FORM 10-K

WINDTREE THERAPEUTICS INC /DE/ - WINT

Filed: March 14, 2008 (period: December 31, 2007)

Annual report with a comprehensive overview of the company

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

FORM 10-K

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

For the fiscal year ended December 31, 2007

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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 ☐ NO ☒

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on The Nasdaq Global Market under the symbol DSCO on June 29, 2007, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $228 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 14, 2008 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 6, 2008, 96,651,532 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 2008 definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2007 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; remediation manufacturing issues related to the April 2006 process validation stability failures and plans with respect to the 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 and profitably develop and market our products;
- risks relating to our research and development activities, which involve time-consuming and expensive pre-clinical studies, multi-phase clinical trials and other studies, and which may be subject to potentially significant delays or regulatory holds, or fail;
- risks relating to the rigorous regulatory approval processes required for approval of any drug or medical device products that we may develop, independently, with development partners or pursuant to collaboration arrangements;
- the risk that the Food and Drug Administration (FDA) or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, including our New Drug Application (NDA) for Surfaxin, or may limit approval to particular indications or other label limitations;
- the risk that, even 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;
- 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;
- the risk that we may not have successfully resolved the Chemistry, Manufacturing and Controls (CMC) and other cGMP-related matters at our manufacturing operations in Totowa, New Jersey, with respect to Surfaxin and our other Surfactant Replacement Therapies presently under development, including those matters related to our April 2006 process validation stability failures and noted by the FDA in inspectional reports on Form FDA 483;
- the risk that our November 2007 Complete Response to the April 2006 Approvable Letter will not satisfy the FDA;
- the risk that we, our collaborators and development partners will be unable to develop and successfully manufacture and commercialize products that combine our drug products with innovative aerosolization technologies;
- the risk that we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances on a timely basis or in an amount sufficient to meet demand;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- risks relating to the ability of our development partners and third-party suppliers of materials, drug substances and aerosolization systems and related components to timely provide us with adequate supplies and expertise to support manufacture of drug product and aerosolization systems for initiation and completion of our clinical studies;
- the risk that, upon approval of a product candidate, we do not adequately forecast customer demand;

- risks that financial market conditions may change, additional financings could result in equity dilution, or we will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;
- the risk that we 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 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 a successful sales and marketing organization in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products;
- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- the risk that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- 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 us and our 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 the forward-looking statements, whether as a result of new information, future events or otherwise.

DISCOVERY LABORATORIES, INC.
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For the Fiscal Year Ended December 31, 2007

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 Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our proprietary 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 to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of this NDA. We are also developing Surfaxin for the treatment of Acute Respiratory Failure (ARF) in children up to two years of age suffering and 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 and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine.

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

We have implemented a business strategy that includes:

- continued investment in the development of our SRT pipeline programs, initially focused on Surfaxin and Aerosurf for neonatal and pediatric conditions, including ongoing efforts intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States;
- preparing for the potential approval and launch of Surfaxin for RDS in the United States, including building our own commercial sales and marketing organization specialized in neonatal and pediatric indications to execute the launch of Surfaxin in the United States;
- seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT product candidates, including Surfaxin and Aerosurf;
- continued investment in our quality systems and manufacturing capabilities, including our recently-completed analytical laboratories in Warrington, Pennsylvania and our manufacturing operations in Totowa, New Jersey. We plan to manufacture sufficient drug product to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT product candidates. For our aerosolized SRT, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our development and potential future commercial requirements. Our long-term manufacturing strategy includes potentially expanding our existing facilities or building or acquiring additional manufacturing capabilities for the production and development of our precision-engineered SRT drug products; and

- seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although we cannot assure you that we will identify or enter into any specific actions or transactions.

SRT TECHNOLOGY

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, KL-4 (sinapultide). KL-4 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 elimination of the risk of animal-borne diseases and a unique ability to lessen inflammatory response in the lung.

We also believe that our precision-engineered surfactant may be uniquely beneficial in reducing lung inflammation and preserving pulmonary function. In May 2007, we announced the results of two studies that were presented at the *Pediatric Academic Societies* Annual Meeting in Toronto, Canada, the first of which concluded that Surfaxin reduced the inflammatory response, and therefore improved cell survival and function compared with both a saline control as well as Survanta® (beractant), an animal-derived surfactant and the most prescribed surfactant in the United States. The second study objective was to determine the impact of Surfaxin on cytokine-driven lung inflammation and focused specifically on the transforming growth factor-beta (TGF-beta) superfamily. In this study, Surfaxin suppressed two central members of the TGF-beta superfamily (BMP10 and BMP15), which could have implications in reducing inflammation and fibrosis (scarring) of the lung in a variety of pulmonary diseases. Members of the TGF-beta superfamily are known to induce fibrosis (scar tissue formation) in the lung. These results support our strategy to focus on diseases in which respiratory inflammation plays in integral part in development, such as BPD, ARF, ALI and Cystic Fibrosis.

Aerosol Technology

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

We 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.

In September 2005, we completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf for the prevention of RDS in premature infants, 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 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.

Through our strategic alliance with Chrysalis Technologies, a Division of Philip Morris USA Inc. (Chrysalis) we gained worldwide exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. See "Strategic Alliances - Chrysalis Technologies, a Division of Philip Morris USA Inc." This novel, proprietary aerosol-generation technology has the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications and 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.

Developmental studies, the data of which were presented at the 2007 Annual *Hot Topics in Neonatology* meeting held in Washington, DC, demonstrated that Aerosurf improves lung function and reduces inflammatory markers associated with lung injury and chronic lung disease. These studies were conducted using a well-established pre-clinical model of RDS, which was selected because it closely resembles the development, structure, and function of human lungs and is regarded as the most relevant system to study the pathophysiology and treatment of RDS. Additionally, studies presented at the *Pediatric Academic Societies* Annual Meeting in 2007 compared our novel capillary aerosol generator technology to commercially available aerosol devices. The data from these studies demonstrate that (i) Aerosurf maintains its chemical composition and essential functional activity post-aerosolization, and (ii) the Chrysalis aerosolization system generated as much as a 10-fold higher aerosol output rate compared with the other devices studied.

We believe this new aerosolization technology will expand the therapeutic options for a broad range of patients with respiratory diseases.

SURFACTANT THERAPY FOR RESPIRATORY MEDICINE

Products for the Neonatal and Pediatric Intensive Care Units

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 presently 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 currently 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 compared 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.

These data supported the filing of our NDA which is currently being reviewed by the FDA. The FDA has established May 1, 2008 as its target date to complete the review of the Surfaxin NDA.

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 our NDA, predominately involving drug product specifications and stability, analytical methods 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 conducted a comprehensive investigation, which focused on analysis of our manufacturing processes, analytical methods and method validation, and active pharmaceutical ingredient suppliers. As a result of our investigation, we identified a most probable root cause to the process validation stability failures and executed a corrective action and preventative action (CAPA) plan.

In December 2006, we attended a meeting with the FDA to clarify certain of the key CMC matters identified in the Approvable Letter, provide information concerning our comprehensive investigation into the process validation stability failures and remediation of the related manufacturing issues, and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. In February 2007, we completed manufacture of three new Surfaxin process validation batches, which are subject to ongoing comprehensive stability testing in accordance with an established protocol that complies with guidelines established by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). We included six-month stability data on these batches in our response to the Approvable Letter and, as of March 2008, we have submitted our 12-month stability data to the FDA.

In November 2007, we submitted to the FDA our formal response to the April 2006 Approvable Letter. The FDA accepted our response as a Complete Response and established May 1, 2008 as its target date to complete its review of the NDA for Surfaxin for the prevention of RDS in premature infants.

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

The FDA has granted us Orphan Drug designation for Surfaxin as a treatment for RDS in premature infants. “Orphan Drugs” are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of Orphan Drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. 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, affects premature infants and 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 during the initial inpatient stay. 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 Phase 2 clinical trial for Surfaxin for the prevention and treatment of BPD, which was designed as an estimation study to evaluate the safety and potential efficacy of Surfaxin in infants at risk for BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD. We currently plan to seek scientific advice from the FDA and other regulatory agencies with respect to potential clinical trial designs to support the further development of Surfaxin for the prevention of BPD.

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, 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.

Surfaxin for Infants and Children Suffering from Acute Respiratory Failure

ARF occurs when lung tissue is significantly damaged, leading to an impairment in lung function and the requirement for endotracheal intubation and mechanical ventilation (the current standard of care). Children with ARF have reduced levels of functional surfactant. Damage to the lung that causes ARF usually leads to surfactant dysfunction and decreased surfactant production. When there is insufficient functional surfactant in the lung, the air sacs collapse and are unable to support sufficient oxygenation. The most common cause of respiratory failure in these children is viral infection of the lung, particularly influenza and respiratory syncytial virus (RSV). ARF affects approximately 15,000 children under two years of age in the United States with an estimated 30,000 - 40,000 children afflicted in developed countries each year, depending on severity of the viral season. Presently there are no approved drugs for the treatment of ARF.

In June 2007, we initiated a clinical trial to determine if restoration of surfactant with Surfaxin will improve lung function and result in a shorter duration of mechanical ventilation and NICU/PICU stay for children up to two years of age suffering with ARF. The Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care represented by a sham air control. Approximately 180 children under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 20 - 25 sites throughout the world in both the Northern and Southern Hemispheres. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. Patient enrollment has been slower than expected and, as a result, we have extended the period for patient enrollment, originally expected to conclude in mid-2008, through an additional viral season at existing and planned new clinical sites in the Northern and Southern Hemispheres. At that time, we will assess the status of patient enrollment in this trial and determine whether further adjustments to our timeline are required. Currently, we believe that data from this trial will be available in the first half of 2009.

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 nasal continuous positive airway pressure (nCPAP) and is intended to treat premature infants at risk for RDS. In September 2005, we completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf for the prevention of RDS in premature infants, 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 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 a novel aerosolization system to deliver Aerosurf to patients in the NICU. In anticipation of planned clinical trials, we are executing a series of supportive pre-clinical studies. Our design engineers, together with Chrysalis and our contract manufacturers, are optimizing the initial prototype version of this novel aerosolization system. Once development milestones have been achieved, we expect to receive from Chrysalis the prototype aerosolization system technology platform, with which we plan to manufacture aerosolization systems for use in clinical trials. In that regard, we have met with and received guidance from the FDA with respect to the design of a proposed Phase 2 clinical program, which we currently expect to initiate in mid-2008, utilizing our novel aerosolization technology.

We are also currently discussing with Chrysalis a plan for the further development of our Aerosurf program, including conceptualization and development of the next-generation aerosolization system. For this phase of development, we anticipate seeking the assistance of design engineers and medical device experts who have a track record of developing and gaining regulatory approval for medical devices and drug-device combination products, both in the United States and other international markets. If we are successful, we plan to use our next-generation version of the aerosolization system in our planned Phase 3 clinical trials and, if approved, in future commercial activities.

With the knowledge that we gain from our development activities related to the NICU and PICU, we plan to develop a program utilizing this novel aerosolization technology to develop aerosolized SRT administered as a prophylactic for adult patients in the hospital setting.

Products for the Critical Care Unit and other Hospital Settings

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 cystic fibrosis, ALI, COPD, asthma, and other debilitating respiratory conditions. We plan on applying the experience obtained in the development of Aerosurf to potentially develop our aerosolized SRT to treat some or all these respiratory disorders.

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 (a measurement of the efficiency of oxygen exchange at the alveolar level in the lung) 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 clinical trial of our SRT for the treatment of ARDS in adults, which was designed as an open-label, controlled, multi-center, international study of surfactant lavage for the treatment of ARDS in adults. The key preliminary results of this trial included that 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. In May 2007, data from this trial was presented at the Annual American Thoracic Society Medical Congress. We plan in the future 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).

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 $26.2 million, $23.7 million and $24.1 million during the years ended December 31, 2007, 2006 and 2005, respectively.

STRATEGIC ALLIANCES

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis through which we gained exclusive license 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.

We are presently collaborating with Chrysalis on a novel aerosolization system to deliver Aerosurf to patients in the NICU. Chrysalis is responsible for developing the design for the initial prototype aerosolization device platform and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and further development, manufacturing and commercialization of the combination drug–device products. See "Business – Surfactant Therapy for Respiratory Medicine – Products for the Neonatal and Pediatric Intensive Care Units – *Aerosurf, Aerosolized Surfactant Replacement Therapy in the NICU*."

Laboratorios del Dr. Esteve, S.A.

In December 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. Under the restructuring, we 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 any 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 our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

LICENSING ARRANGEMENTS; PATENTS AND PROPRIETARY RIGHTS

Patents and Proprietary Rights

Johnson & Johnson, Ortho Pharmaceutical Corporation and The Scripps Research Institute

Our precision-engineered surfactant platform technology, including Surfaxin, is based on the proprietary peptide, KL_4 (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 its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, 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 seven issued United States patents: U.S. Patent No. 5,164,369; U.S. Patent No. 5,260,273; U.S. Patent No. 5,407,914; U.S. Patent No. 5,789,381; U.S. Patent 5,952,303; U.S. Patent No. 6,013,619; and U.S. Patent No. 6, 613,734 (along with certain 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.

Our licensed patent estate also includes United States and foreign patents and applications that relate to methods of manufacturing Surfaxin and certain peptides that may be used in the manufacture of Surfaxin, and other aspects of our precision-engineered surfactant technology. These patents include U.S. Patent 5,748,891; U.S. Patent 6,013,764; U.S. Patent 6,120,795; and U.S. Patent 6,492,490 (along with certain corresponding issued and pending foreign counterparts).

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.

We also have licensed certain pending applications that relate to combination therapies of pulmonary surfactant and other drugs, and methods of use. These patent applications are pending in the United States and a number of foreign jurisdictions, including Europe and Japan.

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

Each of the above-listed PCT applications has been filed nationally in Europe and Japan, among other countries.

In September 2007, we filed U.S. and International patent applications (US 11/901,866 and PCT US/2007/090260) directed to surfactant compositions and methods of promoting mucus clearance and treating pulmonary disorders such as cystic fibrosis.

In November 2007, we filed a U.S. provisional patent application (US 61/001,586) directed to an aerosolizable liquid formulation of pulmonary surfactant, and a method and system for delivering an aerosolized pulmonary surfactant.

Chrysalis Technologies, a Division of Philip Morris USA Inc.

Through our strategic alliance with Chrysalis, we hold an exclusive license to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2022, or, in some cases, possibly later. The 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 Chrysalis' technology extend to innovations to the aerosolization technology that are made in connection with the alliance. With these proprietary rights, we believe that our aerosol SRT can be developed to potentially address a broad range of serious respiratory conditions. 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 good manufacturing practices (cGMP) established by the FDA and other international regulatory authorities. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications.

Our product candidates are manufactured by combining raw materials, such as KL_4, which is provided by Bachem California, Inc., and PolyPeptide 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, Inc. Containers, closures and excipients used in our manufacturing process are provided by suppliers including West Pharmaceutical Services, Inc., Gerresheimer Glass Inc. and Spectrum Chemical Mfg. Corp. In addition, we plan to utilize the services of Catalent Pharma Solutions, for labeling and packaging of Surfaxin, if approved, in the United States.

Our manufacturing facility is located in Totowa, New Jersey 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 cGMP. In December 2005, we purchased these operations from Laureate, our then-contract manufacturer, and entered into a transitional services arrangement under which Laureate agreed to provide us with certain manufacturing-related support services through December 2006. In July 2006, we completed the transition and terminated the transitional arrangement with Laureate. This facility is the only facility in which we produce our drug product.

Owning the Totowa manufacturing operations 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. We view our acquisition of these 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 January 2005, the FDA conducted an inspection of the Totowa operations and issued to Laureate a FDA Form 483, citing inspectional observations related to basic quality controls, process assurances and documentation requirements necessary to comply with cGMP. In response, Laureate and we implemented improved quality systems and documentation controls. In April 2006, the FDA concluded a re-inspection of the facility and issued a FDA Form 483 citing inspectional observations related predominantly to the clarification of procedures, documentation and preventative maintenance. Also in April 2006, ongoing testing of Surfaxin process validation batches that had been manufactured for us in 2005 by Laureate indicated that certain stability parameters no longer met acceptance criteria. We immediately conducted a comprehensive investigation and thereafter implemented a corrective action and preventative action (CAPA) plan. We expect the FDA to complete a re-inspection of this facility as part of its review of our NDA, for which the FDA has currently established a target date of May 1, 2008. For a discussion of these manufacturing issues, see "See Management's Discussion and Analysis of Financial Condition and Results of Operations - Manufacturing"*;* and "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."

