unit and other hospital settings, where there are few or no approved therapies available.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU. We have filed a NDA with the FDA for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, we received an Approvable Letter from the FDA in connection with this NDA. We are also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf™ is our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU, we also believe that our SRT potentially will address a variety of debilitating respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, such as Acute Respiratory Failure (ARF), cystic fibrosis, Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), chronic obstructive pulmonary disorder (COPD), asthma and other debilitating respiratory conditions.

We are implementing a business strategy that includes:

- undertaking actions intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, including (i) finalizing and submitting our response to the April 2006 Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA; and (ii) completing analysis and remediation of manufacturing issues related to the April 2006 process validation stability failure;

- continued investment in the development of our SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);

- continued investment in enhancements to our quality systems and our manufacturing capabilities, including our operations in Totowa, NJ (which we acquired in December 2005). We plan to (i) produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial needs of Surfaxin and our other SRT product candidates, beginning with Aerosurf, and (ii) potentially develop new and enhanced formulations of Surfaxin and our other SRT product candidates. We view the acquisition of our own manufacturing operation as an initial step in our long-term manufacturing strategy. Our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered SRT drug products; and

- seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. In June 2006, we engaged Jefferies & Company, Inc., a New York-based investment banking firm, under an arrangement that expires in June 2007, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised $10 million in a private placement transaction. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

Since our inception, we have incurred significant losses and, as of December 31, 2006, we had an accumulated deficit of $248.3 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities and, during 2005 and the first half of 2006, also include significant general and administrative expense, primarily pre-commercialization activities. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.”

Historically, we have funded our operations with working capital provided principally through public and private equity financings, debt arrangements and strategic collaborations. As of December 31, 2006, we had: (i) cash of $27.0 million; (ii) approximately 8.0 million shares potentially available for issuance under the CEFF with Kingsbridge for future financings (not to exceed $42.5 million), subject to the terms and conditions of the agreement; (iii) $8.9 million outstanding ($8.5 million principal and $0.4 million of accrued interest as of December 31, 2006) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp. (Quintiles), which, after a recent restructuring, is due and payable, together with all accrued interest, on April 30, 2010; and (iv) $4.7 million outstanding on a capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), which expired on October 31, 2006, of which an aggregate of $7.9 million was drawn during the life of the facility. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.”

RESEARCH AND DEVELOPMENT

Research and development expenses for the years ended December 31, 2006, 2005 and 2004 were $23.7 million, $24.1 million, and $25.8 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, formulation development, manufacturing development, clinical and regulatory operations and other direct preclinical and clinical projects. 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 Formulation Development

Research and formulation development activities, primarily conducted at our operations located in California, reflect research and development of aerosolized and other related formulations of our precision-engineered lung surfactant, engineering of aerosol delivery systems and analytical chemistry activities to support the continued development of Surfaxin. Research and formulation development 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: (1) costs associated with operating our manufacturing facility in Totowa, NJ (which we acquired from our then-contract manufacturer, Laureate Pharma, Inc. (Laureate) in December 2005) to support the production of clinical and anticipated commercial drug supply for the Company’s SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; and (2) continued investment in our quality assurance and analytical chemistry capabilities, including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding the operations to meet production needs for our SRT pipeline in accordance with cGMP. In addition, manufacturing activities include expenses associated with our ongoing comprehensive investigation, analysis of the April 2006 Surfaxin process validation stability failure and remediation of the Company’s related manufacturing issues.

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 Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include pre-clinical activities associated with the development of SRT formulations prior to the initiation of any potential human clinical trials and activities associated with conducting clinical trials, including 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, 2006, 2005 and 2004:

(Dollars in thousands)	**Year Ended December 31,**		
Research and Development Expenses:	**2006** [1]	**2005**	**2004**
Research and formulation development	$ 2,040	$ 2,211	$ 2,916
Manufacturing development	10,057	11,416	7,010
Unallocated development - clinical and regulatory operations	8,248	7,274	8,588
Direct pre-clinical and clinical program expenses	3,371	3,236	7,279
Total Research and Development Expenses	**$ 23,716**	**$ 24,137**	**$ 25,793**

(1) Included in research and development expenses for the year ended December 31, 2006 is a charge of $1.6 million associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

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. The status and anticipated completion date of each of our lead SRT programs are discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.” Successful completion of development of our SRT is contingent on numerous risks, uncertainties and other factors, some of which are described in detail in “Risk Factors.”

Development risk factors include, but are not limited to:

- Completion of pre-clinical and clinical trials of our SRT product candidates with scientific results that are sufficient to support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant active drug substances on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Obtaining strategic partnerships and collaboration agreements for the development of our SRT pipeline, including Surfaxin and Aerosurf;
- Performance of our third-party collaborators and suppliers on whom we rely for supply of drug substances, medical device components and related services necessary to manufacture our SRT drug product candidates, including Surfaxin and Aerosurf;
- Timely and successful resolution of the Chemistry, Manufacturing and Controls (CMC) and cGMP-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other SRTs presently under development, including those we have identified in connection with our recent process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- Successful manufacture of SRT drug product candidates, including Surfaxin, at our operations in New Jersey;
- Successful development and implementation of a manufacturing strategy for the Chrysalis aerosolization device and related materials to support clinical studies and commercialization of Aerosurf; and
- Obtaining additional manufacturing operations, for which we presently have limited resources.

Because these factors, many of which are outside our control, could have a potentially significant effect on our activities, 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 and generate revenues from the sale of our products, such a failure would have a material adverse effect on our value, financial condition and results of operations.

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as neonatal respiratory failure, ALI, cystic fibrosis, chronic obstructive respiratory disorder, asthma, and others. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to deliver 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. We and Chrysalis are utilizing our respective capabilities and resources to support and fund the design and development of combination 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 aerosolization device platform, disposable dose packets and patient interface. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination 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, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. We are also planning an adult program utilizing the Chrysalis aerosolization technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI and will be assessing the timing for implementation of our adult program in 2007.

Laboratorios del Dr. Esteve, S.A.

In December 2004, we further restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. We had first entered into the alliance in 1999 and had revised it in 2002 to broaden the territory to include all of Europe, Central and South America, and Mexico. Under the revised alliance, we have regained full commercialization rights to our SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults, in key European markets, Central America and South America. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay us a transfer price on sales of Surfaxin and other SRT. 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. We also agreed to pay to Esteve 10% of cash up-front and milestone fees (not to exceed $20 million in the aggregate) 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. 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 Dompé farmaceutici s.p.a. (Dompé), a privately owned Italian company. Under the sublicense agreement, Dompé will be responsible for sales, marketing and distribution of Surfaxin in Italy.

PLAN OF OPERATIONS

We have incurred substantial losses since inception and expect to continue to expend substantial amounts for continued product research, development, manufacturing, and general business activities.

We anticipate that during the next 12 to 24 months:

Research and Development

We will focus our research, development and regulatory activities in an effort to develop a pipeline of potential SRT for respiratory diseases. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the applicable risks discussed in "Risk Factors." See "Management's Discussion and Analysis - Research and Development."

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.

Surfaxin for the Prevention of RDS in Premature Infants

In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested information primarily focused on the chemistry, manufacturing and controls (CMC) section of the NDA, predominately involving the further tightening of active ingredient and drug product specifications and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our contract manufacturer, Laureate Pharma, Inc. (Laureate) as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. On December 21, 2006, we attended a meeting with the FDA, the purpose of which was to clarify the issues identified by the FDA in the Approvable Letter and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. Following that meeting and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing. This stability data is expected to support our formal response to the Approvable Letter, which we presently anticipate filing in September or October 2007. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants.

In June 2006, we voluntarily withdrew the Marketing Authorization Application (MAA) filed in October 2004 with the European Medicines Agency (EMEA) for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMEA procedure. Our withdrawal of the MAA precluded final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials, which had been the focus of a recent EMEA clinical expert meeting and were expected to be reviewed at a planned Oral Explanation before the Committee for Medicinal Products for Human Use (CHMP) in late June 2006. We plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe.

Surfaxin for BPD in Premature Infants

In October 2006, we announced preliminary results of our recently completed Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD.

Comprehensive analysis of the data from this trial is ongoing. Following this analysis, in collaboration with our Steering Committee and Investigators, we expect to present the study results to the medical community and submit the data for publication in a peer review journal as well as determine the next development steps for this program.

Aerosurf, Aerosolized SRT

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 using a commercially-available aerosolization device (Aeroneb Pro®) 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.

We are presently collaborating with Chrysalis on the development of a prototype aerosolization system to deliver Aerosurf to patients in the NICU and, if successful, plan to initiate multiple Phase 2 clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in the second half of 2007. See "*Surfaxin for the Prevention of RDS in Premature Infants,"* above.

SRT for Critical Care and Hospital Indications

In March 2006, we announced preliminary results of a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of ARDS in adults. The trial was designed to enroll up to 160 patients and was structured in two parts. Total enrollment in the trial was 124 patients.

The objective of the surfactant lavage was to restore functional surfactant levels in the patients' lungs, thereby improving oxygenation (measured by an increase the P/F ratio), in order to remove critically ill patients from mechanical ventilation sooner. We plan to submit data from the study for publication in a peer review journal. We also plan to seek potential partners, with which we can apply the scientific and clinical observations generated from this trial to support the design of potential future trials to treat ARDS.

We are also evaluating the potential development of our proprietary precision-engineered SRT to address respiratory disorders such as ARF, cystic fibrosis, ALI, COPD, asthma, and other debilitating respiratory conditions. We plan on initiating clinical studies in 2007 for certain of these respiratory disorders.

Manufacturing

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

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

Manufacturing - New Jersey Operations

In December 2005, we purchased our manufacturing operations from Laureate (our contract manufacturer at that time) and entered into a transitional services arrangement under which Laureate agreed to provide us with certain limited manufacturing-related support services through December 2006. In July 2006, we completed the transition and terminated the arrangement with Laureate.

Owning the Totowa operation has provided us with direct operational control and, we believe, potentially improved economics for the production of clinical and potential commercial supply of our lead product, Surfaxin, and our SRT pipeline products. This facility is the only facility in which we produce our drug product. We view our acquisition of the Totowa operations as an initial step of our long-term manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

I in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our then contract manufacturer, Laureate, as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. Following a meeting with the FDA on December 21, 2006, and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing.

Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential 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 Aerosurf.

We view our acquisition of manufacturing operations in Totowa, NJ as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our Totowa, NJ facility extends through December 2014. In addition to customary lease 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, which may cause us to move out of our Totowa, NJ facility as early as December 2009, our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

Aerosol Devices and Related Componentry

To manufacture aerosolization systems for our planned clinical trials, we expect to utilize third-party contract manufacturers, suppliers and assemblers. The manufacturing process will require assembly of the key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, the disposable dose delivery packet and patient interface system necessary to administer our aerosolized SRT in patients in the NICU and ICU. We expect that third-party vendors will manufacture these key device sub-components, and ship them to one central location for assembly and integration into the aerosolization system. Once assembled, critical/product contact components and/or assemblies are packaged and sterilized. Each of the aerosolization systems will be quality-control tested prior to release for use in our clinical trials or, potentially, for commercial use. To complete the combination drug-device product, we plan to manufacture the SRT drug product at our Totowa, NJ facility.

See the applicable risks discussed in “Risk Factors.”

General and Administrative

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

Potential Collaboration Agreements and Strategic Partnerships

We intend to seek investments of additional capital and potentially enter into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. We have engaged Jefferies & Company, Inc., a New York-based investment banking firm, under an arrangement that expires in June 2007, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised $10 million in a private placement transaction. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability. Through December 31, 2006, 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, 2006, we had not generated taxable income. On December 31, 2006, net operating losses available to offset future taxable income for Federal tax purposes were approximately $229.8 million. The future utilization of such loss carryforward may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we had a research and development tax credit carryforward of $5.2 million at December 31, 2006. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 through 2026.

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 “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, 2006, 2005 and 2004 were $46.3 million (or $0.74 per share), $58.9 million (or $1.09 per share) and $46.2 million (or $1.00 per share), respectively.

For each year ending December 31, 2006, 2005 and 2004, we incurred a charge that was identified separately on our statements of operations. In 2006, we incurred a restructuring charge of $4.8 million (or $0.08 per share) related to staff reductions and the close out of certain pre-launch commercial programs. In 2005, we purchased our manufacturing operations in Totowa, NJ for $16.0 million and incurred additional related expenses of $0.8 million ($16.8 million charge or $0.31 per share), which was classified on the Statement of Operations as In-Process Research and Development. In 2004, we incurred non-cash charges totaling $8.1 million (or $0.18 per share) associated with the restructuring of strategic collaborations with Quintiles and Esteve.

Additionally, on January 1, 2006, we adopted Statement of Financial Accounting Standards (Statement) No. 123(R) using the modified prospective method, which resulted in the recognition of stock-based compensation expense totaling $5.5 million (or $0.09 per share) in the statement of operations for the year ended December 31, 2006, without adjusting the prior years.

Excluding these charges, the net loss for the year ended December 31, 2006, 2005 and 2004 was $36.0 million (or $0.57 per share), $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, 2006, 2005 and 2004 were $0, $0.1 million, and $1.2 million, respectively. These revenues are primarily associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in Southern Europe. The primary changes in revenues from 2006, 2005 and 2004 are due to the restructuring of our corporate partnership with Esteve in December 2004 (primarily as it relates to funding of development costs).

Research and Development Expenses

Research and development expenses for the years ended December 31, 2006, 2005 and 2004 were $23.7 million, $24.1 million, and $25.8 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, 2006, 2005 and 2004 primarily reflects:

(i) manufacturing development activities (included in research and development expenses) to support the production of clinical and commercial drug supply for our SRT programs, including Surfaxin, in conformance with cGMPs. Expenses related to manufacturing development activities were $10.1 million, $11.4 million, and $7.0 million for the years ended December 31, 2006, 2005 and 2004, respectively.

For 2006, manufacturing development activities included: (i) operating costs associated with our manufacturing operations in Totowa, NJ (which we acquired in December 2005), such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; (ii) continued investment in our quality assurance and analytical chemistry capabilities, including enhancements to quality controls, process assurances and documentation requirements that support the production process; and (iii) expanding the operations to meet production needs for our SRT pipeline in accordance with cGMP. In addition, manufacturing activities include expenses associated with our ongoing comprehensive investigation and analysis of the April 2006 Surfaxin process validation stability failure and development of a corrective action and preventative action plan to remediate the related manufacturing issues. Also, there was a charge of $0.5 million included in manufacturing development activities for the year ended December 31, 2006 associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

For 2005, manufacturing development activities included (i) costs associated with contract manufacturing services provided by our then contract manufacturer, Laureate; (ii) expenses incurred to implement 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) to respond FDA Form 483 inspectional observations; (iii) enhancements and improvements to Laureate’s Totowa, NJ operations and facility for the production of Surfaxin, SRT formulations and aerosol development capabilities; and (iv) other manufacturing related costs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services. In December 2005, we purchased the manufacturing operation of Laureate in Totowa, NJ For 2004, manufacturing development activities included: (i) the transfer and validation of our manufacturing equipment to Laureate (completed in 2004) for the production of Surfaxin and other SRT formulations; (ii) costs associated with contract manufacturing services provided by Laureate; and (iii) other manufacturing related costs, such as employee expenses, depreciation, quality control and assurance activities, and analytical services.

(ii) direct pre-clinical and clinical program activities related to the advancement of our SRT pipeline. Expenses related to these activities were $3.4 million, $3.2 million and $7.3 million for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 versus 2005 is primarily due to pre-clinical activities associated with the development of Aerosurf for neonatal respiratory disorders and regulatory activities associated with Surfaxin for the prevention of RDS in premature infants, offset by the conclusion of activities, in March 2006, associated with the Phase 2 trial for ARDS in adults. The decrease in 2005 versus 2004 is primarily due to costs in 2004 associated with clinical and regulatory activities for Surfaxin for the prevention of RDS in premature infants, 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.

(iii) clinical and regulatory operations to manage multiple clinical studies related to the advancement of our SRT pipeline. Expenses related to these activities were $8.2 million, $7.3 million and $8.6 million for the years ended December 31, 2006, 2005 and 2004, respectively. These costs are primarily associated with clinical trial management, clinical quality control and regulatory compliance activities, data management and biostatistics, and scientific and medical affairs activities. The increase in 2006 versus 2005 is primarily due to a charge of $1.0 million in 2006 associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R). The decrease in 2005 versus 2004 is primarily related to the use in 2004 of external consultants and temporary help associated with the filing of the Surfaxin NDA.

(iv) research and formulation development activities associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and engineering of aerosol delivery systems for our SRT pipeline. Expenses related to these activities were $2.0 million, $2.2 million and $2.9 million for the years ended December 31, 2006, 2005 and 2004, respectively. In 2006, research and formulation activities were focused on development of aerosolized and other SRT formulations, including Aerosurf for neonatal respiratory disorders. The decrease over the three-year period is primarily related to the conclusion of research efforts and funding associated with The Scripps Research Institute agreement, which expired in February 2005.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2006, 2005 and 2004 were $18.4 million, $18.5 million and $13.3 million, respectively. General and administrative expenses consist primarily of the costs of executive management, finance and accounting, business and commercial development, legal, human resources, information technology, facility and other administrative costs. General and administrative expenses also included, in 2005 and the first half of 2006, pre- launch commercial activities and, in 2006, legal costs to defend the pending securities class actions and derivative proceedings.

Included in general and administrative expenses for the years ended December 31, 2006, 2005 and 2004 were $5.9 million, $10.1 million, $5.9 million, respectively, associated with pre-launch commercialization activities in anticipation of the potential approval and launch of Surfaxin for the prevention of RDS in premature infants in the second quarter of 2006. The change in expenses associated with pre-launch commercialization activities primarily reflects the build-up in 2005 and the discontinuance of commercial activities, in the second quarter of 2006, following receipt of the April 2006 Approvable Letter and the Surfaxin process validation stability failure. The costs associated with the discontinuance of commercial activities are a component of the 2006 Restructuring Charge. Additionally, there was a charge of $0.5 million included in pre-launch commercialization activities for the year ended December 31, 2006 associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

General and administrative expenses, excluding pre-launch commercialization activities, were $12.5 million, $8.4 million, and $7.4 million for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 versus 2005 was primarily due to a charge of $3.4 million in 2006 associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R). Additionally, the increases from 2004 through 2006 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.

2006 Restructuring Charge

In April 2006, we reduced our staff levels and reorganized corporate management to lower our cost structure and re-align our operations with changed business priorities. These actions were taken following the April 2006 Surfaxin process validation stability failure, which caused us to revise our expectations concerning the timing of potential FDA approval and pre-launch commercial launch of Surfaxin for the prevention of RDS in premature infants. Included in the workforce reduction were three senior executives. The reduction in workforce totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on our commercial infrastructure. All affected employees were eligible for certain severance payments and continuation of benefits. Additionally, certain pre-launch commercial programs were discontinued and related costs will no longer be incurred. Such commercial program expenses totaled approximately $5.0 million for the fourth quarter of 2005 and first quarter of 2006.

We incurred a restructuring charge of $4.8 million in the second quarter of 2006 associated with the staff reductions and close-out of certain pre-launch commercial programs, which was accounted for in accordance with Statement No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* and is identified separately on the Statement of Operations as Restructuring Charge. This charge included $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain pre-launch commercial programs. As of December 31, 2006, payments totaling $3.9 million had been made related to these items and $0.9 million were unpaid. Of the $0.9 million that was unpaid as of December 31, 2006, $0.7 million was included in accounts payable and accrued expenses and $0.2 million was classified as a long-term liability.

2005 In-Process Research & Development

In December 2005, we purchased Laureate's manufacturing operations in Totowa, NJ for $16.0 million and incurred additional related expenses of $0.8 million. We are using this facility for pharmaceutical manufacturing and development activities. We believe this acquisition was a logical way to implement a long-term manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

The manufacturing facility in Totowa, NJ consists of 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 cGMP requirements. There are approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the facility. In October 2003, we entered into a manufacturing agreement with Laureate, pursuant to which the transfer of our Surfaxin manufacturing know-how and dedicated equipment to this facility was completed in 2004. From that time and until our acquisition of the operation in December 2005, the facility was predominantly dedicated to Surfaxin and the support of regulatory compliance requirements for our manufacturing operations.

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 Statement No. 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 financed $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.

2004 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 November 2004, we restructured our business arrangements with Quintiles and terminated our commercialization agreement for Surfaxin in the United States, thereby regaining full commercialization rights for Surfaxin in the United States. In consideration for regaining commercialization rights to 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 is exercisable only for cash, with expected total proceeds to us, if exercised, of 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 loan with PharmaBio, which was also amended, remained available with $8.5 million outstanding. The original maturity date of December 10, 2004 has been twice amended such that the outstanding principal and all unpaid interest is now payable on April 30, 2010. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Debt.”

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 alliance, we have regained full commercialization rights to our SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults, in key European markets, Central America and South America. 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, 2006, 2005 and 2004 were $0.6 million, $0.4 million and ($0.2) million, respectively.

Interest and other income for the years ended December 31, 2006, 2005 and 2004 was $2.1 million, $1.3 million, and $0.4 million, respectively. The increase in 2006 versus 2005 is primarily due to the $0.6 million of proceeds from the sale of our Commonwealth of Pennsylvania research and development tax credits and a general increase in earned market interest rates, offset by a lower average cash balance. The increase in 2005 versus 2004 is primarily due to a higher average cash balance and a general increase in interest rates.

Interest, amortization and other expenses for the years ended December 31, 2006, 2005 and 2004 was $1.5 million, $1.0 million and $0.6 million, respectively. The increases are primarily due to higher outstanding balances with our loan and capital lease financing arrangements and a general increase in the prime borrowing rate. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.”

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

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

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

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

- the issuance of equity and debt financings;
- payments from potential strategic collaborators, including license fees and sponsored research funding;

- sales of Surfaxin, if approved;
- sales of our other product candidates, if approved;
- capital lease financings; and
- interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of the product development and commercialization plan. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability. There is no assurance that we will be able to obtain additional capital when needed with acceptable terms, if at all. These factors could significantly limit our ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have developed operating plans that ensure expenditures will only be committed if we have the necessary cash resources. If we are unable to obtain additional capital when needed, on acceptable terms, we have determined we have the ability to adjust our expenditures to ensure that our existing capital will allow us to continue operations through at least January 1, 2008.