The lease for our Totowa facility expires in December 2014. In addition to customary terms and conditions, the lease is subject to a right in the landlord, first exercisable after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. At the present time, we understand that the master tenant continues to be active in the premises. Taking into account this early termination option, which could require us to move out of our Totowa facility as early as March 2010, our long-term manufacturing strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

We are planning to have manufacturing capabilities, primarily through our Totowa manufacturing operations, 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 and all of our anticipated clinical-scale production requirements for development of our SRT pipeline, including 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.

Manufacturing - SRT Aerosolization Systems

We are developing and will potentially commercialize our aerosolized SRT to address a broad range of serious respiratory conditions, initially for hospitalized patients, including those in the NICU, PICU and ICU. "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 our aerosolized SRT, we currently plan to utilize third-party contract manufacturers, suppliers and integrators to manufacture, assemble and integrate the subcomponents of the aerosolization systems and related components. The manufacturing process involves assembly of key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, disposable dose delivery packets, which must be assembled in a clean room environment, and patient interface systems necessary to administer our aerosolized SRT to patients in the NICU, PICU and ICU. Under our manufacturing plan, third-party vendors will manufacture customized parts and assemble the key device sub-components and ship them to one central location for final assembly and integration into the aerosolization system. Once assembled, the critical drug product-contact components and patient interface systems will be packaged and sterilized. The aerosolization systems will be quality-control tested prior to release for use in our clinical trials and, potentially, for commercial use. We have entered into a Master Services Agreement with Kloehn, Inc. to act as integrator of the prototype aerosolization system device sub–components and disposable dose delivery packets that we plan to use in our planned Phase 2 clinical trials. To complete the combination drug-device product, we plan to manufacture the SRT drug product at our Totowa, New Jersey manufacturing 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."

Distribution

We are currently manufacturing Surfaxin as a liquid instillate that requires cold-chain storage and distribution. We plan to provide for appropriate distribution arrangements to commercialize Surfaxin in the United States, if approved, through ASD Specialty Healthcare, Inc., which will act as our sole U.S. wholesaler.

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 has been only one approved synthetic surfactant available, Exosurf®, formerly 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.

Combination drug products, such as our aerosolized SRT, which consists of our proprietary SRT administered through our novel aerosolization system, are similarly subject to extensive regulation by federal, state and local governmental authorities in the United States and in other countries. Combination products involve review of two or more regulated components that might normally be reviewed by different types of regulatory authorities and may involve more complicated and time-consuming regulatory coordination, approvals and clearances than our SRT drug products alone. In the United States, our aerosolized SRT combination drug-device product will be reviewed by the Center for Drug Evaluation and Research (CDER) of the FDA, subject to oversight by the Office of Combination Products. Among other things, we will have to demonstrate compliance with both cGMP, to ensure that the drug possesses adequate strength, quality, identity and purity, and applicable Quality System (QS) regulations, to ensure that the device is in compliance with applicable performance standards. Although cGMP and QS overlap in many respects, each is tailored to the particular characteristics of the types of products to which they apply, such that compliance with both cGMP and QS may present unique problems and manufacturing challenges.

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"; " – Our ongoing clinical trials may be delayed, or fail, which will harm our business"; and " – The regulatory approval process for our products is expensive and time–consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products."

The FDA has granted us Fast Track designation for the indications of ARDS in adults and for the prevention and treatment of BPD in premature infants. Designation as a Fast Track product means that the FDA has determined that the drug is intended to treat a serious or life-threatening condition and demonstrates the potential to address unmet medical needs. An important feature is that it provides for accelerated approval and the possibility of rolling submissions and emphasizes the critical nature of close, early communication between the FDA and sponsor to improve the efficiency of product development. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years.

The Office of Orphan Products Development of the FDA has granted Orphan Drug designation for Surfaxin as a treatment for RDS in premature infants, ARDS in adults 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

As of February 29, 2008, we have approximately 122 full-time employees, all employed in the United States. In connection with our manufacturing operations in Totowa, New Jersey, 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 for download free of charge through our website our annual report on Form 10-K, our quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports 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 need to continue to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval activities 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, 2007, we have an accumulated deficit of approximately $288.3 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.

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, an 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.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. In April 2006, we received a second Approvable Letter requesting additional information predominately involving drug product specifications and stability, analytical methods and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by Laureate as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately conducted a time-consuming comprehensive investigation into the process validation stability failure and implemented a corrective action and preventative action (CAPA) plan. In February 2007, we completed the manufacture of new Surfaxin process validation batches. Stability data at six months from these new process validation batches were included in our November 2007 Complete Response to the Approvable Letter. The FDA has established May 1, 2008 as its target date to complete its review of our NDA. Even thought the FDA has established a target date to complete its review, the FDA might still delay its approval of our NDA, issue another Approvable Letter or reject our NDA. Any such delay or rejection 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 without reaching a final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials. 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, or that, if we do file an MAA in the future, 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 are not 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 at any time 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. Any failure to obtain regulatory approval or any withdrawal or significant restriction on our ability to market our products after approval would have a material adverse effect on our business.

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 failures significantly delayed the FDA's 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 and Pediatric Intensive Care Units–*Surfaxin for the Prevention of Respiratory Distress Syndrome in Premature Infants*." The FDA has now established May 1, 2008 as the target date by which it will complete its review of our NDA. In connection with its review, the FDA may request additional information from us, which could further delay review of our NDA. Although the FDA has not requested additional clinical data to date, it could at any time in its review process request additional data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product and would have a material adverse effect on our business.

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. We believe that other potential products in our SRT pipeline may also qualify for Fast Track designation. 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, 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. Moreover, even if we are successful in gaining Fast Track designation, other factors could result in significant delays in our development activities with respect to our Fast Track products.

Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes.

Development risk factors include, but are not limited to whether we, or our third party collaborators and providers, will be able to:

- complete our pre-clinical and clinical trials of our SRT product candidates with scientific results that are sufficient to support further development and/or regulatory approval;
- receive the necessary regulatory approvals;
- obtain adequate supplies of surfactant active drug substances, manufactured to our specifications and on commercially reasonable terms;
- perform under agreements to supply of drug substances, medical device components and related services necessary to manufacture our SRT drug product candidates, including Surfaxin and Aerosurf;
- successfully resolve the chemistry, manufacturing and controls (CMC) matters identified by the FDA in the April 2006 Approvable Letter and in inspectional reports cited on Form FDA 483;
- provide for sufficient manufacturing capabilities, at our manufacturing operations in Totowa and with third-party contract manufacturers, to produce sufficient SRT drug product, including Surfaxin, and aerosolization systems to meet our pre-clinical and clinical development requirements;
- successfully develop and implement a manufacturing strategy for our aerosolization systems and related materials to support clinical studies of Aerosurf; and
- obtain capital necessary to fund our research and development efforts, including our supportive operations, manufacturing and clinical trials requirements.

Because these factors, many of which are outside our control, could have a potentially significant effect on our development 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;
- failure of a product candidate to demonstrate effectiveness; and
- lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. Failure to obtain and maintain regulatory approval and generate revenues from the sale of our products would have a material adverse effect on our financial condition and results of operations and could reduce the market value of our common stock.

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 many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both.

Patient enrollment 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 willingness of patients or their parents or guardians to participate in the clinical trial;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If we succeed in achieving our patient enrollment targets, patients that enroll in our clinical trials could suffer adverse medical events or side effects that are known to occur with the administration of the surfactant class of drugs generally, such as a decrease in the oxygen level of the blood upon administration. It is also possible that the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we or any regulator believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials.

In addition to our efforts to gain approval of Surfaxin for the prevention of RDS in premature infants, we are currently conducting a Phase 2 clinical trial to evaluate the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure. We are also planning to initiate clinical studies in support of other products in our SRT pipeline, including planned Phase 2 clinical trials with respect to Aerosurf for the treatment and prevention of RDS in premature infants in the NICU. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

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, this could cause us to delay any potential clinical program or product launch or, following approval, cause us to experience shortages of products inventories.

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 other similar requirements that the FDA or foreign regulators establish. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications.

The manufacture of pharmaceutical products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our contract manufacturers or our materials and drug substances suppliers may experience manufacturing or quality control problems that could result in a failure to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, which is necessary to continue manufacturing our drug products, materials or drug substances. Other problems that may be encountered include:

- the need to make necessary modifications to qualify and validate a facility;
- difficulties with production and yields, including scale-up requirements and achieving adequate capacity;
- availability of raw materials and supplies;
- quality control and assurance; and
- shortages of qualified personnel.

Such a failure could result in product production and shipment delays or an inability to obtain materials or drug substances supplies.

Manufacturing or quality control problems have already occurred and may again occur at our Totowa, New Jersey facility or may occur at the facilities of a contract manufacturer or our materials or drug substances suppliers. Such problems, including, for example, our April 2006 process validation stability failure, may require potentially complex, time-consuming and costly comprehensive investigations to determine the root causes of such problems and may also require detailed and time-consuming remediation efforts, which can further delay a return to normal manufacturing and production activities. Any failure by our own manufacturing operations or by the manufacturing operations of any of our suppliers to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our ability to manufacture our drug products, which in turn would adversely affect our clinical research activities and our ability to develop and gain regulatory approval to market our drug products.

Since we acquired Laureate's manufacturing operations in Totowa, New Jersey in December 2005, we have been manufacturing our drug products. This is the only facility at which we produce our drug product. Any interruption in manufacturing operations at this location could result in our inability to satisfy our needs for planned clinical trials, and, if approved, commercial requirements for Surfaxin. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slowdowns;
- damage to or destruction of the facility;
- regional power shortages; and
- product tampering.

To assure adequate drug supplies and continued compliance with cGMP and other FDA or foreign regulatory requirements, we own certain specialized manufacturing equipment, employ experienced manufacturing senior executive and managerial personnel, and continue to invest in enhanced quality systems and manufacturing capabilities. However, we may nevertheless be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards. If we are unable to successfully develop and maintain our manufacturing capabilities and comply with cGMP, it will adversely affect our clinical development activities and, potentially, the sales of our products.

If we fail to maintain relationships with our manufacturers, assemblers and integrator of our aerosolization systems, or if we fail to identify additional, qualified replacement manufacturers, assemblers and integrators to manufacture subcomponents and integrate our initial prototype aerosolization system or our anticipated next-generation and later development versions of our aerosolization systems, the timeline of our plans for the development and, if approved, commercialization of Aerosurf could suffer.

In connection with the development of aerosol formulations of our SRT, including Aerosurf, we currently plan to rely on third-party contract manufacturers to manufacture, assemble and integrate the subcomponents of the aerosolization systems to support our clinical studies and potential commercialization of Aerosurf. Certain of these key components must be manufactured in an environmentally-controlled area and, when assembled, the critical product-contact components and patient interface systems must be packaged and sterilized. Each of the aerosolization system devices must be quality-control tested prior to release and monitored for conformance to designated product specifications, and each manufacturer, assembler and integrator must be registered with the FDA and conduct its manufacturing activities in compliance with cGMP requirements or other FDA or foreign regulatory requirements.

We currently have identified component manufacturers and an integrator to manufacture and integrate the initial prototype aerosolization system that we plan to use in our early Phase 2 clinical trials. However, we may not be able to identify additional or replacement qualified manufacturers and integrators to manufacture subcomponents and integrate our current prototype or next generation and later development versions of our aerosolization systems or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers and integrators that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, requirements regulating manufactures of combination drug-device products. If we do not successfully identify and enter into a contractual agreements with aerosolization systems and components manufacturers, assemblers and integrators, it will adversely affect the timeline of our plans for the development 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, materials and excipient products, and third parties for certain manufacturing-related services to produce drug material that meets appropriate content, quality and stability standards for use in clinical trials and, if approved, 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 Aerosurf, a combination drug-device product, includes the integration of a number of components, 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 to applicable specifications 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.

In some cases, we are dependent upon a single supplier to produce our full requirement of drug substances, drug product or drug product devices. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or vendor and may not be able to 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 our profit margins, if any. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. Such delays could have a material adverse effect on our development activities and our business.

If we do not adequately forecast customer demand for our product candidates, including Surfaxin, if approved, our business could suffer.

The timing and amount of customer demand is difficult to predict and the scale-up requirements to meet changing customer demand is difficult to predict. We may not be able to respond to unanticipated increases in demand quickly enough to fill customer orders on a timely basis. This could cause us to lose business. If we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and timely commercialize our product candidates, we may never require the production capacity that we expect to have available.

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

We have limited experience in marketing or selling pharmaceutical products and have a limited marketing and sales team. As a result of our April 2006 manufacturing problems, we discontinued our commercial activities in the second quarter 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, if approved.

We expect to rely primarily on our marketing and sales team to market Surfaxin, if approved, in the United States. Accordingly, we plan to further develop our marketing and sales team. Developing a marketing and sales team to market and sell products is a difficult, expensive and time-consuming process. Recruiting, training and retaining qualified sales personnel is critical to our success. Competition for skilled personnel can be intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Additionally, we may not be able to provide adequate incentive to our sales force. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, we will have difficulty selling, maintaining and increasing the sales of our products.

We also will need to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates, which will likely require a substantial capital investment. We expect to incur significant expenses in developing our marketing and sales team. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, potentially, 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.

The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Any potential products that we bring to market may not gain or maintain market acceptance by governmental purchasers, group purchasing organizations, physicians, patients, healthcare payers and others in the medical community. If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues with these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the perceived safety and efficacy of our products;
- the potential advantages over alternative treatments;
- the prevalence and severity of any side effects;
- the relative convenience and ease of administration;

- cost effectiveness;
- the willingness of the target patient population to try new products and of physicians to prescribe our products;
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

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, either internationally or in the United States. We may not be successful in identifying such third parties or finalizing such arrangements on terms and conditions that are favorable to us. 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.

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

If we fail to enter into arrangements with third parties in a timely manner or if 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.

We intend to market and sell Surfaxin outside of the United States, if and when approved, through one or more marketing partners. Although our agreement with Esteve provides for collaborative efforts in directing a global commercialization effort, we have somewhat limited influence over the decisions made by Esteve or their sublicensees or the resources they 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.

Our strategy with respect to development and marketing of our products, in many cases, is to enter into collaboration agreements and strategic partnerships with third parties. 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 develop and commercialize our products.

To fund development, clinical testing and marketing and commercialization of our products, our strategy, in many cases, depends upon collaboration arrangements and strategic partnerships with pharmaceutical and other biotechnology companies to develop, market, commercialize and distribute our products. In addition to funding our activities, we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize the covered products. In addition, 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 such additional collaboration partners.

Our collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates is focused on key southern European markets. If we or Esteve should fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products for the Esteve territory in Europe covered by the arrangement. In such events, we may need to seek other partners and collaboration agreements, or we may have to develop our own internal capabilities to market the covered products in the Esteve territory without a collaboration arrangement.

Under our alliance with Chrysalis, Chrysalis is responsible for developing the design for the initial prototype aerosolization device platform and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and further development, manufacturing and commercialization of the combination drug-device products. We are currently discussing with Chrysalis a plan for the further development of our Aerosurf program and anticipate seeking the assistance of design engineers and medical device experts who have a track record of developing and gaining regulatory approval for medical devices and drug-device combination products. If we or Chrysalis should fail in our efforts to develop the initial prototype aerosolization system, or if we are unable to identify design engineers and medical device experts to support our program, or if a dispute should arise under the Chrysalis collaboration arrangements, such events could impair our ability to commercialize or develop our aerosolized SRT products.

We may, in the future, grant to our present or additional collaboration partners rights to license and commercialize our pharmaceutical products. Under such 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 alternative strategies to develop and commercialize our products. If we were to fail to successfully develop these relationships, or if our collaboration partners were to fail to successfully develop, market or commercialize any of the covered products, such failures 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 and our other SRT product candidates. See “Risk Factors - Our limited sales and marketing experience may restrict our success in commercializing our product candidates.”

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. Our operating plans require that expenditures will only be committed if we have the necessary working capital resources. Our existing capital will allow us to continue operations into 2009. 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 financing 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.

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge Capital Limited (Kingsbridge), our loan with PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), and our equipment financing facility with General Electric Capital Corporation (GECC), as successor to Merrill Lynch Capital. Any future financing could be on unattractive terms or result in significant dilution of stockholders’ interests and, in such event, the market price of our common stock may decline. Furthermore, if the market price of our common stock were to decline, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq Global Market.

If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See also "Risk Factors - Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders."

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 take any further specific actions or enter into any transactions.

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

Our capital requirements are funded in part by 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 owed 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.

We finance the acquisition of personal property, machinery and equipment through a $12.5 million equipment financing facility with GECC, as successor to Merrill Lynch Capital (Merrill Lynch) under a facility that we entered with Merrill Lynch in May 2007. The amounts financed by this facility are secured by the acquired assets. Initially, $9 million was made available immediately and a portion applied to the prepayment of all amounts outstanding under our then-existing lending facility with GECC. As we raise additional capital, additional funds become available under the facility. To date, an additional $3 million has become available. Our ability to draw under this facility expires in May 2008. Although the Loan Agreement provides that the Lender will consider extending the draw period, on a best efforts basis, for an additional six months, there can be no assurances that we will obtain an extension. Moreover, although we negotiated the terms of this facility with Merrill Lynch, the decision on the extension will be made by GECC. Failure to gain an extension from GECC or to secure a replacement facility would have an adverse effect on our capital planning and our ability to conduct our business.