We have engaged Jefferies & Company, Inc., a New York-based investment banking firm, under an arrangement that expires in June 2007, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised $10 million in a private placement transaction. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

We have a CEFF that allows us to raise capital, subject to certain conditions that we must satisfy, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions (discussed at “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility” below), including a limitation on the total number of shares of common stock that we may issue under the CEFF (approximately 7.0 million shares were available for issuance under the CEFF as of March 16, 2007). We anticipate using the CEFF, when available, to support working capital needs in 2007.

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2006, we had cash, cash equivalents, restricted cash and marketable securities of $27.0 million, as compared to $50.9 million as of December 31, 2005. The change from December 31, 2005, is primarily due to $39.8 million used in operating activities, $1.4 million used to purchase capital expenditures and $1.7 million used to pay principal payments on capital lease arrangements. These cash outflows were offset by cash inflows, which primarily consisted of: (i) a private placement of 4,629,630 shares resulting in net proceeds of $9.5 million; (ii) three financings pursuant to the CEFF resulting in the issuance of 3,654,902 shares and net proceeds of $7.4 million; (iii) $1.5 million of financing associated with capital lease arrangements; and (iv) $0.7 million received from the exercise of stock options and warrants.

Committed Equity Financing Facility

In April 2006, we entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of our common stock. Our previous Committed Equity Financing Facility, which was with Kingsbridge, entered in July 2004 (2004 CEFF) and under which up to $47.6 million remained available, automatically terminated on May 12, 2006, the date on which the SEC declared effective the registration statement filed in connection with the CEFF. As of December 31, 2006, there were approximately 8.0 million shares available for issuance under the CEFF for future financings (not to exceed $42.5 million in gross proceeds).

The CEFF allows us to raise capital, subject to certain conditions that we must satisfy, at the time and in amounts deemed suitable to us, during a three-year period that began on May 12, 2006. We are not obligated to utilize the entire $50 million available under this CEFF.

The purchase price of shares sold to Kingsbridge under the CEFF is at a discount ranging from 6 to 10 percent of the volume weighted average of the price of our common stock (VWAP) for each of the eight trading days following our initiation of a "draw down" under the CEFF. The discount on each of these eight trading days is determined as follows:

VWAP*	% of VWAP (Applicable Discount)	
Greater than $10.50 per share	94%	(6)%
Less than or equal to $10.50 but greater than $7.00 per share	92%	(8)%
Less than or equal to $7.00 but greater than or equal to $2.00 per share	90%	(10)%

* As such term is set forth in the Common Stock Purchase Agreement.

If on any trading day during the eight trading day pricing period for a draw down, the VWAP is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, no shares will be issued with respect to that trading day and the total amount of the draw down will be reduced by one-eighth of the draw down amount we had initially specified.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of our outstanding shares of our common stock at the time of the draw down or $10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. In addition, Kingsbridge may terminate the CEFF under certain circumstances, including if a material adverse effect relating to our business continues for 10 trading days after notice of the material adverse effect.

In 2006, in connection with the 2006 CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant is exercisable for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.8 million.

In May 2006, we completed a financing pursuant to the CEFF resulting in proceeds of $2.2 million from the issuance of 1,078,519 shares of our common stock at an average price per share, after the applicable discount, of $2.03.

In October 2006, we completed a financing pursuant to the CEFF resulting in proceeds of $2.3 million from the issuance of 1,204,867 shares of our common stock at an average price per share, after the applicable discount, of $1.91.

In November 2006, we completed a financing pursuant to the CEFF resulting in proceeds of $3 million from the issuance of 1,371,516 shares of our common stock at an average price per share, after the applicable discount, of approximately $2.19.

In February 2007, we completed a financing pursuant to the CEFF resulting in proceeds of $2 million from the issuance of 942,949 shares of our common stock at an average price per share, after the applicable discount, of $2.12.

As of March 16, 2007, there were approximately 7.0 million shares available for issuance under the CEFF for future financings (not to exceed $40.5 million in gross proceeds).

In 2004, in connection with the 2004 CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to $12.0744 per share. The warrant, which expires in January 2010, is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds, if exercised, of approximately $4.5 million. As of December 31, 2006, the Class B Investor Warrant had not been exercised.

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 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 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $80 million of equity or debt securities. There can be no assurance, however, that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our research and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

Debt

Payments due under contractual debt obligations at December 31, 2006, including principal and interest, are as follows:

(in thousands)	2007	2008	2009	2010	Total
Loan with PharmaBio	$ —	$ —	$ —	$ 11,641	$ 11,641
Capital lease obligations - GECC	1,595	1,006	467	198	3,266
Note Payable - GECC	833	833	438	33	2,137
Total	$ 2,428	$ 1,839	$ 905	$ 11,872	$ 17,044

Loan with PharmaBio

In connection with a 2001 collaboration arrangement with Quintiles to provide us certain commercialization services in the United States (discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - 2004 Corporate Partnership Restructuring Charges”), PharmaBio, Quintiles’ strategic investment group, extended to us a secured, revolving credit facility of $8.5 to $10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. Interest was payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. The outstanding principal balance was due on December 10, 2004. The facility was renegotiated in November 2004 and, among other things, the maturity date extended to December 31, 2006. Interest remained payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. In October 2006, we restructured the existing $8.5 million loan with PharmaBio and, as a result, the maturity date of the loan has been extended by 40 months from December 31, 2006 to April 30, 2010. Beginning on October 1, 2006, interest on the loan will accrue at the prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, will now be payable on April 30, 2010, the maturity date of the loan. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. As of December 31, 2006, the outstanding balance under the loan was $8.9 million ($8.5 million of principal and $0.4 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

In connection with the restructuring, in October 2006, we and PharmaBio amended and restated the existing loan documents. In addition, our obligations to PharmaBio under the loan documents are now secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the Security Agreement (the PharmaBio Collateral).

Also in October 2006, in consideration of PharmaBio's agreement to restructure the loan, we entered into a Warrant Agreement with PharmaBio, pursuant to which PharmaBio has the right to purchase 1.5 million shares of our common stock at an exercise price equal to $3.5813 per share. The warrants have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we filed a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants.

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

Capital lease liabilities and note payable as of December 31, 2006 and 2005 are as follows:

(in thousands)	**2006**	**2005**
Current		
Capital leases, GECC	$ 1,350	$ 982
Note payable, GECC	665	560
All other	—	26
Capital leases and note payable, current	2,015	1,568
Long Term		
Capital leases, GECC	1,502	1,480
Note payable, GECC	1,185	1,840
All other	—	3
Capital leases and note payable, long term	2,687	3,323
Total capital leases and note payable	$ 4,702	$ 4,891

Our capital lease financing arrangements have been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) pursuant to a Master Security Agreement dated December 20, 2002 (Master Security Agreement).

Under the Master Security Agreement, we purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through capital leases. The capital leases are secured by the related assets. Laboratory and manufacturing equipment are financed over 48 months and all other equipment are financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. As of December 31, 2006, $4.7 million was outstanding ($2 million classified as current liabilities and $2.7 million as long-term liabilities).

The Master Security Agreement, which previously had been extended, expired October 31, 2006. GECC has agreed in the near term to discuss our capital financing needs and we are also seeking alternative capital financing arrangements. We cannot give you assurances that we will receive additional financing from GECC or secure an alternate source to finance our capital lease needs in the future.

In connection with the restructuring of the PharmaBio loan, on October 25, 2006, pursuant to an amendment to the Master Security Agreement, GECC consented to our restructuring the PharmaBio loan and, in consideration of GECC's consent and other amendments to the Master Security Agreement, we granted to GECC, as additional collateral under the Master Security Agreement, a security interest in the same assets that comprise the PharmaBio Collateral (GECC Supplemental Collateral). GECC retains a first priority security interest in the property and equipment financed under the Master Security Agreement, which are not a part of the PharmaBio Collateral. GECC has agreed to release its security interest in the GECC Supplemental Collateral upon: (a) receipt by us of FDA approval for Surfaxin for the prevention of RDS in premature infants or (b) the occurrence of certain milestones to be agreed.

Included in the amounts above, in December 2005, we financed $2.4 million pursuant to our capital lease financing arrangement to support the purchase of our manufacturing operations in Totowa, NJ, which was classified as a note payable on the Consolidated Balance Sheets (of which $0.7 million is current and $1.2 million is long-term as of December 31, 2006). 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, subject to certain conditions.

In August 2006, we extended the lease on our office and laboratory space in Doylestown, Pennsylvania. We reduced our leased space from approximately 11,000 square feet to approximately 5,600 square feet. We maintain analytical laboratory activities at the Doylestown facility under a lease that expires in August 2007, and is thereafter subject to extensions on a monthly basis.

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

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 our 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 our 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 November 2006, we completed the sale of securities in a private placement with an institutional investor resulting in net proceeds to us of $9.5 million. We issued 4,629,630 shares of our common stock and 2,314,815 warrants to purchase shares of our common stock at an exercise price equal to $3.18 per share. The warrants have a five-year term and, subject to certain conditions and except in limited circumstances, are exercisable, in whole or in part, for cash.

As of December 31, 2006, 909,381 of the Class A Investor Warrants to purchase shares of our common stock at an exercise price equal to $6.875 per share issued in connection with the sale of securities in a private placement completed in June 2003 remain unexercised**.**

Other Financing Transactions - Warrants

In October 2006, in connection with the restructuring of the PharmaBio loan (see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Debt"), we and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase 1.5 million shares of our common stock at an exercise price equal to $3.5813 per share. The warrants granted under the Warrant Agreement have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. As of December 31, 2006, no warrants had been exercised.

In April 2006, in connection with the CEFF (see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility"), we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant is exercisable for cash, except in limited circumstances, with expected total proceeds, if exercised, of $2.8 million. As of December 31, 2006, no Class B Investor Warrant had been exercised.

As of December 31, 2006, the warrant to purchase 850,000 shares of our common stock at an exercise price of $7.19 per share (issued to PharmBio in November 2004) and the Class B Investor Warrant to purchase up to 375,000 shares of our common stock at an exercise price equal to $12.0744 per share (issued to Kingsbridge in connection with the 2004 CEFF) have not been exercised.

Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our manufacturing, research and product development activities and to repay our indebtedness. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative 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, the use of which is subject to certain conditions, we currently do not have any contractual arrangements under which we may obtain additional financing.

We have engaged Jefferies & Company, Inc., a New York-based investment banking firm, under an arrangement that expires in June 2007, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised $10 million in a private placement transaction. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

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

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, 2006, including principal and interest, are as follows:

(in thousands)	2007	2008	2009	2010	2011	Thereafter	Total
Loan payable (1)	$ —	$ —	$ —	$ 11,641	$ —	$ —	$ 11,641
Capital lease obligations (1)	1,595	1,006	467	198	—	—	3,266
Note Payable (1)	833	833	438	33	—	—	2,137
Operating lease obligations (2)	1,482	1,296	1,136	314	150	450	4,828
Purchase obligations (3)	1,562	—	—	—	—	—	1,562
Employment agreements (3)	3,272	360	—	—	—	—	3,632
Total	$ 8,744	$ 3,495	$ 2,041	$ 12,186	$ 150	$ 450	$ 27,066

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

(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.

At December 31, 2006, we had employment agreements with 14 executives providing for an aggregate annual salary equal to $3,272,000. Eleven of the agreements expire in December 2007. The remaining three agreements expire in May 2008. The term of each agreement will be extended automatically for one additional year unless at least 90 days prior to the end of the then-current term either the executive or we gives notice of a decision not to extend the agreement. All of the foregoing agreements provide: (i) for the issuance of annual bonuses and the granting of options at the discretion of and subject to approval by the Board of Directors; and, (ii) in the event that the employment of any such executive is terminated without Cause or should any such executive terminate employment for Good Reason, as defined in the respective agreements, including in circumstances of a change of control, such executive shall be entitled to certain cash compensation, benefits continuation and beneficial modifications to the terms of previously granted equity securities.

In addition to the contractual obligations above, we have certain milestone payment obligations, aggregating $2,500,000, and royalty payment obligations to Johnson & Johnson 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, 2006. 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, 2006.

Our independent registered public accounting firm has audited management's assessment of our internal control over financial reporting, and issued an unqualified opinion dated March 7, 2007 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 herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of our 2006 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

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.

Signature	Name & Title	Date
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. President, Chief Executive Officer and Director	March 16, 2007
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer	March 16, 2007
/s/ Kathleen A. McGowan	Kathleen A. McGowan Controller (Principal Accounting Officer)	March 16, 2007
/s/ W. Thomas Amick	W. Thomas Amick Chairman of the Board of Directors	March 16, 2007
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	March 16, 2007
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 16, 2007
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 16, 2007
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 16, 2007

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.

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

Exhibit No.	Description	Method of Filing
4.6	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.7	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.
4.8	Registration Rights Agreement, dated as of April 17, 2006, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.9	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. ("PharmaBio")	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.10	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.11	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
10.1	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.

Exhibit No.	Description	Method of Filing
10.7	* 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.
10.8	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.
10.9	Amendment, dated as of December 23, 2002, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.33 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
10.10	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.
10.11	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.
10.12+	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.
10.13+	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.
10.14+	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.
10.15	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.
10.16	Assignment of Lease and Termination and Option Agreement, dated as of December 30, 2005, between Laureate Pharma, Inc. and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, as filed with the SEC on March 16, 2006.
10.17	Common Stock Purchase Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.

Exhibit No.	Description	Method of Filing
10.18	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert J. Capetola, Ph.D.	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.19	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and John G. Cooper.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.20	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and David L. Lopez, Esq., CPA	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.21	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert Segal, M.D.	Incorporated by reference to Exhibit 10.4 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.22	Amendment No. 2, dated as of September 26, 2003, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.6 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.23	Amendment No.3, dated as of December 22, 2004, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.7 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.24	Amendment No.4, dated as of May 9, 2006, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.8 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.25	Common Stock Purchase Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
10.26	Amendment No.5 and Consent, dated as of October 25, 2006, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.27	Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.

Exhibit No.	Description	Method of Filing
10.28	Second Amended and Restated Security Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.29	Securities Purchase Agreement, dated as of November 22, 2006, between Discovery and Capital Ventures International.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
10.30	Registration Rights Agreement, dated as of November 22, 2006, between Discovery and Capital Ventures International.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
10.31	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Charles Katzer.	Filed Herewith.
21.1	Subsidiaries of Discovery.	Incorporated by reference to Exhibit 21.1 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, as filed with the SEC on March 31, 1998.
23.1	Consent of Ernst & Young LLP.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

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

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Contents

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the "Company") as of December 31, 2006 and 2005, 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, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As disclosed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted Financial Accounting Standards Board Statement No. 123(R), "*Share-Based Payment.*"

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, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2007, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

Philadelphia, Pennsylvania
March 7, 2007

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Report on the Company's Internal Control over Financial Reporting, that Discovery Laboratories, Inc. and subsidiary (the "Company") maintained effective internal control over financial reporting as of December 31, 2006, 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, 2006, 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, 2006, 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, 2006 and 2005, 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, 2006 of the Company and our report dated March 7, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 7, 2007

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2006	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,173	$ 47,010
Restricted cash	829	647
Available-for-sale marketable securities	--	3,251
Prepaid expenses and other current assets	565	560
Total Current Assets	27,567	51,468
Property and equipment, net	4,794	4,322
Deferred financing costs and other assets	2,039	218
Total Assets	$ 34,400	$ 56,008
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,953	$ 7,540
Loan payable, current portion	--	8,500
Capitalized leases and note payable, current portion	2,015	1,568
Total Current Liabilities	7,968	17,608
Loan payable, non-current portion, including accrued interest	8,907	--
Capitalized leases and note payable, non-current portion	2,687	3,323
Other liabilities	516	239
Total Liabilities	20,078	21,170
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized; 69,871 and 61,335 issued, 69,558 and 61,022 outstanding at December 31, 2006 and December 31, 2005, respectively	70	61
Additional paid-in capital	265,604	240,028
Unearned portion of compensatory stock options	--	(230)
Accumulated deficit	(248,298)	(201,965)
Treasury stock (at cost); 313 shares at December 31, 2006 and 2005.	(3,054)	(3,054)
Accumulated other comprehensive income	--	(2)
Total Stockholders’ Equity	14,322	34,838
Total Liabilities & Stockholders’ Equity	$ 34,400	$ 56,008

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(In thousands, except per share data)

	Year Ended December 31,		
	2006	**2005**	**2004**
Revenues:			
Contracts, licensing, milestones and grants	$ —	$ 134	$ 1,209
Expenses:			
Research & development	23,716	24,137	25,793
General & administrative	18,386	18,505	13,322
Restructuring charges	4,805	—	8,126
In-process research & development	—	16,787	—
Total expenses	46,907	59,429	47,241
Operating loss	(46,907)	(59,295)	(46,032)
Other income / (expense):			
Interest and other income	2,072	1,345	404
Interest and other expense	(1,498)	(954)	(575)
Other income / (expense), net	574	391	(171)
Net loss	$ (46,333)	$ (58,904)	$ (46,203)
Net loss per common share - basic and diluted	$ (0.74)	$ (1.09)	$ (1.00)
Weighted average number of common shares outstanding - basic and diluted	62,767	54,094	46,179

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2006, 2005 and 2004
(In thousands)

	Common Stock		Additional Paid-in	Unearned Portion of Compensatory	Accumulated	Treasury Stock		Accumulated Other Comprehensive	
	Shares	Amount	Capital	Stock Options	Deficit	Shares	Amount	(Loss)	Total
Balance - January 1, 2004	**42,659**	**$ 43**	**$122,409**	**$ (2)**	**$(96,858)**	**(167)**	**$ (1,289)**	**-**	**$ 24,303**
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, 401k 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, CEFF financing	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)	-	-
Balance - December 31, 2004	**48,748**	**$ 49**	**$ 167,627**	**$ (461)**	**$ (143,061)**	**(313)**	**$ (3,054)**	**$ (3)**	**$ 21,097**
Comprehensive loss:									
Net loss	-	-	-	-	(58,904)	-	-	-	(58,904)
Other comprehensive loss - unrealized gains 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, CEFF financings	3,511	3	20,197	-	-	-	-	-	20,200
Balance - December 31, 2005	**61,335**	**$ 61**	**$ 240,028**	**$ (230)**	**$ (201,965)**	**(313)**	**$ (3,054)**	**$ (2)**	**$ 34,838**
Comprehensive loss:									
Net loss	-	-	-	-	(46,333)	-	-	-	(46,333)
Other comprehensive loss - unrealized gains on investments	-	-	-	-	-	-	-	2	2
Total comprehensive loss	-	-	-	-	-	-	-	-	(46,331)
Issuance of common stock, stock option exercises and restricted stock awards	6	-	42	-	-	-	-	-	42
Issuance of common stock, warrant exercises	100	-	687	-	-	-	-	-	687
Issuance of common stock, 401(k) employer match	145	-	417	-	-	-	-	-	417

Issuance of warrants, October 2006 loan restructuring	-	-	1,940	-	-	-	-	-	1,940
Issuance of common stock, November 2006 financing	4,630	5	9,460	-	-	-	-	-	9,465
Issuance of common stock, CEFF financings	3,655	4	7,351	-	-	-	-	-	7,355
Stock-based compensation expense	-	-	5,679	230	-	-	-	-	5,909
Balance - December 31, 2006	**69,871**	**$ 70**	**$ 265,604**	**$ -**	**$ (248,298)**	**(313)**	**$ (3,054)**	**$ -**	**$ 14,322**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2006	**2005**	**2004**
Cash flow from operating activities:			
Net loss	$ (46,333)	$ (58,904)	$ (46,203)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,058	788	816
Stock-based compensation and 401(k) match	6,326	617	1,460
Loss on disposal of property and equipment	48	16	12
Non-cash charge for issuance of common stock and warrants related to corporate partnership restructurings	—	—	7,443
Changes in:			
Prepaid expenses and other current assets	(5)	128	(68)
Accounts payable and accrued expenses	(1,587)	(429)	3,759
Other assets	(17)	14	(21)
Other liabilities	684	105	(538)
Net cash used in operating activities	(39,826)	(57,665)	(33,340)
Cash flow from investing activities:			
Purchase of property and equipment	(1,448)	(1,063)	(2,207)
Restricted cash	(182)	(1)	(646)
Purchase of marketable securities	(4,631)	(33,340)	(18,483)
Proceeds from sale or maturity of marketable securities	7,884	32,834	15,465
Net cash provided by / (used in) investing activities	1,623	(1,570)	(5,871)
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	17,549	72,027	35,911
Proceeds from use of loan	—	2,571	3,493
Proceeds from note payable for manufacturing purchase	—	2,400	—
Equipment financed through capital lease	1,509	916	1,928
Principal payments under capital lease and note payable obligations	(1,692)	(933)	(514)
Purchase of treasury stock	—	—	(1,765)
Net cash provided by financing activities	17,366	76,981	39,053
Net (decrease) / increase in cash and cash equivalents	(20,837)	17,746	(158)
Cash and cash equivalents - beginning of year	47,010	29,264	29,422
Cash and cash equivalents - end of year	$ 26,173	$ 47,010	$ 29,264
Supplementary disclosure of cash flows information:			
Interest paid	$ 1,102	$ 860	$ 186
Non-cash transactions:			
Class H warrants revalued	$ —	$ —	$ (48)
Unrealized gain / (loss) on marketable securities	2	(1)	(3)
Charge for warrant issuance related to loan restructuring	1,940	—	—

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
NOTE 1 - THE COMPANY AND DESCRIPTION OF BUSINESS

Discovery Laboratories, Inc. (the Company) is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory disorders and 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 neonatal intensive care unit (NICU), critical care unit and other hospital settings, to treat conditions for which 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 filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for it lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, the Company received an Approvable Letter from the FDA in connection with this NDA. The Company is also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. Aerosurf™ is the Company's proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU, the Company believes that its SRT will also potentially address a variety of debilitating respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, such as Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), Acute Respiratory Failure (ARF), chronic obstructive respiratory disorder, cystic fibrosis, asthma and other debilitating respiratory conditions.

The Company has implemented a business strategy that includes: (i) taking all actions intended to gain regulatory approvals for Surfaxin for the prevention of RDS in premature infants in the United States; (ii) continued investment in development of SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that the Company has licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in enhancements to the Company's quality systems and manufacturing capabilities, including its operations in Totowa, NJ (which the Company acquired in December 2005), to produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin and the Company's other SRT product candidates, beginning with Aerosurf, and potentially to develop new and enhanced formulations of Surfaxin and our other SRT product candidates. The Company's long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities for the production of its precision-engineered SRT drug products; and (iv) seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of the Company's SRT product candidates.