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.

If we are unable to meet the conditions provided under the CEFF, 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, even if we meet all conditions provided under the CEFF, we are dependent upon the financial ability of Kingsbridge to perform its obligations and purchase shares of our common stock under 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;
- patient adverse reactions to drug products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- 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” or elsewhere in this Annual Report on Form 10-K or our other publics filings.

Our common stock is listed for quotation on The Nasdaq Global Market. During the twelve month period ended December 31, 2007, the price of our common stock has ranged from $1.90 to $3.75. 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, 2007, the average daily trading volume in our common stock was approximately 801,079 shares and the average number of transactions per day was approximately 2,142. 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. See "Legal Proceedings." Even if they or other actions that we may face in the future are ultimately determined to be meritless or unsuccessful, such actions would involve 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 our 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 6, 2008, we had 96,651,532 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 $24.8 million is remaining. 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 5.2 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 issued to Kingsbridge in connection with the CEFF. See "Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

As of December 31, 2007, 19,078,751 shares of our common stock are reserved for issuance pursuant to our equity incentive plans (including 13,929,591 shares underlying outstanding stock options and 56,660 shares underlying unvested restricted stock awards), 6,339,196 shares of our common stock are reserved for issuance upon exercise of outstanding warrants, and 205,626 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, 2007, 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 (USPTO) has not adopted a consistent policy regarding the breadth of claims that it will allow 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 appear to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad or they may expire and others could then 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 USPTO 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 USPTO 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 USPTO 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 Pharmaceutical Corporation (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. For our aerosolized SRT, we hold an exclusive license to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases, which extends to innovations that are made in connection with the alliance. The aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2022, 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 USPTO 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 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.

Following receipt of the Approvable Letter and the manufacturing issues that occurred in April 2006, we reduced our staff levels by approximately 50 people and reorganized our corporate structure. As a consequence, our dependence on our remaining management team was significantly increased. To retain and provide incentives to our key executives and certain officers, in 2006, we entered into amended and new employment agreements that generally include provisions such 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 of February 29, 2008, we have employment agreements with 13 officers, of which three expire in May 2010; the remainder expire in December 2008. Each employment agreement provides that its term shall automatically be extended for one additional year, unless at least 90 days prior to the renewal date either party gives notice that it does not wish to extend the agreement. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel. We may 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 and we may incur substantial costs.

The clinical testing, marketing and use of our products exposes us to product liability claims if the use or misuse of our 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, including by insurers licensed in countries where we conduct our clinical trials, before initiating clinical trials. We expect to obtain product liability insurance coverage before commercializing any of our product candidates; however, such insurance is expensive and may not be available when we need it.

In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product liability claim, even one that is within the limits 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, such claims could result in:

- uninsured expenses related to defense or payment of substantial monetary awards to claimants;
- a decrease in demand for our product candidates;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our product candidates, if approved.

Moreover, the existence of a product liability claim could affect the market price of our common stock.

Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations affecting our activities in the jurisdictions in which we may sell our products, if approved, and a failure to comply with such regulations or prevail in litigation related to noncompliance could harm our business.

Many of our activities, including the research, development, manufacture, sale and marketing of our products, are subject to extensive laws and regulation, including without limitation, health care "fraud and abuse" laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. We have developed and implemented a corporate compliance policy and oversight program based upon what we understand to be current industry best practices, but we cannot assure you that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such investigations, actions or lawsuits are instituted against us, and if we are not successful in defending or disposing of them without liability, such investigations, actions or lawsuits could result in the imposition of significant fines or other sanctions and could otherwise have a significant impact on our business.

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.

To obtain reimbursement from a third party payer, it must determine that our drug product is a covered benefit under its health plan, which is likely to require a determination that our product is:

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining a determination that a product is a covered benefit may be a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data about our products to each payer. We may not be able to provide sufficient data to gain coverage.

Even when a payer determines that a product is covered, the payer may impose limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. Moreover, coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that would permit a health care provider to cover its costs of using our product.

Provisions of our Certificate of Incorporation, Shareholder 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 Shareholder 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 Shareholder 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 Shareholder 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. 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. These actions were consolidated under the caption "In re: Discovery Laboratories Securities Litigation" and the District Court granted our motions to dismiss two Consolidated Amended Complaints. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania. Briefing on this matter is completed and oral argument is scheduled for March 25, 2008.

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 and proceedings 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 USPTO 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 USPTO, 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 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.

We maintain our principal executive offices at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622, which consists of 39,594 square feet of space that we lease at an annual rent of approximately $922,000. In April 2007, the lease, which originally expired in February 2010 with total aggregate payments of $4.6 million, was extended through February 2013, with additional payments of $3.0 million over the three-year extension period. We do not own any real property.

We recently completed construction of a new analytical and development laboratory within our Warrington, Pennsylvania headquarters location. We are consolidating into our new laboratory all of the analytical, quality and development activities that have been conducted in Doylestown, Pennsylvania and Mountain View, California. Our analytical testing activities predominantly involve release and stability testing of raw materials as well as commercial and clinical drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our product candidates.

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

We lease approximately 5,600 square feet of space in Doylestown, Pennsylvania for our analytical laboratory at an annual rent of approximately $93,800. The original term of this lease expired in August 2007 but we have been extending on a month-to-month basis. We are currently consolidating the activities at this location into our new laboratory space in Warrington, Pennsylvania and plan to terminate this lease in the second quarter 2008.

We lease 16,800 square feet at our research facility in Mountain View, California, at an annual rent of approximately $275,000. We have used this facility principally to develop aerosolized and other formulations of our proprietary precision-engineered surfactant. The term of this lease expires at the end of June 2008. In December 2007, we consolidated these activities into our new laboratory space in Warrington, Pennsylvania and will not renew or extend this lease.

ITEM 3. LEGAL PROCEEDINGS.

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendants' motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various of our public statements. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania and filed an opening brief on July 2, 2007. Briefing on this matter is completed and oral argument is scheduled for March 25, 2008.

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

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

No matters were submitted to a vote of security holders during the fourth quarter 2007.

PART II

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

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "DSCO." As of February 29, 2008, the number of stockholders of record of shares of our common stock was 163 and the number of beneficial owners of shares of our common stock was approximately 15,000. As of March 6, 2008, there were 96,651,532 shares of our common stock issued and outstanding.

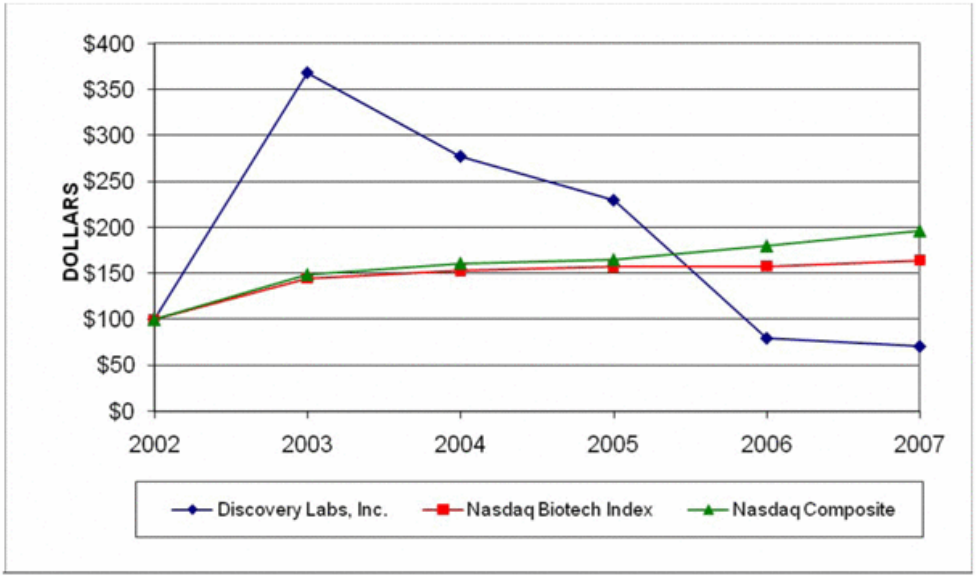
The following table sets forth the quarterly sales price ranges of our common stock for the periods indicated, as reported by Nasdaq.

	Low	High
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	$ 1.90	$ 2.90
Second Quarter 2007	$ 2.20	$ 3.75
Third Quarter 2007	$ 2.07	$ 2.95
Fourth Quarter 2007	$ 2.10	$ 3.25
First Quarter 2008 (through March 6, 2008)	$ 1.75	$ 2.46

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.

Performance Graph[(1)]

The graph below compares the cumulative total stockholder return from the common stock with the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The period shown commences on December 31, 2002, and ends on December 31, 2007. The cumulative total stockholder return assumes that $100 was invested on December 31, 2002 in the Common Stock.



Note: The performance shown in the graph and table represents past performance and should not be considered an indication of future performance.

	2002	2003	2004	2005	2006	2007
Discovery Labs, Inc.	$ 100.00	$ 368.07	$ 277.19	$ 229.44	$ 79.40	$ 70.54
Nasdaq Biotech Index	$ 100.00	$ 144.86	$ 153.00	$ 156.98	$ 157.58	$ 163.89
Nasdaq Composite	$ 100.00	$ 148.74	$ 160.89	$ 164.87	$ 179.65	$ 196.11

[(1)] The material contained in this Performance Graph shall not be deemed to be "soliciting material," or "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing

Sales of Unregistered Securities

During the 12 months ended December 31, 2007, 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 12 months ended December 31, 2007.

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, 2007, 2006 and 2005 and with respect to the Consolidated Balance Sheets as of December 31, 2007 and 2006 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, 2004 and 2003 and the balance sheet data as of December 31, 2005 and 2004 and 2003 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,				
	2007	**2006**	**2005**	**2004**	**2003**
Revenues from collaborative agreements	$ -	$ -	$ 134	$ 1,209	$ 1,037
Operating Expenses:					
Research and development	26,200	23,716	24,137	25,793	19,750
General and administrative	13,747	18,386	18,505	13,322	5,722
Restructuring charges	-	4,805	-	8,126	-
In-process research and development	-	-	16,787	-	-
Total expenses	39,947	46,907	59,429	47,241	25,472
Operating loss	(39,947)	(46,907)	(59,295)	(46,032)	(24,435)
Other income / (expense)	(58)	574	391	(171)	155
Net loss	$ (40,005)	$ (46,333)	$ (58,904)	$ (46, 203)	$ (24,280)
Net loss per common share - basic and diluted	$ (0.49)	$ (0.74)	$ (1.09)	$ (1.00)	$ (0.65)
Weighted average number of common shares outstanding	81,731	62,767	54,094	46,179	37,426

Consolidated Balance Sheet Data:
(in thousands)

	For the year ended December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
Cash and investments	$ 53,007	$ 26,402	$ 50,908	$ 32,654	$ 29,422
Working capital	43,149	18,999	33,860	24,519	23,061
Total assets	62,744	34,400	56,008	37,637	32,715
Long-term obligations, less current potion	13,494	12,110	3,562	7,583	711
Total stockholder's equity	$ 38,781	$ 14,322	$ 34,838	$ 21,097	$ 24,303

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

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 Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our proprietary 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 to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of this NDA. We are also developing Surfaxin for the treatment of Acute Respiratory Failure (ARF) in children up to two years of age suffering and 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 and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine.

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

We are implementing a business strategy that includes:

- continued investment in the development of our SRT pipeline programs, initially focused on Surfaxin and Aerosurf for neonatal and pediatric conditions, including ongoing efforts intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States. The FDA accepted our Complete Response to the April 2006 Approvable Letter and has established May 1, 2008 as its target date to complete its review of our Surfaxin NDA;

- preparing for the potential approval and launch of Surfaxin for RDS in the United States, including building our own commercial sales and marketing organization specialized in neonatal and pediatric indications to execute the launch of Surfaxin in the United States;

- seeking collaboration agreements and strategic partnerships in the international markets for the development and potential commercialization of our SRT pipeline, including Surfaxin and Aerosurf. We have a corporate partnership with Laboratorios del Dr. Esteve, S.A., primarily for the marketing and sales of Surfaxin and certain of our other SRT products in southern Europe. We continue to evaluate a variety of other potential strategic international and domestic collaborations intended to support the future growth of our SRT pipeline and enhance shareholder value;

- continued investment in our quality systems and manufacturing capabilities, including our recently-completed analytical laboratories in Warrington, Pennsylvania and our manufacturing operations in Totowa, New Jersey. We plan to manufacture sufficient drug product to meet the anticipated pre-clinical, clinical, formulation development and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT product candidates. For our aerosolized SRT, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our development and potential future commercial requirements. Our long-term manufacturing strategy includes potentially expanding our existing facilities or building or acquiring additional manufacturing capabilities for the production and development of our precision-engineered SRT drug products; and

- seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although we cannot assure you that we will identify or enter into any specific actions or transactions.

Since our inception, we have incurred significant losses and, as of December 31, 2007, we had an accumulated deficit of $288.3 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 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, 2007, we had: (i) cash of $53.0 million; (ii) approximately 5.2 million shares potentially available for issuance under a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, for future financings (not to exceed $35.5 million), subject to the terms and conditions of the agreement; (iii) $9.6 million outstanding ($8.5 million principal and $1.1 million of accrued interest as of December 31, 2007) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp. (Quintiles), which, after a restructuring, is due and payable, together with all accrued interest, on April 30, 2010; and (iv) $5.6 million outstanding on under our equipment financing facility with GECC, as successor to Merrill Lynch Capital. 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, 2007, 2006 and 2005 were $26.2 million, $23.7 million, and $24.1 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 manufacturing development, research, formulation 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, New Jersey, facility, which was classified as in-process research and development. This non-recurring charge is not reflected in the following discussion.

These cost categories typically include the following expenses:

Manufacturing Development

Manufacturing development primarily reflects costs incurred to develop current good manufacturing practices (cGMP) manufacturing capabilities. Manufacturing development includes: (1) costs associated with manufacturing activities at operations in Totowa, New Jersey to support the production of clinical and anticipated commercial drug supply for our SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; (2) investments in our quality assurance and analytical chemistry capabilities, including ongoing enhancements to quality controls, process assurance and documentation and expanding and upgrading our quality operations to meet production requirements for our SRT pipeline in accordance with cGMP; and (3) expenses associated with our comprehensive investigation of the April 2006 Surfaxin process validation stability failure, remediation of our related manufacturing issues and activities associated with obtaining related data and other information included in our Complete Response to the April 2006 Surfaxin Approvable Letter.

Unallocated Development - Clinical, Regulatory, Formulation Development and Medical Affairs

Clinical, regulatory and formulation development activities include preparation, implementation and management of our clinical trial programs in accordance with current good clinical practices (cGCPs), research and development of aerosolized and other formulations of our precision-engineered SRT, engineering of aerosol delivery systems and analytical chemistry activities to support the continued development of Surfaxin. Included in Unallocated Development are costs of associated personnel, supplies, facilities, fees to consultants, other related costs of clinical trials and management, clinical quality control and regulatory compliance activities, data management and biostatistics, including activities associated with obtaining related data and other information included in our Complete Response to the Surfaxin Approvable Letter. Unallocated development also includes medical affairs activities, primarily consisting of medical science liaisons personnel providing medical education about the use of surfactants.

Direct Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include pre-clinical activities, activities associated with the development of our SRT formulations aerosolization systems prior to initiation of any potential human clinical trials, and activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, costs of clinical drug supply and related external costs such as contract research consultant fees and expenses.

The following summarizes our research and development expenses by each of the foregoing categories for the years ended December 31, 2007, 2006 and 2005:

(Dollars in thousands)

	Year Ended December 31,		
Research and Development Expenses:	**2007** (1)	**2006** (1)	**2005**
Manufacturing development	$ 11,888	$ 10,057	$ 11,416
Unallocated development – clinical, regulatory, etc.	8,885	10,288	9,485
Direct pre-clinical and clinical program expenses	5,427	3,371	3,236
Total Research and Development Expenses	**$ 26,200**	**$ 23,716**	**$ 24,137**

(1) Included in research and development expenses for the year ended December 31, 2007 and 2006 is a charge of $1.7 million and $1.6 million associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R), respectively.

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

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, 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.”

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis through which we gained exclusive license 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.

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 initial prototype aerosolization device platform and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and further development, manufacturing and commercialization of the combination drug-device products. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations - Research and Development - SRT for Neonatal Intensive Care Unit - *Aerosurf, Aerosolized SRT*."

Laboratorios del Dr. Esteve, S.A.

In December 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. Under the restructuring, we 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 any 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 our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

PLAN OF OPERATIONS

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

Through December 31, 2007, we had no revenues from any product sales, and had not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into collaboration and other agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

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

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 herein and those contained in the "Risk Factors." See "Management's Discussion and Analysis of Financial Condition and Results of Operations - 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 and PICU, we are conducting several NICU and PICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal and pediatric community.

Surfaxin for the Prevention of RDS in Premature Infants

We have filed an NDA with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of this NDA.

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 our NDA, predominately involving drug product specifications and stability, analytical methods and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by Laureate as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately conducted a comprehensive investigation, which focused on analysis of our manufacturing processes, analytical methods and method validation, and active pharmaceutical ingredient suppliers. As a result of our investigation, we identified a most probable root cause to the process validation stability failures and executed a corrective action and preventative action (CAPA) plan.

In December 2006, we attended a meeting with the FDA to clarify certain of the key CMC matters identified in the April 2006 Approvable Letter, provide information concerning our comprehensive investigation into the process validation stability failures and remediation of the related manufacturing issues, and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. In February 2007, we completed manufacture of three new Surfaxin process validation batches, which are subject to ongoing comprehensive stability testing in accordance with an established protocol that complies with guidelines established by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). We included six-month stability data on these batches in our response to the Approvable Letter and, as of March 2008, we have submitted our 12-month stability data to the FDA.

In November 2007, we submitted to the FDA our formal response to the April 2006 Approvable Letter. The FDA accepted our response as a complete response and established May 1, 2008 as its target date to complete its review of the NDA for Surfaxin for the prevention of RDS in premature infants.

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

Surfaxin for the Prevention of BPD in Premature Infants

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

Surfaxin for Infants and Children Suffering from Acute Respiratory Failure

In June 2007, we initiated a clinical trial to determine if restoration of surfactant with Surfaxin will improve lung function and result in a shorter duration of mechanical ventilation and NICU/PICU stay for children up to two years of age suffering with ARF. The Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care represented by a sham air control. Approximately 180 children under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 20 - 25 sites throughout the world in both the Northern and Southern Hemispheres. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. Patient enrollment has been slower than expected and, as a result, we have extended the period for patient enrollment, originally expected to conclude in mid-2008, through an additional viral season at existing and planned new clinical sites in the Northern and Southern Hemispheres. At that time, we will assess the status of patient enrollment in this trial and determine whether further adjustments to our timeline are required. Currently, we believe that data from this trial will be available in the first half of 2009.

Aerosurf, Aerosolized SRT

In September 2005, we completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf for the prevention of RDS in premature infants, 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 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 a novel aerosolization system to deliver Aerosurf to patients in the NICU. In anticipation of planned clinical trials, we are executing a series of supportive pre-clinical studies. Our design engineers, together with Chrysalis and our contract manufacturers, are optimizing the initial prototype version of this novel aerosolization system. Once development milestones have been achieved, we expect to receive from Chrysalis the prototype aerosolization system technology platform, with which we plan to manufacture aerosolization systems for use in clinical trials. In that regard, we have met with and received guidance from the FDA with respect to the design of a proposed Phase 2 clinical program, which we currently expect to initiate in mid-2008, utilizing our novel aerosolization technology.

We are also currently discussing with Chrysalis a plan for the further development of our Aerosurf program, including conceptualization and development of the next-generation aerosolization system. For this phase of development, we anticipate seeking the assistance of design engineers and medical device experts who have a track record of developing and gaining regulatory approval for medical devices and drug-device combination products, both in the United States and other international markets. If we are successful, we plan to use our next-generation version of the aerosolization system in our planned Phase 3 clinical trials and, if approved, in future commercial activities.

With the knowledge that we gain from our development activities related to the NICU and PICU, we plan to develop a program utilizing this novel aerosolization technology to develop aerosolized SRT administered as a prophylactic for adult patients in the hospital setting.

SRT for Critical Care and Hospital Indications

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

Manufacturing

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

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

Current Manufacturing Capabilities

In December 2005, we purchased our manufacturing operations from Laureate (our contract manufacturer at that time) and completed the transition of all related activities from Laureate in July 2006. Owning the Totowa manufacturing operations 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.

In April 2006, ongoing analysis of our initial Surfaxin process validation batches that were manufactured for us in 2005 by Laureate as a requirement for our NDA for Surfaxin for the prevention of RDS in premature infants 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 (CAPA) plan to remediate the related manufacturing issues. We expect the FDA to complete an inspection of this facility as part of its review of our Surfaxin NDA, for which the FDA has currently established a target date of May 1, 2008. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations - Research and Development - SRT for Neonatal Intensive Care Unit - *Surfaxin for the Prevention of RDS in Premature Infants.*"

In February 2007, consistent with guidance obtained at a December 2006 meeting with the FDA, we completed the manufacture of three new Surfaxin process validation batches, which are subject to ongoing comprehensive stability testing in accordance with an established protocol that complies with guidelines established by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). We included six-month stability data on these batches in our response to the Approvable Letter and, as of March 2008, we have submitted our 12-month stability data to the FDA.

Our manufacturing strategy includes ongoing investment in our analytical and quality systems to support our manufacturing and development activities. In October 2007, we completed construction of a new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters. The new laboratory will consolidate the analytical, quality and development activities that are presently located in Doylestown, Pennsylvania and Mountain View, California, including release and stability testing of raw materials as well as commercial and clinical drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our product candidates. The laboratory will expand our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our newly consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics.

Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operations in Totowa, New Jersey that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential worldwide demand for our RDS, ARF and BPD programs and all of our anticipated clinical and potential commercial production requirements for Aerosurf.

We view our acquisition of manufacturing operations in Totowa 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 facility expires in December 2014. In addition to customary terms and conditions, the lease is subject to a right in the landlord, first exercisable after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. Taking into account this early termination option, which could require us to move out of our Totowa facility as early as March 2010, our long-term manufacturing strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

Aerosol Devices and Related Componentry

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

See the applicable risks related to our manufacturing activities and our long-term manufacturing strategy discussed in "Risk Factors."

Sales and Marketing

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

We anticipate that the FDA will potentially grant approval of our Surfaxin NDA in May 2008 and that the U.S. commercial launch of Surfaxin will occur later in the year. We have initiated marketing and related activities, including the hiring of experienced management personnel, and plan to hire sales and marketing representatives following receipt of approval to market Surfaxin. Additionally, we are also enhancing our medical affairs capabilities to provide for increased scientific and educational activities.

We expect to rely primarily on our marketing and sales team to market Surfaxin, if approved, in the United States. We expect to incur significant expenses in developing our U.S. marketing and sales team. We also intend to pursue potential collaboration arrangements with international partners to co-develop and/or co-commercialize our neonatal and pediatric pipeline for Surfaxin and Aerosurf.

General and Administrative

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

Potential Collaboration Agreements and Strategic Partnerships

We intend to seek investments of additional capital and potentially enter into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. From June 2006 to July 2007, we engaged Jefferies & Company, Inc. (Jefferies), a New York-based investment banking firm, under an exclusive arrangement to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Registered Public Offerings” and “ - Private Placements”

CRITICAL ACCOUNTING POLICIES

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

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.

There have been no changes to our critical accounting policies since December 31, 2006.

RESULTS OF OPERATIONS

The net loss for the years ended December 31, 2007, 2006 and 2005 was $40.0 million (or $0.49 per share), $46.3 million (or $0.74 per share) and $58.9 million (or $1.09 per share), respectively.

For the years ended December 31, 2006 and 2005, we incurred two restructuring charges that were identified separately on our Statements of Operations: (i) 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 that followed the April 2006 process validation stability failure, and (ii) in 2005, we purchased our manufacturing operations in Totowa, New Jersey, 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.

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 $5.2 million (of $0.06 per share) and $5.5 million (or $0.09 per share) in the Statement of Operations for the years ended December 31, 2007 and 2006, respectively, without adjusting the year ending December 31, 2005.

Revenue

We did not earn revenue during the years ended December 31, 2007 and 2006. For the year ended December 31, 2005, we earned $0.1 million of revenue associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in southern Europe.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2007, 2006 and 2005 were $26.2 million, $23.7 million, and $24.1 million, respectively. For a description of expenses and research and development activities, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Research and Development.” For a description of the clinical programs included in research and development, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.”

The change in research and development expenses for the years ended December 31, 2007, 2006 and 2005 primarily reflects:

(i) Manufacturing development activities (included in research and development expenses) to support the production of clinical and anticipated commercial drug supply for our SRT programs, including Surfaxin, in conformance with cGMP. Expenses related to manufacturing development activities were $11.9 million, $10.0 million, and $11.4 million for the years ended December 31, 2007, 2006 and 2005, respectively.

For 2007 and 2006, manufacturing development activities included: (i) operating costs associated with our manufacturing operations in Totowa, New Jersey, (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) investments in our quality assurance and analytical chemistry capabilities, including ongoing enhancements to quality controls, process assurance and documentation and expanding and upgrading our quality operations to meet production requirements for our SRT pipeline in accordance with cGMP; (iii) activities associated with our comprehensive investigation of the April 2006 Surfaxin process validation stability failure, remediation of our related manufacturing issues, and obtaining data and other information included in our Complete Response to the April 2006 Surfaxin Approvable Letter; (iv) activities to develop additional formulations of our SRT; and (v) activities to develop aerosolization systems, including the aerosol generating device, the disposable dose delivery packet and patient interface system necessary to administer Aerosurf. The increase in 2007 as compared to 2006 is primarily due to investments in our quality assurance and analytical chemistry capabilities that support the production process, expanding and upgrading our quality operations to meet production needs for our SRT pipeline in accordance with cGMP, and other investments that are consistent with our Complete Response to the April 2006 Approvable Letter. Also included in manufacturing development activities for 2007 are activities to develop aerosolization systems for use in our planned Phase 2 clinical trials.

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 supported the production process predominantly at Laureate's Totowa, New Jersey, operation to respond to inspectional observations contained in a FDA Form 483 issued to Laureate in January 2005; (iii) enhancements and improvements to Laureate's Totowa, New Jersey, 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.

For the years ended December 31, 2007 and 2006, manufacturing development expenses include charges of $0.7 million and $0.5 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R), which we adopted on January 1, 2006.

(ii) Direct pre-clinical and clinical program activities related to the advancement of our SRT pipeline. Expenses related to these activities were $5.4 million, $3.4 million and $3.2 million for the years ended December 31, 2007, 2006 and 2005, respectively. These expenses for 2007 primarily include: (i) costs associated with obtaining data and other information necessary for our Complete Response to the April 2006 Surfaxin Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin for ARF in children up to two years of age; and (iii) development activities related to Aerosurf.

Research and development activities in 2006 and 2005 were primarily associated with: (i) regulatory activities associated with Surfaxin for the prevention of RDS in premature infants, (ii) clinical activities related to a Phase 2 clinical trial for the prevention and treatment of BPD in infants (completed in October 2006); (iii) clinical activities related to a Phase 2 clinical trial for the treatment of ARDS in adults (completed in March 2006); and (iv) pre-clinical activities for Aerosurf for neonatal respiratory disorders. The increase in 2007 versus 2006 and 2005 is primarily due to pre-clinical activities in 2007 associated with the development of Aerosurf for neonatal respiratory disorders and the ongoing Phase 2 clinical trial of Surfaxin for ARF in children up to two years of age.

(iii) Research and development operations to manage the development and advancement of our SRT pipeline. Expenses related to these activities for the years ended December 31, 2007, 2006 and 2005 were $8.9 million, $10.3 million and $9.5 million, 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 decrease in 2007 versus 2006 and 2005 primarily reflects an increase in personnel and related costs in 2006 and 2005 in anticipation of the potential approval and commercial launch of Surfaxin for the prevention of RDS in premature infants in April 2006 that were later reduced as a result of staff reductions and a reorganization of corporate management that were implemented following the April 2006 Surfaxin process validation stability failure.

Included in these costs for the years ended December 31, 2007 and 2006 are charges of $0.9 million and $1.1 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R), which we adopted on January 1, 2006. The increase in 2006 versus 2005 is primarily due to a charge of $1.1 million in 2006 associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2007, 2006 and 2005 were $13.7 million, $18.4 million and $18.5 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. Included in these costs for the years ended December 31, 2006 and 2005 are pre-launch commercialization activities of $5.9 million and 10.1 million, respectively, related to the anticipated potential approval in April 2006 and commercial launch of Surfaxin for the prevention of RDS in premature infants. Also included in general and administrative expenses for the years ended December 31, 2007 and 2006 are charges of $3.5 million and $3.8 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R), which we adopted on January 1, 2006.

The decrease in 2007 as compared to 2006 and 2005 is primarily due to costs incurred in 2006 and 2005 in connection with the anticipated potential approval in April 2006 and commercial launch of Surfaxin for the prevention of RDS in premature infants. After receipt of a second Approvable Letter and occurrence of the Surfaxin process validation stability failure in April 2006, we suspended pre-launch commercial activities and took immediate steps to lower our costs, reduced personnel and reorganized corporate management. In November 2007, we filed our Complete Response to the second Approvable letter and are now preparing for the anticipated potential approval in May 2008 and U.S. commercial launch of Surfaxin for RDS in premature infants, including establishing our own U.S. commercial sales and marketing organization specialized in neonatal and pediatric indications.

2006 Restructuring Charge

In April 2006, following the April 2006 Surfaxin process validation stability failure, which delayed FDA review of our NDA for Surfaxin for the prevention of RDS in premature infants, we reduced our staff levels and reorganized corporate management to lower our cost structure and re-align our operations with changed business priorities. 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. Such commercial program expenses totaled approximately $5.0 million for the fourth quarter 2005 and first quarter 2006.

We incurred a restructuring charge of $4.8 million in the second quarter 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, 2007, payments totaling $4.4 million had been made related to these items and $0.4 million were unpaid and included in accounts payable and accrued expenses.

2005 In-Process Research & Development

In December 2005, we purchased Laureate's manufacturing operations in Totowa, New Jersey, for $16.0 million and incurred additional related expenses of $0.8 million. We use this facility for pharmaceutical manufacturing and development activities. We believe this acquisition was a logical initial step to implement a long-term manufacturing strategy to support 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 consists of approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP. There are approximately 30 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the facility.

In consideration for $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 (see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Operating Leases");
- Equipment and leasehold improvements related to the Totowa facility; and

- The right to employ the majority of the 25 personnel that were qualified in sterile pharmaceutical manufacturing and that were employed by Laureate at the Totowa facility at that time.

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, New Jersey, facility.

Additionally, in connection with the acquisition, we financed $2.4 million pursuant to our equipment financing facility, at that time with General Electric Capital Corporation (GECC), to financially support the purchase of the manufacturing operations.

Other Income and (Expense)

Other income and (expense) for the years ended December 31, 2007, 2006 and 2005 was $(0.1) million, $0.6 million and $0.4 million, respectively.

Interest and other income for the years ended December 31, 2007, 2006 and 2005 was $2.0 million, $2.1 million, and $1.3 million, respectively. Interest and other income consists of interest earned on our cash and marketable securities and proceeds of the sale of our Commonwealth of Pennsylvania research and development tax credits ($0.2 million in 2007 and $0.6 million in 2006. We did not sell tax credits in 2005).

Interest, amortization and other expense for the years ended December 31, 2007, 2006 and 2005 was $2.1 million, $1.5 million and $1.0 million, respectively. The increase in 2007 versus 2006 was primarily due to: (i) interest expense of $0.5 million in 2007 compared to $0.1 million in 2006 related to the amortization of deferred financing costs associated with warrants issued to PharmaBio in October 2006 in consideration for renegotiating the terms on the existing $8.5 million loan and (ii) a prepayment penalty of $0.2 million incurred in the second quarter 2007 associated with the prepayment of our outstanding indebtedness with GECC. The increase in 2006 versus 2005 was primarily due to higher outstanding balances with our loan and equipment financing facility. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

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

We are subject to risks customarily associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that our research and development projects will be successful, that products developed 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;
- equipment financings; and
- interest earned on invested capital.

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

From June 2006 to July 2007, we engaged Jefferies under an exclusive arrangement to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. During that period, we raised $10 million in a private placement transaction in November 2006, and in April 2007, we raised $30.2 million ($28.1 million net) in a registered direct offering. Additionally, in December 2007, we raised $25.0 million ($23.6 million net) in a registered direct offering in which Jefferies acted as placement agent.

We have a CEFF that allows us to raise capital, subject to certain conditions and limitations, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions (discussed at "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility"), including a limitation on the total number of shares of common stock that we may issue under the CEFF (currently not more than approximately 5.2 million shares). We anticipate using the CEFF, when available, to support working capital needs in 2008.