Management's Plans and Financings

The Company has incurred substantial losses since inception and expects to continue to make significant investments for continued product research, development, manufacturing and commercialization activities. Historically, the Company has funded its operations primarily through the issuance of equity securities and the use of debt and capital lease facilities.

The Company is subject to customary risks associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

Management plans to fund its research, development, manufacturing and potential commercialization activities with the issuance of additional equity, debt and potential strategic alliances. The Company's capital requirements will depend on many factors, including the success of the product development and commercialization plan. Even if the Company succeeds in developing and subsequently commercializing product candidates, it may never achieve sufficient sales revenue to achieve or maintain profitability. There is no assurance that the Company will be able to obtain additional capital when needed with acceptable terms, if at all. These factors could significantly limit the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The balance sheets do not include any adjustments relating to recoverability and classification of recorded assets or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern. Management has developed operating plans that ensure expenditures will only be committed if the Company has the necessary cash resources. Should the Company not be able to obtain additional capital ,when needed with acceptable terms, management has determined it has the ability to adjust its expenditures to ensure that existing capital will allow the Company to continue operations through at least January 1, 2008.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Accounting Principles

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

Consolidation

The consolidated financial statements include all of the accounts of Discovery Laboratories, Inc. and its inactive subsidiary, Acute Therapeutics, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Cash, cash equivalents and marketable securities

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

The marketable securities are classified as available-for-sale and are comprised of shares of high-quality, corporate bonds. Marketable securities are carried at fair market value. Realized gains and losses are computed using the average cost of securities sold. Any appreciation/depreciation on these marketable securities is recorded as other comprehensive income (loss) in the statements of changes in stockholders' equity until realized.

Marketable securities are purchased pursuant to the Investment Policy approved by the Board of Directors. The policy provides for the purchase of high-quality marketable securities, 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 (Statement) 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, 2006, 2005 and 2004, as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Research and development

Research and development costs are charged to operations as incurred.

Revenue recognition - research and development collaborative agreements

The Company has received non-refundable 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, Licensing and Research Funding Agreements for a detailed description of the Company's revenue recognition methodology under these agreements.

Stock-based compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement No. 123(R), *"Share-Based Payment,"* using the modified-prospective-transition method. Refer to Note 8 - Stock Options and Stock-Based Employee Compensation for a detailed description of the Company's recognition of stock-based compensation expense.

Net loss per common share

Net loss per common share is computed pursuant to the provisions of Statement 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, 2006, 2005 and 2004, 17,275,000, 10,904,000 and 9,684,000 shares of common stock, respectively, were potentially issuable upon the exercise of certain of the Company's stock options and warrants and vesting of restricted stock awards. These potentially issuable shares 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.

Business Segments

The Company currently operates in one business segment, which is the research and development of products focused on SRTs for respiratory disorders and 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 Statement No. 131, "*Disclosure about Segments of an Enterprise and Related Information*."

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109," (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for the Company beginning January 1, 2007. The Company is evaluating the potential impact of the implementation of FIN 48 and does not believe it will have a material impact on its financial statements.

NOTE 3 - MARKETABLE SECURITIES

The available-for-sale marketable securities held by the Company consist 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, 2006, the Company did not own any marketable securities. As of December 31, 2005, available-for-sale marketable securities consisted of the following:

(in thousands)	Year Ended December 31, 2005
Cost of investment	$ 3,190
Interest earned	66
Amortized premium	(3)
Unrealized loss	(2)
Fair market value	$ 3,251

NOTE 4 - RESTRICTED CASH

There are cash balances that are restricted as to use and the Company discloses such amounts separately on the Company's balance sheets. There are two primary components of Restricted Cash: (a) a cash security deposit in the amount of $600,000 securing a letter of credit in the same amount related to the Company's lease agreement dated May 26, 2004 for office space in Warrington, Pennsylvania, and (b) a cash security deposit in the amount of approximately $177,800 securing a letter of credit in the same amount issued to support two "Bond to Discharge Liens" filed in Passaic County, New Jersey, in connection with a contractor dispute arising out of work done at the Company's manufacturing facility in Totowa, NJ. Beginning in March 2008, the security deposit and the letter of credit related to the lease agreement will be reduced to $400,000 and 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. The contractor dispute has been settled and, on February 1, 2007, lien discharge papers were filed with the clerk of the court where the Bond to Discharge Lien was filed. The Company is securing return of the letter of credit to release that portion of the restricted cash. Both letters of credit are secured by cash and are recorded in the Company's Consolidated Balance Sheets as "Restricted Cash."

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2006 and 2005 was comprised of the following:

(in thousands)	December 31, 2006	December 31, 2005
Equipment [1]	$ 5,020	$ 4,269
Furniture	959	1,052
Leasehold improvements	360	330
Construction-in-progress	1,600	1,050
Subtotal	7,939	6,701
Accumulated depreciation	(3,145)	(2,379)
Property and equipment, net	$ 4,794	$ 4,322

(1) The equipment balance consists of: (i) manufacturing equipment to produce Surfaxin and other SRT formulations, including aerosol formulations, for use in the Company's clinical trials and 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 commercial activities of the Company.

The property and equipment balance as of December 31, 2006 and 2005 includes $4,993,000 and $3,755,000, respectively, of property and equipment subject to a capital lease. The capitalized leases are secured by the respective assets. The associated accumulated depreciation was $1,457,000 and $862,000 as of December 31, 2006 and 2005, respectively.

The balance of construction-in-progress at both December 31, 2006 and December 31, 2005 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 equipment and construction purchase commitments, yet to be completed, totaling $197,000 as of December 31, 2006.

Depreciation expense for the years ended December 31, 2006, 2005, and 2004 was $922,000, $788,000 and $546,000, respectively.

NOTE 6 - DEBT

Loan with PharmaBio Development, Inc. (PharmaBio), a Strategic Investment Group of Quintiles Transnational Corp.

In 2001, the Company entered into a collaboration arrangement with Quintiles Transnational Corp. (Quintiles), pursuant to which Quintiles agreed to provide certain commercialization services in the United States for Surfaxin. In connection with the collaboration agreement, PharmaBio, a strategic investment group of 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. Interest was payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. The outstanding principal balance was due on December 10, 2004.

In November 2004, the Company restructured its business arrangements with Quintiles and terminated commercialization agreement for Surfaxin in the United States. The existing, secured revolving credit facility with PharmaBio remained available to borrow up to $8.5 million. The original maturity date of the loan was extended from December 10, 2004 to December 31, 2006. Interest remained payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. As of December 31, 2004, the Company had used $5.9 million of the credit facility and $2.6 million remained available. In 2005, the Company used the remaining $2.6 million and the credit facility of $8.5 million was fully utilized. As of December 31, 2005, the outstanding principal balance of $8.5 million was reclassified on the Consolidated Balance Sheets from a long-term credit facility to a short-term loan payable.

In October 2006, the Company restructured its existing $8.5 million loan with PharmaBio and, as a result, the maturity date of the loan was extended by 40 months, from December 31, 2006 to April 30, 2010. Beginning October 1, 2006, interest on the loan accrues at the current prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ended September 30, 2006, is payable on April 30, 2010, the maturity date of the loan. The Company may repay the loan, in whole or in part, at any time without prepayment penalty or premium. As of December 31, 2006, the outstanding balance under the loan was $8.9 million ($8.5 million of principal and $0.4 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

For the years ended December 31, 2006, 2005 and 2004, the Company incurred interest expense associated with the PharmaBio loan of $0.8 million, $0.7 million and $0.3 million, respectively.

In connection with the 2006 restructuring, the Company and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase 1.5 million shares of the Company's common stock at an exercise price equal to $3.5813 per share, which represents a 30% premium over the daily volume weighted average price of our common stock (as reported by Bloomberg, L.P.) for the ten trading days immediately preceding the date of the Warrant Agreement. The warrants have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of the Company's indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise ($5.4 million, if exercised in full). In connection with the issuance of the warrant, the fair value of the warrant using the Black-Scholes model equaled $2.0 million and was recorded as a deferred financing cost, which will be amortized and recorded as interest expense over the extended term of the loan (43 months). As of December 31, 2006, $136,000 had been amortized and recorded as interest expense. Also in connection with the restructuring, the Company's obligation to PharmaBio under the loan is secured by an interest in substantially all of the Company's assets, subject to limited exceptions.

Capital Lease and Note Payable Financing Arrangements

Capital lease liabilities and note payable as of December 31, 2006 and 2005 are as follows:

(in thousands)	2006	2005
Current:		
Capital leases, GECC	$ 1,350	$ 982
Note payable, GECC	665	560
All other	--	26
Capital leases and note payable, current	2,015	1,568
Long-Term:		
Capital leases, GECC	1,502	1,480
Note payable, GECC	1,185	1,840
All other	--	3
Capital leases and note payable, long term	2,687	3,323
Total capital leases and note payable	$ 4,702	$ 4,891

The Company's capital lease financing arrangements have been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) pursuant to a Master Security Agreement dated December 20, 2002 (Master Security Agreement). Under the Master Security Agreement, the Company purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through capital leases. The capital leases are secured by the related assets. Laboratory and manufacturing equipment was financed over 48 months and all other equipment was financed over 36 months. Interest rates varied in accordance with changes in the three and four year treasury rates. As of December 31, 2006, $4.7 million was outstanding ($2.0 million classified as current liabilities and $2.7 million as long-term liabilities).

In connection with the restructuring of the PharmaBio loan, on October 25, 2006, the Company and GECC amended the Master Security Agreement, GECC consented to the amended and restated PharmaBio loan and, in consideration of the consent and other amendments to the Master Security Agreement, the Company granted to GECC, as additional collateral under the Master Security Agreement, a security interest in the same assets that comprise the PharmaBio Collateral (GECC Supplemental Collateral). GECC retains a first priority security interest in the property and equipment financed under the Master Security Agreement, which are not a part of the PharmaBio Collateral. GECC has agreed to release its security interest in the GECC Supplemental Collateral upon (a) receipt by the Company of FDA approval for Surfaxin for the prevention of RDS in premature infants or (b) the occurrence of certain milestones to be agreed.

The Master Security Agreement expired October 31, 2006. The Company is in discussions with GECC and other lending institutions to secure equipment financing for anticipated capital expenditure requirements. There is no assurance that the Company will receive additional financing from GECC or secure an alternate source to finance its capital lease needs in the future.

Included in the amounts above, in December 2005, the Company financed $2.4 million pursuant to a capital lease financing arrangement to support the purchase of the manufacturing operations in Totowa, NJ, which was classified as a note payable on the Consolidated Balance Sheets (of which $0.7 million is current and $1.2 million is long-term as of December 31, 2006). 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.