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.

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2007, we had cash, cash equivalents and marketable securities of $53.0 million, as compared to $26.4 million as of December 31, 2006. The increase is primarily due to: (i) in April 2007, a registered direct offering of 14,050,000 shares of our common stock to select institutional investors. The shares were priced at $2.15 per share resulting in gross proceeds of $30.2 million ($28.1 million net). This offering was made pursuant to our October 2005 universal shelf registration statement; (ii) in December 2007, a registered direct offering of 10,000,000 shares of our common stock to select institutional investors. The shares were priced at $2.50 per share resulting in gross proceeds of $25.0 million ($23.6 million net). This offering was made pursuant to our October 2005 universal shelf registration statement, (iii) proceeds of $7.0 million from financings under the CEFF (discussed below); and (iii) $2.9 million from the use of the equipment financing facility with Merrill Lynch; offset by (iv) $35.6 million used in operating activities, purchases of capital expenditures and principal payments on equipment loans.

Committed Equity Financing Facility

2006 CEFF

In April 2006, we entered into a new Committed Equity Financing Facility (CEFF) in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of our common stock. Our previous Committed Equity Financing Facility, which we entered with Kingsbridge 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 Securities and Exchange Commission (SEC) declared effective the registration statement filed in connection with the new CEFF.

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 for that pricing period will be reduced for each such trading day by one-eighth of the draw down amount that 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. As of December 31, 2007, there were approximately 5.2 million shares available for issuance under the CEFF (up to a maximum of $35.5 million in gross proceeds) for future financings.

The financings completed under the CEFF are as follows:

In May 2006, we completed a financing under 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 under 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 under the CEFF resulting in proceeds of $3.0 million from the issuance of 1,371,516 shares of our common stock at an average price per share, after the applicable discount, of $2.19.

In February 2007, we completed a financing under the CEFF resulting in proceeds of $2.0 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.

In October 2007, we completed a financing under the CEFF resulting in proceeds of $5.0 million from the issuance of 1,909,172 shares of our common stock at an average price per share, after the applicable discount, of $2.62.

As of December 31, 2007, there were approximately 5.2 million shares available for issuance under the CEFF (up to a maximum of $35.5 million in gross proceeds) for future financings.

In connection with the CEFF, in 2006, 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 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, 2007, the Class C Investor Warrant had not been exercised.

2004 CEFF

In 2004, we entered into a Committed Equity Financing Facility (2004 CEFF) with Kingsbridge in to which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $75 million or up to 15 million shares of our common stock. Under the 2004 CEFF agreement, the lowest VWAP per share was $5.00. The 2004 CEFF terminated when the registration statement for the new CEFF was declared effective on May 12, 2006.

The financings under the 2004 CEFF are as follows:

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

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

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

In connection with the 2004 CEFF, in 2004, 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 excercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, 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. In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors resulting in gross proceeds of $30.2 million. In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors resulting in gross proceeds of $25.0 million.

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

Investments in Property and Equipment

In October 2007, we completed construction of a new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters. The new laboratory will consolidate the analytical, quality and development activities that are presently located in Doylestown, Pennsylvania and Mountain View, California, including release and stability testing of raw materials as well as commercial and clinical drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our product candidates. The laboratory will expand our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our newly consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics.

Investments in the new laboratory are expected to be approximately $3.3 million. We anticipate that approximately 95% of the total project will be financed under: (i) our existing secured credit facility with Merrill Lynch; (ii) $650,000 from the Commonwealth of Pennsylvania (including a $500,000 loan from the Machinery and Equipment Loan Fund and grants of up to $150,000 through the Opportunities Grant Program and Customized Job Training Funds); and (iii) a $400,000 landlord contribution under our existing lease agreement.

Debt

Payments due under contractual debt obligations at December 31, 2007, including principal and interest, are as follows:

(in thousands)	2008	2009	2010	2011	Total
Loan with PharmaBio	$ —	$ —	$ 11,366	$ —	$ 11,366
Equipment loan obligations	3,100	2,688	512	6	6,306
Total	$ 3,100	$ 2,688	$ 11,878	$ 6	$ 17,672

Loan with PharmaBio

PharmaBio, the strategic investment group of Quintiles, extended to us a secured, revolving credit facility of $8.5 to $10 million in 2001. In October 2006, we amended and restated the loan documents for a second time and restructured the loan, such that the outstanding principal amount of $8.5 million matures on April 30, 2010. After October 1, 2006, interest on the loan accrues 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. 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.

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 PharmaBio loan agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we filed a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants.

As of December 31, 2007, the outstanding balance under the loan was $9.6 million ($8.5 million of pre-restructured principal and $1.1 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

Equipment Financing Facility

Equipment loan obligations as of December 31, 2007 and 2006 are as follows:

(in thousands)	2007	2006
Current		
Equipment loan, current portion	$ 2,625	$ 2,015
Equipment loan, non-current portion	2,991	2,687
Total	5,616	4,702

Loan Agreement with GECC as successor to Merrill Lynch Capital

On May 21, 2007, we and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. (Lender), entered into a Credit and Security Agreement (Loan Agreement), pursuant to which the Lender agreed to provide us a $12.5 million credit facility (Facility) to fund our capital programs. Previously, our capital financing arrangements had been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) under a Master Security Agreement dated December 20, 2002, as amended (GECC Agreement). Upon entering into the Loan Agreement, we terminated our arrangement with GECC. However, effective in February 2008, as a consequence of GECC's acquisition of Merrill Lynch Capital, GECC, as successor to Merrill Lynch Capital, is now the Lender under the Loan Agreement and the provider of the Facility.

Under the Facility, $9.0 million of the $12.5 million was made available immediately. Approximately $4.0 million of the Facility was drawn immediately to fund the prepayment of all our then outstanding indebtedness to GECC. The remaining $3.5 million under the Facility becomes available, at a rate of $1 million for each $10 million raised by us through business development partnerships, stock offerings and other similar financings. In the fourth quarter 2007, we raised $30 million through stock offerings ($25.0 million from a registered direct offering in December 2007 and $5.0 million from a CEFF financing in October 2007) and, as a result, an additional $3.0 million became available for use under the Facility.

The right to draw funds under the Facility will expire on May 30, 2008, subject to a best efforts undertaking by the Lender to extend the draw down period beyond the expiration date for an additional six months. The minimum advance under the Facility is $100,000. Interest on each advance accrues at a fixed rate per annum equal to LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances will be payable in equal installments on the first business day of each month. We may prepay advances, in whole or in part, at any time, subject to a prepayment penalty, which, depending on the period of time elapsed from the closing of the Facility, will range from 4% to 1%.

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

Our obligations under the Facility are secured by a security interest in (a) the financed property and equipment, including the property and equipment securing GECC under the previous arrangement at the time of prepayment, and (b) all of our intellectual property, subject to limited exceptions set forth in the Loan Agreement (Supplemental Collateral). The Supplemental Collateral will be released on the earlier to occur of (i) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (ii) the date on which we shall have maintained over a continuous 12-month period ending on or after March 31, 2008, measured at the end of each calendar quarter, a minimum cash balance equal to our projected cash requirements for the following 12-month period. In addition, we, Merrill Lynch and PharmaBio entered into an Intercreditor Agreement under which Merrill Lynch agreed to subordinate its security interest in the Supplemental Collateral (which does not include financed property and equipment) to the security interest in the same collateral that we previously granted to PharmaBio (discussed above).

As of December 31, 2007, approximately $5.6 million was outstanding under the Facility ($2.6 million classified as current liabilities and $3.0 million as long-term liabilities) and $5.1 million remained available for use, subject to the conditions of the Facility.

Loan Agreement with GECC

Under the GECC Agreement, which we terminated in May 2007, we financed the purchase of capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets. The advances were secured by the related assets. We financed laboratory and manufacturing equipment over 48 months and all other equipment over 36 months. Interest rates varied in accordance with changes in the three and four year treasury rates. The right to draw funds under the GECC Agreement expired in October 2006. 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).

Included in the amounts above, in December 2005, we financed $2.4 million to support the purchase of our manufacturing operations in Totowa, New Jersey, of which, at December 31, 2006, $0.7 million was classified as current and $1.2 million was classified as long-term.

Commonwealth of Pennsylvania

In 2007, we arranged with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), under a jobs creation program to receive grants and equipment loans in the aggregate amount of up to $650,000. In consideration of these funds, we have agreed to create a number of new jobs at out headquarters location in Warrington, Pennsylvania. In July 2007, the Department granted our request for an opportunity grant in the amount of up to $100,000 and agreed to accept our application for a training grant in the amount of up to $50,000. The opportunity grant is to be used for working capital needs at our headquarters facility to fund costs incurred prior to June 30, 2008. The proceeds of this grant have been applied to defray the costs of construction of our new analytical and research laboratory in Warrington, Pennsylvania. In October 2007, the Department accepted our application for a Machinery and Equipment Loan Fund (MELF) loan in the maximum amount of up to $500,000. The MELF loan is to be used to defray part of the cost of purchasing laboratory equipment for our new analytical and development laboratory and will be secured by a security interest in the purchased equipment. The MELF loan will accrue interest at a rate of 5% per annum and is expected to close in the second quarter 2008.

Operating Lease Agreements

Our operating leases consist primarily of facility leases for our operations in Pennsylvania, New Jersey and California.

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

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

In August 2006, we reduced our leased office and analytical laboratory space in Doylestown, Pennsylvania from approximately 11,000 square feet to approximately 5,600 square feet, with an annual rent of approximately $93,800, and extended the lease that expired in August 2007 on a monthly basis. We are currently consolidating the activities at this location into our new laboratory space in Warrington, Pennsylvania and plan to terminate this lease in the first half 2008.

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

Rent expense under all of these leases for the years ended December 31, 2007, 2006, and 2005 was $1,512,000, $1,428,000 and $1,367,000, respectively.

Registered Public Offerings

In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors. The shares were priced at $2.50 per share resulting in gross and net proceeds to us of $25.0 million and $23.6 million, respectively. This offering was made pursuant to our October 2005 universal shelf registration statement.

In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors. The shares were priced at $2.15 per share resulting in gross and net proceeds to us of $30.2 million and $28.1 million, respectively. This offering was made pursuant to our October 2005 universal shelf registration statement.

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.

Private Placements

In November 2006, we completed the sale of securities in a private placement with an institutional investor resulting in net proceeds 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 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.

Each financing under the CEFF is pursuant to a private placement exemption. See discussion at “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility.”

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, 2007, 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, 2007, no Class B Investor Warrant had been exercised.

As of December 31, 2007, the warrant to purchase 850,000 shares of our common stock at an exercise price of $7.19 per share (issued to PharmaBio in November 2004), 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), and the Class C Investor Warrant to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share (issued to Kingsbridge in connection with the new CEFF) have not been exercised.

As of December 31, 2007, 809,381 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.

Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our manufacturing, research and product development activities and to repay our indebtedness. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative or joint development or commercialization arrangements with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our CEFF with Kingsbridge and our equipment financing facility with GECC (as successor to Merrill Lynch), the use of which are subject to certain conditions, we have no contractual arrangements under which we may obtain additional financing.

From June 2006 to July 2007, we engaged Jefferies & Company, Inc. (Jefferies), a New York-based investment banking firm, under an exclusive arrangement to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. During that period, in November 2006, we raised $10.0 million in a private placement transaction and in April 2007, we raised $30.2 million ($28.1 million net) in a registered direct offering. In December 2007 we raised an additional $25.0 million ($23.6 million net) in a registered direct offering in which Jefferies acted as placement agent. 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. See “Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders. 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, 2007, including principal and interest, are as follows:

(in thousands)	2008	2009	2010	2011	2012	Thereafter	Total
Loan payable (1)	$ —	$ —	$ 11,366	$ —	$ —	$ —	$ 11,366
Equipment loan obligations(1)	3,100	2,688	512	6	—	—	6,306
Operating lease obligations (2)	1,323	1,143	1,135	1,151	1,167	470	6,389
Purchase obligations (3)	4,686	—	—	—	—	—	4,686
Employment agreements (3)	2,761	—	—	—	—	—	2,761
Total	$ 11,870	$ 3,831	$ 13,013	$ 1,157	$ 1,167	$ 470	$ 31,508

(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 - Equipment Financing Facility.*"
(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, 2007, we had employment agreements with 14 executives. On January 3, 2008, three senior executives entered into amendments to their employments to extent the term of each such agreement from May 3, 2008 to May 3, 2010. After these amendments, the aggregate annual base salary in 2008 for our executives is $3,606,500. Eleven of the agreements expire in December 2008. The remaining three agreements, as a result of subsequent amendments, expire in May 2010. 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 Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Management's Report on our 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, 2007. 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, 2007.

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 10, 2008 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 2007 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 "Investors" tab in the 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 14, 2008

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 14, 2008
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer (Principal Accounting Officer)	March 14, 2008
/s/ W. Thomas Amick	W. Thomas Amick Chairman of the Board of Directors	March 14, 2008
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	March 14, 2008
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 14, 2008
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 14, 2008
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 14, 2008

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	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.
3.3	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.
3.4	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, 2005, as filed with the SEC on August 5, 2005.
3.5	Amended and Restated By-Laws of Discovery as amended effective December 11, 2007.	Filed herewith.
4.1	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.3	Class B Investor Warrant dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.4	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, as filed with the SEC on November 9, 2004.
4.5	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.

Exhibit No.	Description	Method of Filing
4.6	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.
4.7	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.
4.8	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+	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).
10.2	* Restated 1993 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.3	* 1995 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.4	* 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).
10.5	Registration Rights Agreement, dated June 16, 1998, among Discovery, Johnson & Johnson Development Corporation and The Scripps Research Institute.	Incorporated by reference to Exhibit 10.28 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.6	* 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.
10.7	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.
10.8	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.
10.9	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.

Exhibit No.	Description	Method of Filing
10.10+	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.
10.11+	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.
10.12+	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17	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.
10.18	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.
10.19	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.
10.20	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.

Exhibit No.	Description	Method of Filing
10.21	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.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Charles Katzer.	Incorporated by reference to Exhibit 10.31 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, as filed with the SEC on March 16, 2007
10.27	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Discovery Laboratories, Inc.	Incorporated by reference to Exhibits 10.1 and 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.28	Credit and Security Agreement, dated as of May 21, 2007, by and between Discovery Laboratories, Inc. and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services, Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 24, 2007.
10.29	Discovery Laboratories, Inc. 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.
10.30	Form of Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.

Exhibit No.	Description	Method of Filing
10.31	Form of Stock Issuance Agreement, dated as of October 30, 2007, between the Discovery Laboratories, Inc. and the Grantees	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 5, 2007.
10.32	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert J. Capetola and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008
10.33	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between John G. Cooper and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008
10.34	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between David L. Lopez and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008
10.35	Master Services Agreement between Discovery Laboratories, Inc. and Kloehn Ltd., dated as of August 10, 2007	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, independent registered public accounting firm.	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.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the "Company") as of December 31, 2007 and 2006, 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, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for uncertainties in income taxes in 2007. As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for share-based payments in 2006.