Future payments due under contractual debt obligations at December 31, 2006, including principal and interest, are as follows:

(in thousands)	**2007**	**2008**	**2009**	**2010**	**Total**
Loan with PharmaBio	$ --	$ --	$ --	$ 11,641	$ 11,641
Capital lease obligations - GECC	1,595	1,006	467	198	3,266
Note Payable - GECC	833	833	438	33	2,137
Total	$ 2,428	$ 1,839	$ 905	$ 11,872	$ 17,044

NOTE 7 - STOCKHOLDERS' EQUITY

Registered Public Offerings and Private Placements

In November 2006, the Company completed the sale of securities in a private placement with an institutional investor resulting in net proceeds of $9.5 million. The Company issued 4,629,630 shares of the its common stock and 2,314,815 warrants to purchase shares of the its common stock at an exercise price equal to $3.18 per share. The warrants have a five-year term and, subject to an aggregate share ownership limitation, are exercisable for cash or, in the event that the related registration statement is not available for the resale of the Warrant Shares, on a cashless basis.

In December 2005, the Company completed a registered direct offering of 3,030,304 shares of the its 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 the its common stock to Laboratorios del Dr. Esteve, S.A. (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 the its 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 the its 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 the its common stock and 999,577 Class A Investor Warrants to purchase shares of the its common stock at an exercise price equal to $6.875 per share. The Class A Investor Warrants have a seven-year term and are exercisable for cash, except for limited exceptions. As of December 31, 2006, 809,381 Class A Investor Warrants remained outstanding**.**

Committed Equity Financing Facility (CEFF)

2004 CEFF

In 2004, the Company entered into a Committed Equity Financing Facility (2004 CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, pursuant to which Kingsbridge committed to finance up to $75 million of capital for newly-issued shares of the Company's common stock. The Company filed a registration statement pursuant to the 2004 CEFF, which reserved 15 million shares of common stock for future issuance under the 2004 CEFF calculated as the full amount available, $75 million, divided by the lowest price per share as determined by the 2004 CEFF agreement, $5.00 per share.

The Company entered into three financings pursuant to the 2004 CEFF as follows:

In December 2004, the Company completed a financing pursuant to the 2004 CEFF resulting in proceeds of $7.2 million from the issuance of 901,742 shares of its common stock at an average price per share, after the applicable discount, of $7.98.

In September 2005, the Company completed a financing pursuant to the 2004 CEFF resulting in proceeds of $17.0 million from the issuance of 3,012,055 shares of its common stock at an average price per share, after the applicable discount, of $5.64.

In November 2005, the Company completed a financing pursuant to the 2004 CEFF resulting in proceeds of $3.2 million from the issuance of 498,552 shares of its common stock at an average price per share, after the applicable discount, of $6.42.

In connection with the 2004 CEFF, in 2004 the Company issued a Class B investor warrant to Kingsbridge to purchase up to 375,000 shares of the Company's common stock at an exercise price equal to $12.0744 per share. The warrant, which expires in January 2010, is excercisable, in whole or in part, for cash, except in limited circumstances, for total proceeds equal to approximately $4.5 million. As of December 31, 2006, the Class B investor warrant had not been exercised.

2006 CEFF

In April 2006, the Company entered into a new CEFF (2006 CEFF) with Kingsbridge, in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of the Company's common stock. The Company's 2004 CEFF, under which up to $47.6 million remained available, automatically terminated on May 12, 2006, the date on which the SEC declared effective the registration statement filed in connection with the 2006 CEFF. As of December 31, 2006, the Company had approximately 8.0 million shares available for issuance under the CEFF for future financings (not to exceed $42.5 million in gross proceeds).

The purchase price of the shares sold to Kingsbridge is at a discount ranging from 6 to 10 percent of the volume weighted average of the price of the Company's common stock (VWAP) for each of the eight trading days following the Company's election to sell shares, or "draw down" under the 2006 CEFF.

In addition, if on any trading day during the eight trading day pricing period for a draw down, the VWAP is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of the Company's common stock for the trading day immediately preceding the beginning of the draw down period, no shares will be issued with respect to that trading day and the total amount of the draw down will be reduced by one-eighth of the draw down amount the Company had initially specified.

The Company's ability to require Kingsbridge to purchase common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of the outstanding shares of the Company's common stock at the time of the draw down or $10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. In addition, Kingsbridge may terminate the 2006 CEFF under certain circumstances, including if a material adverse effect relating to the Company's business continues for ten trading days after notice of the material adverse effect.

The Company has entered into four financings pursuant to the 2006 CEFF as follows:

In May 2006, the Company completed a financing pursuant to the 2006 CEFF resulting in proceeds of $2.2 million from the issuance of 1,078,519 shares of its common stock at an average price per share, after the applicable discount, of $2.03.

In October 2006, the Company completed a financing pursuant to the 2006 CEFF resulting in proceeds of $2.3 million from the issuance of 1,204,867 shares of its common stock at an average price per share, after the applicable discount, of $1.91.

In November 2006, the Company completed a financing pursuant to the 2006 CEFF resulting in proceeds of $3.0 million from the issuance of 1,371,516 shares of its common stock at an average price per share, after the applicable discount, of $2.19.

In February 2007, the Company completed a financing pursuant to the 2006 CEFF resulting in proceeds of $2.0 million from the issuance of 942,949 shares of its common stock at an average price per share, after the applicable discount, of $2.12.

The Company currently has approximately 7.0 million shares available for issuance under the 2006 CEFF for future financings (not to exceed $40.5 million in gross proceeds).

In connection with the 2006 CEFF, in 2006 the Company issued a Class C investor warrant to Kingsbridge to purchase up to 490,000 shares of the Company's common stock at an exercise price of $5.6186 per share. The warrant, which expires in October 2011, is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.8 million. As of December 31, 2006, the Class C investor warrant had not been exercised.

Shares Issued Pursuant to the 2004 Restructuring of Esteve Partnership

In December 2004, the Company restructured its strategic alliance with Esteve for the development, marketing and sales of the Company's products in Europe and Latin America. For a description of the Esteve strategic alliance, refer to Note 9 - Corporate Partnership, Licensing and Research Funding Agreements. In consideration for regaining commercial rights in the restructuring, the Company issued to Esteve 500,000 shares of the Company's common stock for no cash consideration. The Company incurred a non-cash charge of $3.5 million in 2004, included in the 2004 Restructuring Charge on the Statements of Operations, representing the fair market value of the shares on the date of issuance.

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 the Company's 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 the Company's common stock.

In connection with the PharmaBio loan, in December 2001, the Company issued Class H Warrants to purchase 320,000 shares of the Company's common stock. The Class H Warrants were exercisable at $3.03 per share and were exercisable upon the achievement of certain milestones and availability of funding under 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 the Company's common stock.

401(k) Employer Match

The Company has a voluntary 401(k) savings plan covering eligible employees that 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 145,397 and 36,750 shares of common stock for the years ended December 31, 2006 and 2005, respectively. The Company had shares reserved for potential future issuance under the Company's 401(k) Plan of 323,956 and 69,353 for the years ended December 31, 2006 and 2005, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Common Shares Reserved for Future Issuance

Common shares reserved for potential future issuance upon exercise of warrants

The chart below details shares of the Company's common stock reserved for future issuance upon the exercise of warrants.

	Shares Reserved for Issuance upon Exercise of Warrants December 31,		Exercise Price	Expiration Date
	2006	2005		
Private placement - 2006 (1)	2,314,815	--	$ 3.18	11/22/2011
PharmaBio - 2006 Loan Restructuring (2)	1,500,000	--	$ 3.58	10/26/2013
Class C Investor Warrants - 2006 CEFF (3)	490,000	--	$ 5.62	10/17/2011
PharmaBio - 2004 Partnership Restructuring (4)	850,000	850,000	$ 7.19	11/3/2014
Class B Investor Warrants - 2004 CEFF (3)	375,000	375,000	$ 12.07	1/6/2010
Class A Investor Warrants - 2003 (1)	809,381	909,381	$ 6.88	9/19/2010
Placement Agent - 2000	185,822	185,822	$ 7.47 (5)	9/21/2007
Placement Agent - 1996	--	4,615	$ 0.54 (5)	11/15/2006
Placement Agent - 1996	--	138,953	$ 2.27 (5)	11/15/2006
Total	6,525,018	2,463,771		

(1) Refer to the Registered Public Offerings and Private Placements section of this Note.
(2) Refer to Note 6 - Debt
(3) Refer to the Committed Equity Financing Facility (CEFF) section of this Note.
(4) Refer to Note 9 - Corporate Partnership, Licensing and Research Funding Agreements
(5) Original warrant price adjusted for dilution provision

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

The Company has a Stock Incentive Plan, which includes three equity programs. See Note 8 - Stock Options and Stock-Based Employee Compensation. As of December 31, 2006 and 2005, the Company had shares reserved for potential future issuance under the Stock Incentive Plan of 11,268,888 and 10,104,710, respectively, for stock options and restricted stock awards available and outstanding for future grants. As of December 31, 2006 and 2005, 10,690,160 and 8,439,771 stock options were granted and outstanding, respectively, and 59,991 and 29,964 restricted stock awards were granted and reserved for future issuance, respectively. As of December 31, 2006 and 2005, there were 518,737 and 1,634,975 shares reserved for potential future issuance under the Stock Incentive Plan, 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 debt or equity securities. In December 2005, the Company completed a registered direct offering of 3,030,304 shares of the Company's 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 2006 CEFF

In April 2006, the Company entered into a new CEFF with Kingsbridge, in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of the Company's common stock. The Company's previous 2004 CEFF, under which up to $47.6 million remained available, automatically terminated on May 12, 2006, the date on which the SEC declared effective the registration statement filed in connection with the 2006 CEFF. As of December 31, 2006, the Company had approximately 8.0 million shares available for issuance under the 2006 CEFF for future financings (not to exceed $42.5 million in gross proceeds).

In February 2007, the Company completed a financing pursuant to the 2006 CEFF resulting in proceeds of $2.0 million from the issuance of 942,949 shares of its common stock at an average price per share, after the applicable discount, of $2.12. After giving effect to the shares issued in the February 2007 financing under the 2006 CEFF, the Company currently has approximately 7.0 million shares available for issuance under the CEFF for future financings (not to exceed $40.5 million in gross proceeds).

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 that allows for periodic discretionary matches as a percentage of each participant's contributions in newly issued shares of common stock. For the years ended December 31, 2006 and 2005, the Company match resulted in the issuance of 145,397 and 36,750 shares of common stock, respectively. As of December 31, 2006 and 2005, the Company had shares reserved for potential future issuance under the Company's 401(k) Plan of 323,956 and 69,353, respectively.

NOTE 8 - STOCK OPTIONS AND STOCK-BASED EMPLOYEE COMPENSATION

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

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, eligible persons may be issued shares of the common stock. In 2006 and 2005, the Company issued 69,201 and 30,263 restricted stock awards, respectively, to certain employees for no cash consideration. The Company did not issue any such shares for the year ended December 31, 2004.

Automatic Option Grant Program

Under the Automatic Option Grant Program, eligible non-employee directors 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 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 1998 Plan currently allows for the grant of stock options and shares of common stock to eligible employees, officers, consultants, independent advisors and non-employee directors for up to 11,268,888 shares of common stock. As of December 31, 2006, the Company had shares reserved for potential future issuance under the 1998 Plan of 11,268,888 for stock options and restricted stock awards available and outstanding for future grants. As of December 31, 2006, 10,690,160 stock options were granted and outstanding and 59,991 restricted stock awards were granted and reserved for future issuance, respectively. As of December 31, 2006, there were 518,737 shares reserved for potential future issuance under the 1998 Plan, respectively. The Company believes that such awards better align the interests of its eligible participants with those of its shareholders. Option awards are granted with an exercise price equal to or greater than the closing price per share of the Company's common stock on the Nasdaq Global Market on the option grant date. Although the terms of any award vary, option awards generally vest based upon three years of continuous service and have 10-year contractual terms.