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, 2007, 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 10, 2008, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2008

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited Discovery Laboratories, Inc.'s and subsidiary's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Discovery Laboratories, Inc.'s and subsidiary'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 included in the accompanying *Management's Report on the Company's Internal Control over Financial Reporting*. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, Discovery Laboratories, Inc. and subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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 balance sheets of Discovery Laboratories, Inc. and subsidiary as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of Discovery Laboratories, Inc. and subsidiary and our report dated March 10, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2008

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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

	December 31, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 36,929	$ 26,402
Available-for-sale marketable securities	16,078	—
Prepaid expenses and other current assets	611	565
Total current assets	53,618	26,967
Property and equipment, net	7,069	4,794
Restricted cash	600	600
Deferred financing costs and other assets	1,457	2,039
Total assets	$ 62,744	$ 34,400
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,844	$ 5,953
Equipment loan, current portion	2,625	2,015
Total current liabilities	10,469	7,968
Loan payable, non-current portion, including accrued interest	9,633	8,907
Equipment loan, non-current portion	2,991	2,687
Other liabilities	870	516
Total liabilities	23,963	20,078
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized; 96,953 and 69,871 shares issued, 96,640 and 69,558 shares outstanding at December 31, 2007 and December 31, 2006, respectively	97	70
Additional paid-in capital	329,999	265,604
Accumulated deficit	(288,303)	(248,298)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Accumulated other comprehensive income	42	—
Total stockholders' equity	38,781	14,322
Total Liabilities & Stockholders' Equity	$ 62,744	$ 34,400

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,		
	2007	**2006**	**2005**
Revenues:	$ —	$ —	$ 134
Expenses:			
Research & development	26,200	23,716	24,137
General & administrative	13,747	18,386	18,505
Restructuring charges	—	4,805	—
In-process research & development	—	—	16,787
Total expenses	39,947	46,907	59,429
Operating loss	(39,947)	(46,907)	(59,295)
Other income / (expense):			
Interest and other income	2,029	2,072	1,345
Interest and other expense	(2,087)	(1,498)	(954)
Other income / (expense), net	(58)	574	391
Net loss	$ (40,005)	$ (46,333)	$ (58,904)
Net loss per common share - basic and diluted	$ (0.49)	$ (0.74)	$ (1.09)
Weighted average number of common shares outstanding - basic and diluted	81,731	62,767	54,094

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2007, 2006 and 2005
(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	Income / (Loss)	Total
Balance – January 1, 2005	**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	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**
Comprehensive loss:									
Net loss	-	-	-	-	(40,005)	-	-	-	(40,005)
Other comprehensive loss – unrealized gains on investments	-	-	-	-	-	-	-	42	42
Total comprehensive loss	-	-	-	-	-	-	-	-	(39,963)
Issuance of common stock, stock option exercises	62	-	106	-	-	-	-	-	106
Issuance of common stock, 401(k) employer match	118	-	294	-	-	-	-	-	294
Issuance of common stock, April 2007 financing	14,050	14	28,131	-	-	-	-	-	28,145
Issuance of common stock, December 2007 financing	10,000	10	23,550	-	-	-	-	-	23,560
Issuance of common stock, CEFF financings	2,852	3	6,997	-	-	-	-	-	7,000
Stock-based compensation expense	-	-	5,317	-	-	-	-	-	5,317
Balance – December 31, 2007	**96,953**	**$ 97**	**$ 329,999**	**$ -**	**$ (288,303)**	**(313)**	**$ (3,054)**	**$ 42**	**$ 38,781**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2007	**2006**	**2005**
Cash flow from operating activities:			
Net loss	$ (40,005)	$ (46,333)	$ (58,904)
Adjustments to reconcile net loss to net cash used In operating activities:			
Depreciation and amortization	2,062	1,058	788
Stock-based compensation and 401(k) match	5,613	6,326	617
Loss on disposal of property and equipment	18	48	16
Changes in:			
Prepaid expenses and other current assets	(89)	(5)	128
Accounts payable and accrued expenses	1,891	(1,587)	(429)
Other assets	35	(17)	14
Other liabilities	1,080	684	105
Net cash used in operating activities	(29,395)	(39,826)	(57,665)
Cash flow from investing activities:			
Purchase of property and equipment	(3,765)	(1,448)	(1,063)
Purchase of marketable securities	(38,355)	(4,621)	(33,349)
Proceeds from sale or maturity of marketable securities	22,319	7,884	32,834
Net cash (used in) / provided by investing activities	(19,801)	1,815	(1,578)
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	58,809	17,549	72,027
Proceeds from use of loan	—	—	2,571
Equipment financed through equipment loan	2,862	1,509	3,316
Principal payments under equipment loan obligations	(1,948)	(1,692)	(933)
Net cash provided by financing activities	59,723	17,366	76,981
Net increase / (decrease) in cash and cash equivalents	10,527	(20,645)	17,738
Cash and cash equivalents – beginning of year	26,402	47,047	29,309
Cash and cash equivalents – end of year	$ 36,929	$ 26,402	$ 47,047
Supplementary disclosure of cash flows information:			
Interest paid	$ 676	$ 1,102	$ 860
Non-cash transactions:			
Unrealized gain / (loss) on marketable securities	42	2	(1)
Exchange of equipment loan obligation	3,968	—	—
Charge for warrant issuance related to loan restructuring	—	1,940	—

See notes to consolidated financial statements

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to in these Notes as "we", "us" and "our") is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our proprietary 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 to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of this NDA. We are also developing Surfaxin for the treatment of Acute Respiratory Failure (ARF) in children up to two years of age and for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) 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 and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine.

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

We have implemented a business strategy that includes: (i) continued investment in the development of SRT pipeline programs, initially focused on Surfaxin and Aerosurf for neonatal and pediatric conditions, including ongoing efforts intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States; (ii) preparing for the potential approval and commercial launch of Surfaxin for RDS in the United States; (iii) seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT product candidates; (iv) continued investment in our quality systems and manufacturing capabilities to meet the anticipated pre-clinical, clinical and potential future commercial requirements of our SRT product candidates; and (v) seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although we cannot assure you that we will identify or enter into any specific actions or transactions. For Aerosurf, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our development and potential future commercial requirements. Our long-term manufacturing strategy includes potentially expanding our existing facilities or building or acquiring additional manufacturing capabilities for the production and development of our precision-engineered SRT drug products.

Management's Plans and Financings

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

We are subject to customary risks 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.

Management plans to fund its research, development, manufacturing and potential commercialization activities with the issuance of additional equity, debt and potential strategic alliances. 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.

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

We consider all highly liquid marketable securities purchased with a maturity of three months or less to be cash equivalents.

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. Realized gains (losses) on disposition of marketable securities are recorded in the statement of operations when disposed.

Marketable securities are purchased pursuant to an 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 (three to ten years). Leasehold improvements are amortized over the lesser 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*", we are 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, 2007, 2006 and 2005, 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

We have received non-refundable fees from companies under license, sublicense, collaboration and research funding agreements. We initially record such funds as deferred revenue and recognize research and development collaborative contract revenue when the amounts are earned, which occurs over a number of years as we perform research and development activities. See Note 10 – Corporate Partnership, Licensing and Research Funding Agreements for a detailed description of our revenue recognition methodology under these agreements.

Stock-based compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement No. 123(R), *"Share-Based Payment,"* using the modified-prospective-transition method. See Note 9 – Stock Options and Stock-Based Employee Compensation for a detailed description of our 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, 2007, 2006 and 2005, 20,325,000, 17,275,000 and 10,904,000 shares of common stock, respectively, were potentially issuable upon the exercise of certain 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

We currently operate in one business segment, which is the research and development of products focused on SRTs for respiratory disorders and diseases. We are managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. We do not operate separate lines of business with respect to our product candidates. Accordingly, we do not have separately reportable segments as defined by Statement No. 131, "*Disclosure about Segments of an Enterprise and Related Information*."

Income taxes

We provide for income taxes in accordance with Statement of Financial Accounting Standards No. 109 (SFAS 109), *Accounting for Income Taxes*. SFAS 109 requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities.

Under FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, (FIN 48), we use 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. The adoption of FIN 48 on January 1, 2007 did not have a material impact on the consolidated financial statements. Due to the fact that we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

Recent Accounting Pronouncements

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

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

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities,"* which is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, *"Fair Value Measurements."* SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The Statement also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. We are currently evaluating the effect that the adoption of SFAS 159 will have on its results of operations and financial condition.

The Company adopted FASB Interpretation No. 48, *"Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement 109"*, or FIN 48, on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *"Accounting for Income Taxes."* This interpretation requires that companies determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authority. This interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The adoption of FIN 48 did not have a material impact on the Company's financial statements. See Note 15, "Income Taxes," for additional information.

Note 3 – Marketable Securities

The available-for-sale marketable securities that we own 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. These assets are measured at fair market value at each reporting period. The fair market value is recorded using quoted prices from active markets.

Marketable securities are purchased pursuant to an 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. As of December 31, 2006, we did not own any marketable securities. As of December 31, 2007, available-for-sale marketable securities consisted of the following:

(in thousands)	As of December 31, 2007
Cost of investment	$ 15,891
Interest earned	65
Amortized discount	80
Unrealized gain	42
Fair market value	$ 16,078

Note 4 – Restricted Cash

The sole component of Restricted Cash is a cash security deposit in the amount of $600,000 securing a letter of credit in the same amount related to our Lease Agreement dated May 26, 2004 for our headquarters in Warrington, Pennsylvania, which consists of 39,594 square feet and serves as the main operating facility for clinical development, regulatory, analytical technical services, research and development, sales and marketing, and administration. Beginning in March 2010, the security deposit and the letter of credit related to this lease 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 February 2013, the letter of credit will expire. The letter of credit is secured by cash and is recorded in our Consolidated Balance Sheets as "Restricted Cash."

Note 5 - Property and Equipment

Property and equipment as of December 31, 2007 and 2006 was comprised of the following:

(in thousands)	December 31, 2007	2006
Equipment	$ 6,830	$ 5,020
Furniture	948	959
Leasehold improvements	2,889	360
Construction-in-progress	—	1,600
Subtotal	10,667	7,939
Accumulated depreciation	(3,598)	(3,145)
Property and equipment, net	$ 7,069	$ 4,794

Equipment primarily consists of: (i) manufacturing equipment to produce our SRT product candidates, including Surfaxin and Aerosurf, for use in our clinical trials and potential commercial needs; (ii) laboratory equipment for manufacturing and research and development activities; and (iii) computers and office equipment to support our overall business activities.

In October 2007, we completed construction of a new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters. The new laboratory will consolidate the analytical, quality and development activities that are presently located in Doylestown, Pennsylvania and Mountain View, California, including release and stability testing of raw materials as well as commercial and clinical drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our product candidates.

As of December 31, 2007, our investment in the new laboratory was $2.3 million (classified as leasehold improvements), including $35,000 of capitalized interest associated with this project. As of December 31, 2007, investments in laboratory equipment for the new laboratory were $0.7 million. We plan to invest an additional $0.3 million in early 2008 to fully equip the new laboratory. We expect consolidation of our laboratory activities into the new laboratory to be completed by mid-2008. The amortization associated with the new laboratory will be expensed through the end of company's lease term at its Warrington, PA facility in February 2013.

The balance of construction-in-progress at December 31, 2006 primarily consisted of projects for our current manufacturing operations, including new manufacturing and laboratory equipment yet to be completed and installed. As of December 31, 2007 we did not have any projects requiring classification as construction-in-progress.

Depreciation expense for the years ended December 31, 2007, 2006, and 2005 was $1,471,000 (including $358,000 of depreciation expense associated with the adjustment to the useful lives of fixed assets), $922,000 and $788,000, respectively.

In accordance with established policy, we review and assess the estimated useful lives of our fixed assets from time to time. As a result of this assessment in 2007, we changed our estimate of the useful lives of certain machinery and equipment to better reflect the estimated periods during which these assets will remain in service. We incurred a charge to depreciation expenses in 2007 as a result of the change in our estimate of the useful lives, as follows:

(in thousands)

Equipment Class	2007 Depreciation Charge	Revised Useful Life	Prior Useful Life
Computer equipment	$ 374	3 years	5 years
Laboratory equipment	318	5 years	7 years
Manufacturing equipment	(335)	10 years	5 years
Office equipment	1	5 years	7 years
Total useful life adjustment	$ 358		

As of December 31, 2007 and 2006, property and equipment of $7.9 million and $5.0 million, respectively, was subject to an equipment loan obligation. The associated accumulated depreciation was $2,.4 million and $1.4 million as of December 31, 2007 and 2006, respectively. The equipment loans are secured by the respective assets.

Note 6 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2007 and 2006 were comprised of the following:

(in thousands)	December 31, 2007	2006
Accounts payable	$ 758	$ 1,629
Accrued compensation	2,347	1,742
Accrued research and development	1,298	324
Accrued manufacturing	734	546
All other accrued expenses	2,707	1,712
Total accounts payable and accrued expenses	$ 7,844	$ 5,953

Note 7 – Debt

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

PharmaBio, the strategic investment group of Quintiles, extended to us a secured, revolving credit facility of $8.5 to $10 million in 2001. In October 2006, we amended and restated the loan documents and restructured the loan, such that the outstanding principal amount of $8.5 million matures on April 30, 2010. After October 1, 2006, interest on the loan accrues 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. 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.

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

As of December 31, 2007, the outstanding balance under the loan was $9.6 million ($8.5 million of pre-restructured principal and $1.1 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

For the years ended December 31, 2007, 2006 and 2005, we incurred interest expense associated with the PharmaBio loan of $0.7 million, $0.8 million and $0.7 million, respectively. Additionally, for the years ended December 31, 2007 and 2006, we incurred interest expense associated with the warrants issued to PharmaBio in October 2006 of $0.5 million and $0.1 million, respectively.

Equipment Loan

Our equipment loan liabilities as of December 31, 2007 and 2006 are as follows:

(in thousands)	2007	2006
Equipment loan, current portion	$ 2,625	$ 2,015
Equipment loan, non-current portion	2,991	2,687
Total	$ 5,616	$ 4,702

For the years ended December 31, 2007, 2006 and 2005, we incurred interest expense associated with our equipment financing facility of $0.6 million, $0.5 million and $0.3 million, respectively.

Loan Agreement with GECC as successor to Merrill Lynch Capital

On May 21, 2007, we and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. (Lender), entered into a Credit and Security Agreement (Loan Agreement), pursuant to which the Lender agreed to provide us a $12.5 million credit facility (Facility) to fund our capital programs. Previously, our capital financing arrangements had been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) under a Master Security Agreement dated December 20, 2002, as amended (GECC Agreement). Upon entering into the Loan Agreement, we terminated our arrangement with GECC. However, effective in February 2008, as a consequence of GECC's acquisition of Merrill Lynch Capital, GECC, as successor to Merrill Lynch Capital, is now the Lender under the Loan Agreement and the provider of the Facility.

Under the Facility, $9.0 million of the $12.5 million was made available immediately. Approximately $4.0 million of the Facility was drawn immediately to fund the prepayment of all our then outstanding indebtedness to GECC. The remaining $3.5 million under the Facility becomes available, at a rate of $1 million for each $10 million raised by us through business development partnerships, stock offerings and other similar financings. In the fourth quarter 2007, we raised $30 million through stock offerings and, as a result, an additional $3.0 million became available for use under the Facility.

The right to draw funds under the Facility will expire on May 30, 2008, subject to a best efforts undertaking by the Lender to extend the draw down period beyond the expiration date for an additional six months. The minimum advance under the Facility is $100,000. Interest on each advance accrues at a fixed rate per annum equal to LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances will be payable in equal installments on the first business day of each month. We may prepay advances, in whole or in part, at any time, subject to a prepayment penalty, which, depending on the period of time elapsed from the closing of the Facility, will range from 4% to 1%.

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

Our obligations under the Facility are secured by a security interest in (a) the financed property and equipment, including the property and equipment securing GECC under the previous arrangement at the time of prepayment, and (b) all of our intellectual property, subject to limited exceptions set forth in the Loan Agreement (Supplemental Collateral). The Supplemental Collateral will be released on the earlier to occur of (i) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (ii) the date on which we shall have maintained over a continuous 12-month period ending on or after March 31, 2008, measured at the end of each calendar quarter, a minimum cash balance equal to our projected cash requirements for the following 12-month period. In addition, we, Merrill Lynch and PharmaBio entered into an Intercreditor Agreement under which Merrill Lynch agreed to subordinate its security interest in the Supplemental Collateral (which does not include financed property and equipment) to the security interest in the same collateral that we previously granted to PharmaBio (discussed above).

As of December 31, 2007, we had (i) drawn $6.8 million under the Facility, $4.0 million of which was associated with the prepayment of all our outstanding indebtedness to GECC under the 2002 Master Services Agreement and $2.3 associated with construction and equipment of the new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters; (ii) approximately $5.6 million outstanding under the Facility ($2.6 million classified as current liabilities and $3.0 million as long-term liabilities) and (iii) $5.1 million remained available for use, subject to the conditions of the Facility.

Loan Agreement with GECC

In December 2002, we entered into a capital financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation that provided up to $9.0 million, subject to certain conditions. Under the GECC Agreement, we financed the purchase of capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets. The advances were secured by the related assets. The right to draw funds under the GECC Agreement expired in October 2006. 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 May 2007, we entered into the Loan Agreement with Merrill Lynch Capital and terminated our arrangement with GECC by prepaying $4.0 million that remained outstanding to GECC with funds from the new arrangement with Merrill Lynch Capital. However, effective in February 2008, as a consequence of GECC's acquisition of Merrill Lynch Capital, GECC, as successor to Merrill Lynch Capital, is now the Lender under the Loan Agreement and the provider of the Facility.

Included in the amounts above, in December 2005, we financed $2.4 million to support the purchase of our manufacturing operations in Totowa, New Jersey, of which, at December 31, 2006, $0.7 million was classified as current and $1.2 million was classified as long-term.

Commonwealth of Pennsylvania

In 2007, we arranged with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), under a jobs creation program, to receive grants and equipment loans in the aggregate amount of up to $650,000. In consideration of these funds, we have agreed to create a number of new jobs at out headquarters location in Warrington, Pennsylvania. In July 2007, the Department granted our request for an opportunity grant in the amount of up to $100,000 and agreed to accept our application for a training grant in the amount of up to $50,000. The opportunity grant is to be used for working capital needs at our headquarters facility to fund costs incurred prior to June 30, 2008. The proceeds of this grant will be applied to defray the costs of construction of our new analytical and research laboratory in Warrington, Pennsylvania. In October 2007, the Department accepted our application for a Machinery and Equipment Loan Fund (MELF) loan in the maximum amount of up to $500,000. The MELF loan will to be used to defray part of the cost of purchasing laboratory equipment for our new analytical and development laboratory and will be secured by a security interest in the purchased equipment. The MELF loan will accrue interest at a rate of 5% per annum and is expected to close in the second quarter 2008.

Summary of future payments

Future payments due under contractual debt obligations at December 31, 2007, including principal and interest, are as follows:

(in thousands)	2008	2009	2010	2011	Total
Loan with PharmaBio	$ —	$ —	$ 11,366	$ —	$ 11,366
Equipment loan obligations	3,100	2,688	512	6	6,306
Total	$ 3,100	$ 2,688	$ 11,878	$ 6	$ 17,672

Note 8 - Stockholders' Equity

Registered Public Offerings and Private Placements

In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors. The shares were priced at $2.50 per share resulting in gross and net proceeds to us of $25.0 million and $23.6 million, respectively. This offering was made pursuant to our October 2005 universal shelf registration statement.

In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors. The shares were priced at $2.15 per share resulting in gross and net proceeds to us of $30.2 million and $28.1 million, respectively. This offering was made pursuant to our October 2005 universal shelf registration statement.

In November 2006, we completed the sale of securities in a private placement with an institutional investor resulting in net proceeds 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 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, 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.

Each financing under the CEFF is pursuant to a private placement exemption. See discussion at Note 8, Committed Equity Financing Facility (CEFF), below.

Committed Equity Financing Facility (CEFF)

2006 CEFF

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 entered with Kingsbridge 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 Securities and Exchange Commission (SEC) declared effective the registration statement filed in connection with the new CEFF.

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 for that pricing period will be reduced for each such trading day by one-eighth of the draw down amount that 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.

The financings under the CEFF are as follows:

In May 2006, we completed a financing under 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 under 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 under the CEFF resulting in proceeds of $3.0 million from the issuance of 1,371,516 shares of our common stock at an average price per share, after the applicable discount, of $2.19.

In February 2007, we completed a financing under the CEFF resulting in proceeds of $2.0 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.

In October 2007, we completed a financing under the CEFF resulting in proceeds of $5.0 million from the issuance of 1,909,172 shares of our common stock at an average price per share, after the applicable discount, of $2.62.

As of December 31, 2007, we had approximately 5.2 million shares available for issuance under the 2006 CEFF for future financings (not to exceed $35.5 million in gross proceeds).

In 2006, in connection with the CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share, which 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, 2007, the Class C Investor Warrant had not been exercised.

2004 CEFF

In 2004, we entered into a Committed Equity Financing Facility (2004 CEFF) with Kingsbridge in to which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $75 million or up to 15 million shares of our common stock. Under the 2004 CEFF agreement, the lowest VWAP per share was $5.00. The 2004 CEFF terminated when the registration statement for the new CEFF was declared effective on May 12, 2006.

The financings under the 2004 CEFF are as follows:

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

In September 2005, we completed a financing under the 2004 CEFF, resulting in proceeds of $17.0 million from the issuance of 3,012,055 shares of our common stock at an average price per share, after the applicable discount, of $5.64. The proceeds of this financing were applied to the purchase of our manufacturing operations from Laureate, our contract manufacturer at that time.

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

In connection with the 2004 CEFF, in 2004, 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 excercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $4.5 million. As of December 31, 2006, the Class B Investor Warrant had not been exercised.

401(k) Employer Match

We have 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, 2007 and 2006, the match resulted in the issuance of 118,330 and 145,397 shares of common stock, respectively.

Common Shares Reserved for Future Issuance

Common shares reserved for potential future issuance upon exercise of warrants

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

	Shares Reserved for Issuance upon Exercise of Warrants December 31,			
	2007	2006	Exercise Price	Expiration Date
Private Placement – 2006 (1)	2,314,815	2,314,815	$ 3.18	11/22/2011
PharmaBio - 2006 Loan Restructuring (2)	1,500,000	1,500,000	$ 3.58	10/26/2013
Class C Investor Warrants - 2006 CEFF (3)	490,000	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	809,381	809,381	$ 6.88	9/19/2010
Placement Agent – 2000 (5)	—	185,822	$ 7.47	9/21/2007
Total	6,339,196	6,525,018		

(1) Refer to the Registered Public Offerings and Private Placements section of this Note.

(2) Refer to Note 7 – Debt

(3) Refer to the Registered Public Offerings and Private Placements section of this Note.

(4) Issued in connection with a restructuring of a 2003 arrangement with Quintiles Transnational Corp that resulted in cancellation of a 2001 commercialization agreement and extension of the PharmaBio Loan. Refer to Note 7 – Debt.

(5) Expired in 2007 without being exercised.

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

In June 2007, our stockholders approved the adoption of the 2007 Long-Term Incentive Plan (the "2007 Plan"). The 2007 Plan provides for the grant of long-term equity and cash incentive compensation awards and replaced the Amended and Restated 1998 Stock Incentive Plan (the "1998 Plan") whose ten-year term was to expire in March 2008. The 2007 Plan continues many of the features of the 1998 Plan, but is updated to reflect changes to Nasdaq rules regarding equity compensation, other regulatory changes and market and corporate governance developments. Awards outstanding under the 1998 Plan will continue to be governed by the terms of the 1998 Plan and the agreements under which they were granted.

As of December 31, 2007, (i) under the 2007 Plan, options to purchase 3,407,500 shares of common stock were outstanding and 5,092,500 shares were available for potential future grants under the plan, and (ii) under the 1998 Plan, options to purchase 8,837,091 shares of common stock were outstanding and no shares were available for future grants as the issuance of new awards was suspended upon approval of the 2007 Plan. As of December 31, 2006, under the 1998 Plan, options to purchase 10,690,160 shares of common stock were outstanding and 518,737 shares were available for potential future grants. See Note 9 – Stock Options and Stock-Based Employee Compensation.

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

In October 2005, we filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering, from time to time, of up to $100.0 million of debt or equity securities. As of December 31, 2007, there was $24.8 million remaining available under this shelf registration statement.

Financings pursuant to this registration statement are as follows:

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 of $20.0 million.

In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors resulting in gross proceeds of $30.2 million

In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors resulting in gross proceeds of $25.0 million

Common shares reserved for potential future issuance under the 2006 CEFF

In April 2006, we 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 our common stock. Our 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.

Common shares reserved for potential future issuance under our 401(k) Plan

We have 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. As of December 31, 2007, we had shares reserved for potential future issuance under the 401(k) Plan of 205,626, which we anticipate will be adequate to meet the requirements under the 401(k) Plan in 2008. As of December 31, 2006, we had shares reserved for potential future issuance under the 401(k) Plan of 323,956.

Note 9 – Stock Options and Stock-Based Employee Compensation

The 2007 Plan provides for the granting of long-term equity and cash incentive compensation awards.

Long-Term Incentive Plans

In June 2007, our shareholders approved the adoption of a new 2007 Long-Term Incentive Plan (2007 Plan). The purposes of the 2007 Plan are to (i) encourage eligible participants to acquire a proprietary interest in our company, (ii) provide employees incentives to contribute to our future success and enhance shareholder value, and (iii) attract and retain exceptionally qualified individuals upon whom, in large measure, our sustained progress, growth and profitability depend.

Under the 2007 Plan, we may grant awards for up to 8,500,000 shares of our common stock. An administrative committee (the Committee is currently the Compensation Committee of the Board of Directors) or Committee delegates may determine the types, the number of shares covered by, and the terms and conditions of, such awards. Eligible participants may include any of our employees, directors, advisors or consultants.

The 2007 Plan replaces the Amended and Restated 1998 Stock Incentive Plan (1998 Plan) which by its terms would have expired in March 2008. The 2007 Plan continues many of the features of the 1998 Plan, but is updated to reflect changes to Nasdaq rules regarding equity compensation, other regulatory changes and market and corporate governance developments. Awards outstanding under the 1998 Plan will continue to be governed by the terms of that plan and the applicable award agreements.

The plans provide for:

Stock Options and Stock Appreciation Rights (SARs)

We may award nonqualified stock options, incentive stock options, or SARs with a term not to exceed ten years and a purchase price not be less than 100% of the fair market value on the date of grant. Although individual grants may vary, option awards generally are exercisable upon vesting, vest based upon three years of continuous service and have 10-year contractual terms. In addition, the 2007 Plan provides for limits on the number of options and SARs granted to any one participant and the terms of any incentive stock option must comply with the provisions of Section 422 of the Internal Revenue Code. All other terms, including vesting schedules and method of payment for the exercise price are determined by the Committee.

Under the 1998 Plan, Options granted and outstanding through November 2003 are exercisable immediately upon grant, however, we have a repurchase right with respect to any shares issuable upon the exercise of such options. Our 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.

Restricted Stock and Restricted Stock Units

We may award restricted stock and restricted stock units. The Committee may, among other things, establish the applicable restrictions and the manner and timing under which such awards will lapse, decide whether to include dividends or dividend equivalents as part of an award, and determine whether restricted stock and restricted stock units are subject to forfeiture upon termination of employment.

No restricted stock awards have been made under the 2007 Plan. Under the 1998 Plan, in 2007, 56,660 restricted stock awards were issued to certain employees for no cash consideration. These restricted stock awards will fully vest and the restrictions removed on the date that Surfaxin for RDS first becomes widely commercially available, as determined by the Company.

Performance Awards and Other Stock-Based Awards

We also may grant performance awards, which may be denominated in cash, shares, other securities or other awards, may include dividends or dividend equivalents as part of performance criteria, and make such awards payable to, or exercisable by, the participant upon the achievement of company or participant performance goals during a performance period. The Committee may grant other stock-based awards that are denominated or payable in shares under such terms and conditions as the Committee determines.

No Performance Awards of other stock-based awards have been issued under either the 2007 Plan or the 1998 Plan.

Automatic Grant of Non-Employee Director Options

Under the 2007 Plan, each non-employee director, upon election to the Board of Directors, is automatically entitled to a non-qualified option to purchase 40,000 shares of our common stock and, on the date of each subsequent Annual Shareholders' Meeting, a non-qualified option to purchase 30,000 shares of our common stock, in each case at an exercise price equal to the fair market value per share on the date of grant. Such options vest on the first anniversary of the date of the grant and expire no later than 10 years from the date of the grant.

Under the 2007 Plan, as of December 31, 2007, options to purchase 3,407,500 shares of common stock were outstanding and 5,092,500 shares were available for potential future grants under the plan. Under the 1998 Plan, as of December 31, 2007, options to purchase 8,837,091 shares of common stock were outstanding and there were no shares available for future grants as the plan terminated upon the effectiveness of the 2007 Plan. Although the terms of any award vary, option awards generally vest based upon three years of continuous service and have 10-year contractual terms.

A summary of option activity under the 2007 Plan and 1998 Plan as of December 31, 2007 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, 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
Granted	2.08 – 3.58	3,907	2.94	
Exercised	0.19 – 2.46	(61)	1.72	
Forfeited or expired	0.19 – 9.80	(606)	$ 5.07	
Outstanding at December 31, 2007	$ 0.19 – $10.60	13,930	$ 4.35	7.2
Vested at December 31, 2007	$ 0.19 – $10.60	8,991	$ 5.02	6.2
Exercisable at December 31, 2007	$ 0.19 – $10.60	8,991	$ 5.02	6.2

Based upon application of the Black-Scholes option-pricing formula described below, the weighted-average grant-date fair value of options granted during the years ended December 31, 2007, 2006 and 2005 was $2.05, $2.33 and $5.59, respectively. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was $57,000, $79,000 and $948,000, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2007 is $510,000, $440,000 and $440,000, respectively.

A summary of the status of our nonvested shares issuable upon exercise of outstanding options and changes during 2007 is presented below:

(shares in thousands)

	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2006	3,344	$ 2.46
Granted	3,907	2.05
Vested	(2,151)	2.29
Forfeited	(161)	2.67
Non-vested at December 31, 2007	4,939	$ 2.18

Options granted and outstanding through November 2003 are exercisable immediately upon grant, however, we have a repurchase right with respect to any shares issuable upon the exercise of such options. Our repurchase rights lapse as the options vest according to their stated terms. As of December 31, 2007, 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, 2007:

(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	1,045	$ 1.68	6.18 years	879	$ 1.66	6.18 years
$2.01 - $4.00	7,904	$ 2.70	8.31 years	3,587	$ 2.61	8.31 years
$4.01 - $6.00	820	$ 4.72	2.59 years	808	$ 4.70	2.59 years
$6.01 - $8.00	1,747	$ 6.90	6.45 years	1,303	$ 6.84	6.45 years
$8.01 - $10.00	2,364	$ 8.93	6.24 years	2,364	$ 8.93	6.24 years
$10.01 - $10.60	50	$ 10.52	3.24 years	50	$ 10.52	3.24 years
	13,930			8,991		

Stock-Based Employee Compensation

Prior to January 1, 2006, we accounted for the stock incentive 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, we 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, 2007 and 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 2005 and before have not been restated.

As a result of adopting Statement No. 123(R) on January 1, 2006, we recognized compensation expense for the years ended December 31, 2007 and 2006 of $5.2 million and $5.5 million, respectively. For the year ended December 31, 2007, $1.7 million of compensation expense was classified as research and development and $3.5 million of compensation expense was classified as general and administrative. 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 we had applied the fair value recognition provisions of Statement 123(R) to options granted under our stock option plan for the year ended December 31, 2005. 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 assumptions set forth immediately below the following table and amortized to expense over the options' vesting periods.

(in thousands, except per share data)		**Year Ended December 31, 2005**
Net loss, as reported	$	(58,904)
Net loss per share, as reported	$	(1.09)
Add: Stock-based employee compensation expense included in reported net loss		231
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards		(14,571)
Pro forma net loss	$	(73,244)
Pro forma net loss per share	$	(1.35)

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 our historical volatility and other factors. We also use 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,		
	2007	**2006**	**2005**
Expected volatility	77% - 99%	81% - 101%	77%
Weighted average expected volatility	88%	96%	77%
Expected term	4 and 5 years	4 and 5 years	3.5 years
Risk-free rate	3.5% - 4.6%	4.4% - 5.0%	4.1%
Expected dividends	—	—	—

The total fair value of the underlying shares of the options vested during 2007 and 2006 equals $4.9 million and $5.4 million, respectively. As of December 31, 2007, there was $8.6 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 2.06 years.

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, the Board of Directors approved full acceleration of vesting of certain unvested stock options granted under our the 1998 Plan that are held by our employees and officers and that have an exercise price of $9.02 or greater. Options to purchase approximately 1,050,706 shares of our common stock were accelerated, including options to purchase approximately 948,749 shares of our 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 we would otherwise be required to recognize in our consolidated Statements of Operations with respect to these options pursuant to Statement No. 123(R), which became effective for us January 1, 2006. We estimate 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 our 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 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 we may have with such individual), if such last date of employment or "change in control" is earlier.

Note 10 – Corporate Partnership, Licensing and Research Funding Agreements

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

In December 2005, we entered into a strategic alliance with Chrysalis through which we gained exclusive license 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.

We are presently collaborating with Chrysalis on a novel aerosolization system to deliver Aerosurf to patients in the NICU. Chrysalis is responsible for developing the design for the initial prototype aerosolization device platform and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and further development, manufacturing and commercialization of the combination drug-device products.

Under our Agreement with Chrysalis, Chrysalis will generally 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.

Laboratorios del Dr. Esteve, S.A.

In December 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. Under the restructuring, we 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 any 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 our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

Licensing and Research Funding Agreements

Johnson & Johnson and Pharmaceutical Corporation

We, Johnson & Johnson and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, are parties to an agreement granting to us an exclusive worldwide license of the proprietary SRT technology, including Surfaxin, in exchange for certain license fees, future milestone payments (aggregating $2,500,000) and royalties. To date, we have paid $450,000 for milestones achieved.

The Scripps Research Institute

We and The Scripps Research Institute (Scripps) were parties to a research funding and option agreement which expired in February 2005. Pursuant to this agreement, we have 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. We exercised our license option with respect to certain inventions developed under the agreement. We had the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed under the agreement and for which we did not exercise our option to acquire an exclusive license. Payments to Scripps under this agreement were $0, $0 and $400,000 in 2007, 2006 and 2005, respectively.

Note 11 – Purchase of Manufacturing Operations – Classified as In-process Research and Development

In December 2005, we purchased the manufacturing operations of Laureate Pharma, Inc. (Laureate) in Totowa, New Jersey, (our then contract manufacturer) for $16.0 million and incurred additional related expenses of $0.8 million. We use this facility for pharmaceutical manufacturing and development activities. We believe this acquisition was a logical initial step to implement a long-term manufacturing strategy to support 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 consists of approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP. There are approximately 30 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the facility.