Stock-Based Employee Compensation

Prior to January 1, 2006, the Company accounted for this plan under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, (Opinion 25) and related interpretations, as permitted by Statement No. 123, *Accounting for Stock-Based Compensation*. Generally, no stock-based employee compensation cost was recognized in the statements of operations, as options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of the grant. Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement No. 123(R), using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the year ended December 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair market value estimated in accordance with the original provisions of Statement 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based upon the grant-date fair value estimated in accordance with the provisions of Statement No. 123(R). Results from prior years have not been restated.

As a result of adopting Statement No. 123(R) on January 1, 2006, the Company's net loss for the year ended December 31, 2006 was $5.5 million (or $0.09 per share) higher than if it had continued to account for share-based compensation under Opinion 25. For the year ended December 31, 2006, $1.6 million of compensation expense was classified as research and development and $3.9 million of compensation expense was classified as general and administrative.

For comparative purposes, the following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement 123(R) to options granted under the Company's stock option plan for the years ended December 31, 2005 and 2004. For purposes of this pro forma disclosure, the value of the option is estimated using a Black-Scholes option-pricing formula that uses the December 31, 2005 and 2004 assumptions set forth immediately below the following table and amortized to expense over the options' vesting periods.

(in thousands, except per share data)	Years Ended December 31, 2005	2004
Net loss, as reported	$ (58,904)	$ (46,203)
Net loss per share, as reported	$ (1.09)	$ (1.00)
Add: Stock-based employee compensation expense included in reported net loss	230	459
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(14,570)	(4,455)
Pro forma net loss	$ (73,244)	$ (50,199)
Pro forma net loss per share	$ (1.35)	$ (1.09)

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the Company's historical volatility and other factors. The Company also uses historical data and other factors to estimate option exercises, employee terminations and forfeiture rates within the valuation model. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

	Years Ended December 31, 2006	2005	2004
Expected volatility	96%	77%	81%
Expected term	4 & 5 years	3.5 years	3.5 years
Risk-free rate	4.4% - 5.0%	4.1%	3.5%
Expected dividends	--	--	--

A summary of option activity under the Plan as of December 31, 2006 and changes during the period is presented below:

(in thousands, except for weighted-average data)

Options	Price Per Share	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)
Outstanding at December 31, 2003	$0.0026 - $9.17	5,555	$ 3.80	7.4
Granted	5.92 - 10.60	2,681	8.60	
Exercised	0.3205 - 9.17	(1,271)	3.41	
Forfeited or expired	1.42 - 10.60	(120)	5.64	
Outstanding at December 31, 2004	$0.0026 - $10.60	6,845	$ 5.69	7.8
Granted	5.15 - 9.02	2,079	7.97	
Exercised	1.46 - 7.22	(226)	2.87	
Forfeited or expired	1.50 - 10.60	(258)	7.19	
Outstanding at December 31, 2005	$0.0026 - $10.60	8,440	$ 6.28	7.3
Granted	1.40 - 7.97	4,213	3.30	
Exercised	0.0026 - 6.47	(36)	1.16	
Forfeited or expired	1.50 - 10.02	(1,927)	$ 7.55	
Outstanding at December 31, 2006	$0.19 - $10.60	10,690	$ 4.89	7.4
Vested at December 31, 2006	$0.19 - $10.60	7,346	$ 5.54	6.4
Exercisable at December 31, 2006	$0.19 - $10.60	7,346	$ 5.54	6.4

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the years ended December 31, 2006, 2005 and 2004 were $2.33, $5.59 and $6.45, respectively. The total intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004 were $79,000, $948,000 and $10.8 million, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2006 is $1.1 million, $654,000 and $654,000, respectively.

A summary of the status of the Company's nonvested shares issuable upon exercise of outstanding options and changes during the year are presented below:

(shares in thousands)

	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2005	1,907	$ 3.68
Granted	4,213	2.33
Vested	(2,251)	2.41
Forfeited	(525)	4.38
Non-vested at December 31, 2006	3,344	$ 2.46

The total fair value of shares vested during 2006 equals $5.4 million. As of December 31, 2006, there was $7.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.25 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. As of December 31, 2006, all stock option grants that were exercisable immediately upon grant had vested, therefore stock options exercisable equals stock options vested.

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2006:

(shares in thousands)

Price per share	Shares Outstanding	Weighted Average Price per Share	Weighted Average Remaining Contractual Life	Shares Exercisable	Weighted Average Price per Share	Weighted Average Remaining Contractual Life
$0.1923 - $2.00	1,162	$1.65	7.15 years	706	$1.62	7.15
$2.01 - $4.00	4,158	$2.46	8.15 years	2,138	$2.55	8.15
$4.01 - $6.00	947	$4.70	3.36 years	922	$4.67	3.36
$6.01 - $8.00	1,924	$6.91	7.88 years	1,081	$6.81	7.88
$8.01 - $10.00	2,449	$8.94	7.28 years	2,449	$8.94	7.28
$10.01 - $10.60	50	$10.52	7.33 years	50	$10.52	7.33
	10,690			7,346		

In December 2004, the Board of Directors approved the issuance of options to management to purchase up to 1,148,500 shares of the Company's 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 the Company's 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 the Company's 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 the Company's 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. For the years ended December 31, 2006, 2005 and 2004, the Company incurred a non-cash charge of $230,000, $231,000 and $461,000, respectively, related to the vesting of such options.

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 Statement No. 123(R),which became effective for the Company January 1, 2006. The Company estimates that the aggregate future compensation expense that was eliminated as a result of the acceleration of the vesting of these options was approximately $7.2 million, calculated in accordance with Statement No. 123(R) (of which approximately $6.6 million was 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 the Company's 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.

NOTE 9 - CORPORATE PARTNERSHIP, LICENSING AND RESEARCH FUNDING AGREEMENTS

Chrysalis Technologies, Division of Philip Morris USA Inc. (Chrysalis)

In December 2005, the Company entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as neonatal respiratory failure, chronic obstructive respiratory disorder, asthma, ALI and others. The alliance unites two 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 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 Company and Chrysalis are utilizing their respective capabilities and resources to support and fund the design and development of integrated combination 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. The Company 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 neonatal program utilizing the Chrysalis technology is Aerosurf, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. The Company are planning an adult program utilizing the Chrysalis technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI.

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

In 2002, the Company significantly expanded its existing relationship with Laboratorios del Dr. Esteve, S.A. (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. The Company's exclusive supply agreement with Esteve provided that Esteve would purchase all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for ARDS and make certain milestone payments to the Company upon the attainment of European marketing regulatory approval for Surfaxin. In connection with the 2002 expanded agreement, Esteve purchased 821,862 shares of the Company's common stock at $4.867 per share for $4.0 million in gross proceeds and paid a non-refundable licensing fee of $500,000. The Company accounted for the license fees and reimbursement of research and development expenditures associated with the Esteve collaboration as deferred revenue.

In December 2004, the Company further restructured its strategic alliance with Esteve for the development, marketing and sales of the Company's products in Europe and Latin America. Under the revised alliance, the Company 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 maintained commercialization rights in Andorra, Greece, Italy, Portugal, and Spain, and obtained development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay the Company a transfer price on sales of Surfaxin and other SRT that is increased from that provided for in the previous collaborative arrangement. The Company 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. The Company also agreed to pay to Esteve 10% of cash up-front and milestone fees (not to exceed $20 million in the aggregate) 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 SRTs in the territory for which the Company had previously granted a license to Esteve. Esteve has agreed to make stipulated cash payments to the Company upon 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 Dompé farmaceutici Spa (Dompé), a privately owned Italian company. Under the sublicense agreement, Dompé 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 occurred over a number of years as the Company performs research and development activities. For the years ended December 31, 2006, 2005 and 2004, the Company recorded revenue related to the Esteve collaboration of $0, $0.1 million and $1.2 million, respectively.

Restructuring of Certain 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 the Company's 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 the 2004 Restructuring Charge on the Statements 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 SRTs 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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
2004 Restructuring / Termination of Quintiles Collaboration

In 2001, the Company entered into a collaboration arrangement 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 in full-term infants. In connection with the commercialization agreement, PharmaBio 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.

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

In connection with the restructuring, the Company issued a warrant to PharmaBio to purchase 850,000 shares of the Company's common stock at an exercise price equal to $7.19 per share. The warrant has a 10-year term and is exercisable only for cash or as an offset to cancel indebtedness of the Company in connection with the existing loan, with expected total proceeds to the Company, if exercised, of approximately $6.0 million. The warrant was valued at its fair value on the date of issuance and the Company incurred a non-cash charge equal to $4.0 million in connection with the issuance. This charge is a component of the 2004 Restructuring Charge on the Statements of Operations. Also, in connection with the restructuring, the Company retained availability of the existing credit facility and the maturity date was extended from December 10, 2004 until December 31, 2006. As of December 31, 2004, the Company had $5.9 million outstanding under the credit facility. In 2006, the Company restructured its loan with PharmaBio. Refer to Note 6 - Debt.

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. The Company had the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed under the agreement and for which the Company did not exercise its option to acquire an exclusive license. Payments to Scripps under this agreement were $0, $400,000 and $600,000 in 2006, 2005 and 2004, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
NOTE 10 - 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 is used for the production of Surfaxin and other SRT formulations, including aerosolized formulations. 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, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

The 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 cGMP requirements. There are approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the operations. In October 2003, the Company entered into a manufacturing agreement with Laureate, pursuant to which the transfer of the Company's Surfaxin manufacturing know-how and dedicated equipment to this facility was completed in 2004. From that time and until the Company's acquisition of the operation in December 2005, the facility was predominantly dedicated to Surfaxin and the support of regulatory compliance requirements for the Company's manufacturing operations.

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 the Company.

- 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, the Company incurred a non-recurring charge, classified as In-process research & development on the Statements of Operations in accordance with Statement No. 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 financed $2.4 million pursuant to its capital lease financing arrangement with GECC to partially finance the purchase of the manufacturing operations. See Note 6 - Debt.

NOTE 11 -2006 RESTRUCTURING CHARGE

In April 2006, the Company received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested information primarily focused on the CMC section of the NDA and predominately involving the further tightening of active ingredient and drug product specifications and related controls. Also in April 2006, ongoing analysis of data from Surfaxin process validation batches that the Company had manufactured as a requirement for our NDA indicated that certain stability parameters had not been achieved. The Company immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure and develop a corrective action and preventative action plan to remediate the related manufacturing issues. These events caused the Company to revise its expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants.

As a result, in April 2006, the Company reduced its staff levels and reorganized corporate management to lower the its cost structure and re-align its operations with changed business priorities. The reduction in workforce totaled 52 employees, representing approximately 33% of the Company's workforce, and was focused primarily on the Company's commercial infrastructure. Included in the workforce reduction were three senior executives. All affected employees were eligible for certain severance payments and continuation of benefits. Additionally, certain commercial programs were discontinued.

The Company incurred a restructuring charge of $4.8 million in the second quarter of 2006 associated with staff reductions and the close-out of certain commercial programs, which was accounted for in accordance with Statement No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* and is identified separately on the Statements of Operations as 2006 Restructuring Charge. This charge included $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain commercial programs.

As of December 31, 2006, payments totaling $3.9 million had been made related to these items and $0.9 million was unpaid. Of the $0.9 million that was unpaid as of December 31, 2006, $0.7 million was included in accounts payable and accrued expenses and $0.2 million was classified as a long-term liability. A reconciliation of these amounts is set forth in the table below:

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
Restructuring Charge	$ 2,497	$ 2,308	$ 4,805
Payments / Adjustments	(2,361)	(1,509)	(3,870)
Liability as of December 31, 2006	$ 136	$ 799	$ 935

NOTE 12 - COMMITMENTS

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

Future payments due under contractual obligations at December 31, 2006 are as follows:

(in thousands)	**2007**	**2008**	**2009**	**2010**	**2011**	**Thereafter**	**Total**
Operating lease obligations	$ 1,482	$ 1,296	$ 1,136	$ 314	$ 150	$ 450	$ 4,828
Purchase obligations	1,562	--	--	--	--	--	1,562
Employment agreements	3,272	360	--	--	--	--	3,632
Total	$ 6,316	$ 1,656	$ 1,136	$ 314	$ 150	$ 450	$ 10,022

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 corporate headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, business development, 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, subject to certain conditions.

The Company leases office and laboratory space in Doylestown, Pennsylvania for analytical laboratory activities, which expires in May 2007, and is thereafter subject to extensions on a monthly basis.

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

Rent expense under all of these leases for the years ended December 31, 2006, 2005, and 2004 were $1,428,000, $1,367,000 and $752,000, 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 other SRT formulations.

At December 31, 2006, the Company had employment agreements with 14 executives providing for an aggregate annual salary equal to $3,272,000. Eleven of the agreements expire in December 2007. The remaining three agreements expire in May 2008. The term of each agreement will be extended automatically for one additional year unless at least 90 days prior to the end of the then-current term the Company or the executive gives notice of a decision not to extend the agreement. All of the foregoing agreements provide: (i) for the issuance of annual bonuses and the granting of options at the discretion of and subject to approval by the Board of Directors; and, (ii) in the event that the employment of any such executive is terminated without Cause or should any such executive terminate employment for Good Reason, as defined in the respective agreements, including in circumstances of a change of control, such executive shall be entitled to certain cash compensation, benefits continuation and beneficial modifications to the terms of previously granted equity securities.

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 13 - LITIGATION

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased the Company's publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by the Company. The amended complaint had been filed on November 30, 2006 against the Company, its Chief Executive Officer, Robert J. Capetola, and its former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief.

In each of May and June 2006, a shareholder derivative complaint was filed in the United States District Court for the Eastern District of Pennsylvania against certain of the Company's directors and executive officers. In July 2006, these actions were consolidated under the caption "In re: Discovery Laboratories Derivative Litigation." The consolidated actions were initially subject to a stipulation agreement between the parties deferring defendants' obligation to respond to the complaints until after the filing of defendants' answer or a dispositive ruling on defendants' Motion to Dismiss the class actions, described above. Nevertheless, in response to an order issued by the court on November 28, 2006, plaintiffs filed a Consolidated Amended Complaint on December 29, 2006, naming as defendants the Company's Chief Executive Officer, Robert J. Capetola, and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, all directors of the Company, and Christopher J. Schaber, the Company's former Chief Operating Officer. To cure a jurisdictional defect, Mr. McDade was dismissed from the action on January 29, 2007. The Consolidated Amended Complaint alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, which were alleged to have occurred between 2005 and April 2006. The plaintiffs generally seek an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. Defendants filed a Motion to Dismiss on January 26, 2007, plaintiffs filed opposition papers on February 13, 2007 and defendants filed a motion for leave to file a reply memorandum, with an accompanying reply memorandum, on February 16, 2007.

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

The Company has from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination of its commercial programs (discussed in Note 11 - 2006 Restructuring Charge). Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, the Company believes they are unlikely to have a material adverse effect on its financial condition or results of operations. However, there can be no assurance that the Company will be successful in any proceeding to which it may be a party.

NOTE 14 - 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, 2006, 2005 and 2004 are as follows:

(in thousands)	December 31,		
	2006	2005	2004
Income tax benefit, statutory rates	$ 15,753	$ 20,027	$ 15,739
State taxes on income, net of federal benefit	2,770	3,721	2,776
Research and development tax credit	966	840	623
Other	(38)	(47)	(87)
Income tax benefit	19,451	24,541	19,051
Valuation allowance	(19,451)	(24,541)	(19,051)
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, 2006 and 2005, are as follows:

(in thousands)	December 31,	
	2006	2005
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	$ 89,881	$ 72,725
Research and development tax credits	5,169	3,818
Compensation Expense on Stock	2,143	680
Charitable Contribution Carryforward	5	16
Other Accrued	852	452
Depreciation	2,736	3,025
Capitalized research and development	2,802	3,025
Total long-term deferred tax assets	103,588	83,741
Long-term deferred tax liabilities	--	--
Net deferred tax assets	103,588	83,741
Less: valuation allowance	(103,588)	(83,741)
Deferred tax assets, net of valuation allowance	$ —	$ —

The Company is in a net deferred tax asset position at December 31, 2006 and 2005 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, 2006 and 2005, the Company had available carryforward net operating losses for Federal tax purposes of $229.8 million and $187.0 million, respectively, and a research and development tax credit carryforward of $5.2 million and $3.8 million, respectively. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2026. At December 31, 2006, the Company had available carryforward federal and state net operating losses of $1.8 million and $24,000 respectively, related to stock based compensation. Additionally, at December 31, 2006 and 2005, the Company had available carryforward losses of approximately $208.2 million and $167.5 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 15 - RELATED PARTY TRANSACTIONS

Laboratorios del Dr. Esteve, S.A.

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, Licensing and Research Funding Agreements.

In November 2005, the Company sold 650,000 shares of its 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.

In 2001, the Company entered into a collaboration arrangement with Quintiles and its strategic investment group affiliate, PharmaBio, to provide certain commercialization services in the United States. In connection with the collaboration arrangement, PharmaBio extended to the Company a secured credit facility of $8.5 to $10.0 million. In November 2004, the arrangement was restructured and the commercialization agreement for Surfaxin in the United States was terminated. In consideration for regaining commercialization rights to Surfaxin, the Company issued a warrant to PharmaBio to purchase 850,000 shares of the Company's common stock at an exercise price equal to $7.19 per share. In 2006, the Company restructured its $8.5 million loan with PharmaBio and, in consideration for restructuring the loan, the Company issued a warrant to PharmaBio to purchase 1.5 million shares of the Company's common stock at an exercise price equal to $3.5813 per share. See Note 9 - Corporate Partnership, Licensing and Research Funding Agreements.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
NOTE 16 - SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table contains unaudited statement of operations information for each quarter of 2006 and 2005. The operating results for any quarter are not necessarily indicative of results for any future period.

(in thousands, except per share data)

2006 Quarters Ended:	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	$ --	$ --	$ --	$ --	$ --
Expenses:					
Research and development	7,613	5,911	5,204	4,988	23,716
General and administrative	8,682	4,024	2,723	2,957	18,386
Restructuring charges	—	4,805	—	—	4,805
In-process research & development	—	—	—	—	—
Total expenses	16,295	14,740	7,927	7,945	46,907
Operating loss	(16,295)	(14,740)	(7,927)	(7,945)	(46,907)
Other income / (expense), net	500	45	(71)	100	574
Net loss	$ (15,795)	$ (14,695)	$ (7,998)	$ (7,845)	$ (46,333)
Net loss per common share - basic and diluted	$ (0.26)	$ (0.24)	$ (0.13)	$ (0.12)	$ (0.74)
Weighted average number of common shares outstanding	61,170	61,652	62,312	66,195	62,767

(in thousands, except per share data)

2005 Quarters Ended:	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
Restructuring charges	—	—	—	—	—
In-process research & development	—	—	—	16,787	16,787
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 income / (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

EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "Agreement") is made as of this 4th day of May, 2006, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and CHARLES KATZER (the "Executive").

WHEREAS, the Executive is currently employed by the Company as its Senior Vice President, Manufacturing Operations pursuant to that certain revised and amended employment agreement dated as of January 3, 2006, by and between the Company and the Executive (the "Employment Agreement"); and

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

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

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

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through December 31, 2007; provided, however, that commencing on January 1, 2008, 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 January1st date, the Company or the Executive shall have given notice that it does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions thereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the then current expiration date of the Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination.

3. Executive's Duties and Obligations.

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

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

(c) Proprietary Information and Inventions Matters. In consideration of the covenants contained herein, and further in consideration of the Term extension provided by this Agreement in relation to the Employment Agreement, the Executive hereby agrees to execute the Company's standard form of Proprietary Information and Inventions Agreement (the "Confidentiality Agreement"), a copy of which is attached to this Agreement as Exhibit B. The Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

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

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

(c) Non-Competition During and After Employment. During the Term and for 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.

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

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

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to the Executive (i) base annual compensation ("Base Salary") of at least $215,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. The Base Salary shall be reviewed at least annually for the purposes of determining increases, if any, based on the Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any such increase in Base Salary shall be solely within the discretion of the Company.

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

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

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

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

6. Change of Control Benefits.

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

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

7. Termination of Employment.

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

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

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

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

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

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

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to fifty percent (50%) of the sum of (A) the Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Highest Annual Bonus;

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

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

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

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

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

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

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

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

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

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

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

8. Notice of Termination.

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

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

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

10. Excise Tax Gross-Up.

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

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

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

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

(a) if to the Board or the Company:

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

(b) if to the Executive:

Charles Katzer
The address on file with the records of the Company

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

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

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

15. Arbitration.

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

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

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

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

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

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

(iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.

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

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

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

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

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

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

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

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

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

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

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

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

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

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

DISCOVERY LABORATORIES, INC.

By: /s/ Robert Capetola
Name: Robert J. Capetola, Ph.D.
Title: President and CEO

/s/ Charles Katzer
Charles Katzer

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) **"Highest Annual Bonus"** means the largest annual cash bonus paid to the Executive by the Company with respect to the three fiscal years of the Company immediately preceding the year containing the Change of Control Date or the Date of Termination, as applicable (annualized for any fiscal year consisting of less than 12 full months); provided, however, that, solely in the event of a Change of Control occurring prior to Executive's receipt of an annual cash bonus paid to the Executive by the Company, the Highest Annual Bonus shall mean that amount which is equal to 25% of Executive's then current base salary.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (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, Form S-3 No. 333-128929, Form S-3 No. 333-133786 and Form S-3 No. 333-139173) of Discovery Laboratories, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-110412, Form S-8 No. 333-116268, Form S-8 No. 333-127790, Form S-8 No. 333-137643 and Form S-8 No. 333-138476) pertaining to the Amended and Restated 1988 Stock Incentive Plan of Discovery Laboratories, Inc.;

of our report dated March 7, 2007, with respect to the consolidated financial statements of Discovery Laboratories, Inc., our report dated March 7, 2007, with respect to Discovery Laboratories, Inc. management's assessment of 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

Philadelphia, PA
March 14, 2007

Exhibit 31.1

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, 2007

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

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

Exhibit 31.2

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, 2007

By: /s/ John G. Cooper

John G. Cooper
Executive Vice President, Chief Financial Officer

Exhibit 32.1

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, 2006 (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, 2007

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

/s/ John G. Cooper
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.