In consideration for $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 (refer to Note 13 – Commitments)";
- equipment and leasehold improvements related to the Totowa facility; and

- the right to employ the majority of the 25 personnel that were qualified in sterile pharmaceutical manufacturing and that were employed by Laureate at the Totowa facility at that time.

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, New Jersey, facility.

Also, in connection with the acquisition, we financed $2.4 million pursuant to our equipment financing facility, at that time with General Electric Capital Corporation (GECC), to financially support the purchase of the manufacturing operations.

Note 12 –Restructuring Charges

April 2006 Corporate Restructuring

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 our NDA, predominately involving drug product specifications and stability, analytical methods and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by Laureate, our contract manufacturer at the time, as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately conducted a comprehensive investigation, which focused on analysis of our manufacturing processes, analytical methods and method validation, and active pharmaceutical ingredient suppliers. As a result of our investigation, we identified a most probable root cause to the process validation stability failures and executed a corrective action and preventative action (CAPA) plan.

As a result of the April 2006 Surfaxin process validation stability failure, which delayed FDA review of our NDA for Surfaxin for the prevention of RDS in premature infants, we reduced our staff levels and reorganized corporate management to lower our cost structure and re-align our operations with changed business priorities. 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.

We incurred a restructuring charge of $4.8 million in the second quarter 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 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 pre-launch commercial programs.

As of December 31, 2007, the remaining balance of the unpaid restructuring charge was $0.4 million, which was included in accounts payable and accrued expenses.

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
Restructuring Charge	$ 2,497	$ 2,308	$ 4,805
Payments / Adjustments	(2,497)	(1,895)	(4,392)
Liability as of December 31, 2007	$ —	$ 413	$ 413

Note 13 – Commitments

Our 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, 2007 are as follows:

(in thousands)	2008	2009	2010	2011	2012	Thereafter	Total
Operating lease obligations	$ 1,323	$ 1,143	$ 1,135	$ 1,151	$ 1,167	$ 470	$ 6,389
Purchase obligations	4,686	—	—	—	—	—	4,686
Employment agreements	2,761	—	—	—	—	—	2,761
Total	$ 8,770	$ 1,143	$ 1,135	$ 1,151	$ 1,167	$ 470	$ 13,836

Our operating leases consist primarily of facility leases for our operations in Pennsylvania, New Jersey and California.

We maintain our headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, analytical technical services, research and development, sales and marketing, and administration. We recently completed construction of a new analytical and development laboratory at this location. We are consolidating into this new laboratory all of the analytical, quality and development activities that have been located in Doylestown, Pennsylvania and Mountain View, California. In April 2007, the lease, which originally expired in February 2010 with total aggregate payments of $4.6 million, was extended through February 2013 with additional payments of $3.0 million over the three-year extension period.

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

In August 2006, we reduced our leased office and analytical laboratory space in Doylestown, Pennsylvania from approximately 11,000 square feet to approximately 5,600 square feet, with an annual rent of approximately $93,800, and extended the lease that expired in August 2007 on a monthly basis. We are currently consolidating the activities at this location into our new laboratory space in Warrington, Pennsylvania and plan to terminate this lease in the first half 2008.

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

Rent expense under all of these leases for the years ended December 31, 2007, 2006, and 2005 was $1,512,000, $1,428,000 and $1,367,000, respectively.

Our purchase obligations include commitments entered in the ordinary course of business, primarily commitments to purchase manufacturing equipment and services for the enhancement of our manufacturing capabilities for Surfaxin and other SRT formulations.

At December 31, 2007, we had employment agreements with 14 executives. On January 3, 2008, three senior executives entered into amendments to their employments to extent the term of each such agreement from May 3, 2008 to May 3, 2010. After these amendments, the aggregate annual base salary in 2008 for our executives is $3,606,500. Eleven of the agreements expire in December 2008. The remaining three agreements, as a result of subsequent amendments, expire in May 2010. 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.

Note 14 – Litigation

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendants' motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various of our public statements. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania and filed an opening brief on July 2, 2007. Briefing on this matter is completed and oral argument is scheduled for March 25, 2008.

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

Note 15 – Income Taxes

Since our inception, we have 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 our recorded tax benefit for the years ended December 31, 2007, 2006 and 2005 are as follows:

(in thousands)	December 31, 2007	2006	2005
Income tax benefit, statutory rates	$ 13,601	$ 15,753	$ 20,027
State taxes on income, net of federal benefit	2,363	2,770	3,721
Research and development tax credit	960	966	840
Employee Related	(1,118)	—	—
Other	(24)	(38)	(47)
Income tax benefit	15,782	19,451	24,541
Valuation allowance	(15,782)	(19,451)	(24,541)
Income tax benefit	$ —	$ —	$ —

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2007 and 2006, are as follows:

(in thousands)	December 31, 2007	2006
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	$ 102,397	$ 89,881
Research and development tax credits	6,130	5,169
Compensation expense on stock	3,615	2,143
Charitable contribution carryforward	6	5
Other accrued	1,386	852
Depreciation	2,653	2,736
Capitalized research and development	2,613	2,802
Total long-term deferred tax assets	118,800	103,588
Long-term deferred tax liabilities	—	—
Net deferred tax assets	118,800	103,588
Less: valuation allowance	(118,800)	(103,588)
Deferred tax assets, net of valuation allowance	$ —	$ —

We are in a net deferred tax asset position at December 31, 2007 and 2006 before the consideration of a valuation allowance. Due to the fact that we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

At December 31, 2007 and 2006, we had available carryforward net operating losses for Federal tax purposes of $258.7 million and $229.8 million, respectively, and a research and development tax credit carryforward of $6.1 million and $5.2 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, 2007, we had available carryforward federal and state net operating losses of $1.8 million and $26,000 respectively, related to stock based compensation. Additionally, at December 31, 2007 and 2006, we had available carryforward losses of approximately $250.2 million and $208.2 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 16 - Related Party Transactions

Laboratorios del Dr. Esteve, S.A.

Dr. Antonio Esteve serves as a member of our Board of Directors and is an executive officer of Esteve. We have a strategic corporate partnership with Esteve. See Note 10 - Corporate Partnership, Licensing and Research Funding Agreements.

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. The shares were issued pursuant to a registration statement on Form S-3MEF filed with the SEC on February 17, 2005.

Note 17 – Selected Quarterly Financial Data (unaudited)

The following table contains unaudited statement of operations information for each quarter of 2007 and 2006. The operating results for any quarter are not necessarily indicative of results for any future period.

2007 Quarters Ended:	*(in thousands, except per share data)*				
	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	$ —	$ —	$ —	$ —	$ —
Expenses:					
Research and development	5,422	6,794	6,184	7,800	26,200
General and administrative	2,754	3,465	3,147	4,381	13,747
Restructuring charges	—	—	—	—	—
Total expenses	8,176	10,259	9,331	12,181	39,947
Operating loss	(8,176)	(10,259)	(9,331)	(12,181)	(39,947)
Other income / (expense), net	(134)	(125)	(16)	217	(58)
Net loss	$ (8,310)	$ (10,384)	$ (9,347)	$ (11,964)	$ (40,005)
Net loss per common share - basic and diluted	$ (0.12)	$ (0.12)	$ (0.11)	$ (0.14)	$ (0.49)
Weighted average number of commonshares outstanding	69,989	83,825	84,642	88,469	81,731

2006 Quarters Ended:	*(in thousands, except per share data)*				
	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
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 commonshares outstanding	61,170	61,652	62,312	66,195	62,767

AMENDED AND RESTATED
BY-LAWS OF
DISCOVERY LABORATORIES, INC.
(A Delaware Corporation)

ARTICLE I

Meetings of Stockholders

Section 1. Annual Meeting. The annual meeting of the stockholders of Discovery Laboratories, Inc. (the "Corporation"), for the election of directors and for the transaction of such other business as may come before the meeting shall be held at such date and time as shall be designated by the Board of Directors (the "Board"), the Chairman of the Board or the President.

Section 2. Special Meeting. Special meetings of the stockholders, unless otherwise prescribed by statute, may be called at any time by the Board, the Chairman of the Board or the Chief Executive Officer. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

Section 3. Notice of Meetings. Notice of the place, date and time of the holding of each annual and special meeting of the stockholders and, in the case of a special meeting, the purpose or purposes thereof shall be given personally or by mail in a postage prepaid envelope to each stockholder entitled to vote at such meeting, not less than 10 nor more than 60 days before the date of such meeting, and, if mailed, it shall be directed to such stockholder at his or her address as it appears on the records of the Corporation, unless such stockholder shall have filed with the Secretary of the Corporation a written request that notices to such stockholder be mailed to some other address, in which case it shall be directed to the stockholder at such other address. If mailed, such notice shall be deemed to be delivered when deposited in United States mail so addressed with postage thereon prepaid. Notice of any meeting of stockholders shall not be required to be given to any stockholder who shall attend such meeting in person or by proxy and shall not, at the beginning of such meeting, object to the transaction of any business because the meeting is not lawfully called or convened, or who shall, either before or after the meeting, submit a signed waiver of notice, in person or by proxy. Unless the Board shall fix after the adjournment a new record date for an adjourned meeting, notice of such adjourned meeting need not be given if the time and place to which the meeting shall be adjourned were announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which may have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 4. Place of Meetings. Meetings of the stockholders my be held at such place, within or without the State of Delaware, as the Board or other officer calling the same shall specify in the notice of such meeting, or in a duly executed waiver of notice thereof.

Section 5. Quorum. At all meetings of the stockholders, the holders of a majority of the votes of the shares of stock of the Corporation issued and outstanding and entitled to vote shall be present in person or by proxy to constitute a quorum for the transaction of any business, except when stockholders are required to vote by class, in which event a majority of the issued and outstanding shares of the appropriate class shall be present in person or by proxy, or except as otherwise provided by statute or in the Corporation's Restated Certificate of Incorporation (the "Certificate of Incorporation"). In the absence of a quorum, the holders of a majority of the votes of the shares of stock present in person or by proxy and entitled to vote, or if no stockholder entitled to vote is present, then the chairman of the meeting, as set forth in Section 6 below, may adjourn the meeting from time to time. At any such adjourned meeting at which a quorum may be present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 6. Organization. At each meeting of the stockholders, the Chairman of the Board, or in his absence or inability to act, the President, or in the absence or inability to act of the Chairman of the Board and the President or an Executive Vice President, or in the absence of all the foregoing, any person chosen by a majority of those stockholders present shall act as chairman of the meeting. The Secretary, or, in his absence or inability to act, the Assistant Secretary or any person appointed by the chairman of the meeting shall act as secretary of the meeting and keep the minutes thereof.

Section 7. Order of Business. The order of business at all meetings of the stockholders shall be as determined by the chairman of the meeting.

Section 8. Voting. Except as otherwise provided by statute, the Certificate of Incorporation or any certificate duly filed in the office of the Secretary of State of the State of Delaware, each holder of record of shares of stock of the Corporation having voting power shall be entitled at each meeting of the stockholders to one vote for every share of such stock standing in his name on the record of stockholders of the Corporation on the date fixed by the Board as the record date for the determination of the stockholders who shall be entitled to notice of and to vote at such meeting; or if such record date shall not have been so fixed, then at the close of business on the day next preceding the day on which the meeting is held; or each stockholder entitled to vote at any meeting of stockholders may authorize another person or persons to act for him by a proxy signed by such stockholder or his attorney-in-fact. Any such proxy shall be delivered to the secretary of such meeting at or prior to the time designated in the order of business for so delivering such proxies. No proxy shall be valid after the expiration of three years from the date thereof, unless otherwise provided in the proxy. Every proxy shall be revocable at the pleasure of the stockholder executing it, except in those cases where an irrevocable proxy is permitted by law. Except as otherwise provided by statute, these Amended and Restated By-Laws (the "By-Laws"), or the Certificate of Incorporation, any corporate action to be taken by vote of the stockholders shall be authorized by a majority of the total votes, or when stockholders are required to vote by class by a majority of the votes of the appropriate class, cast at a meeting of stockholders by the holders of shares present in person or represented by proxy and entitled to vote on such action. Unless required by statute, or determined by the chairman of the meeting to be advisable, the vote on any question need not be by written ballot. On a vote by written ballot, each ballot shall be signed by the stockholder voting, or by his proxy, if there be such proxy, and shall state the number of shares voted

Section 9. Nominations. The procedures governing stockholder nominees of candidates to elections of the Board of Directors or to fill vacancies, as applicable, shall be administered by the Company's Nomination Committee. For nominations for election to the Board or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Company. In addition to other applicable requirements, to be timely, a notice of nominations or other business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Company to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Company did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the date of the Company's proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, that if (A) the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, or (B) no proxy statement was delivered to stockholders by the Company in connection with the preceding year's annual meeting, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Company. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Company. Any stockholder delivering notice to the Secretary under this Section 9, Article I must be a stockholder of record on the date such notice is delivered. The Secretary shall deliver the notice to the Nomination Committee. No stockholder nominee may be a candidate for election at any meeting of stockholders or otherwise elected to fill a vacancy in the Board unless such person has been approved by the Nomination Committee and was nominated in accordance with the procedures set forth in this Section 9, Article I. If the facts warrant, the Board, or the chairman of a stockholders meeting at which Directors are to be elected may determine and declare that a nomination was not made in accordance with the foregoing procedure and, if it is so determined, no election may be made with respect to such nominee. The right of stockholders to make nominations pursuant to the foregoing procedure is subject to the superior rights, if any, of the holders of any class or series of stock having a preference over the common stock. The procedures set forth in this Section 9 of Article I for nomination for the election of Directors by stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof.

If a stockholder attempts to nominate a candidate to the Board and complies with the procedure set forth in this Section 9, Article I but the Nomination Committee rejects such stockholder's nomination, such stockholder may nominate such candidate notwithstanding the decision of the Nomination Committee at the next election of Directors after such candidate was rejected by the Nomination Committee if such stockholder delivers to the Secretary written requests that such person be nominated to the Board from stockholders holding at least 50% of the eligible votes as of the record date of such election.

To be in proper written form, each such notice to the Secretary delivered in connection with a stockholder nomination must set forth as to each person whom the stockholder proposes to nominate for election as a director:

(i) the name, age, business address and residence address of the person;

(ii) the principal occupation or employment of the person;

(ii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by the person; and

(iv) any other information relating to the person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder;

Each such notice to the Secretary must also set forth as to the stockholder giving the notice:

(i) the name and record address of such stockholder;

(ii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by such stockholder;

(iii) a description of all arrangements or understandings between such stockholder and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are to be made by such stockholder;

(iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice; and

(v) any other information relating to such stockholder that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Securities Exchange Act of 1934 (the "Exchange Act") and the rules and regulations promulgated thereunder.

All notices delivered to the Secretary in connections must be accompanied by a written consent of each proposed nominee to being named as a nominee and to serve as a Director if elected.

Section 10. Stockholder Proposals. The procedures governing stockholder proposals of business to be conducted at meetings of stockholders shall be administered by the Company's Nomination Committee. At any meeting of the stockholders, only such business shall be conducted as shall have been properly brought before such meeting. To be properly brought before a meeting, business must be: (a) as specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board; (b) otherwise properly brought before the meeting by or at the direction of the Board; or (c) otherwise properly brought before the meeting by a stockholder. For business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Company. In addition to other applicable requirements set forth in the Exchange Act, to be timely, a notice of other business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Company to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Company did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the date of the Company's proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, that if (A) the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, or (B) no proxy statement was delivered to stockholders by the Company in connection with the preceding year's annual meeting, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Company. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Company. Any stockholder delivering notice to the Secretary under this Section 10 of Article I must be a stockholder of record on the date such notice is delivered. The Nomination Committee must approve each stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise. No stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise unless such proposal was approved in accordance with the procedures set forth in this Section 10 of Article I. The procedures set forth in this Section 10 of Article I for nomination for the election of Directors by stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof. If the chairman of a meeting of stockholders determines that business was not properly brought before the meeting in accordance with the foregoing procedures, the chairman shall declare to the meeting that the business was not properly brought before the meeting and such business shall not be transacted.

To be in proper written form, a stockholder's notice to the Secretary must set forth as to each matter such stockholder proposes to bring before the meeting:

(i) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting;

(ii) the name and record address of such stockholder;

(iii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by such stockholder;

(iv) a description of all arrangements or understandings between such stockholder and any other person or persons (including their names) in connection with the proposal of such business by such stockholder and any material interest of such stockholder in such business;

(v) a representation that such stockholder intends to appear in person or by proxy at the meeting to bring such business before the meeting; and

(vi) any other information that is required by law to be provided by the stockholder in his capacity as proponent of a stockholder proposal.

Section 11. List of Stockholders. The officer who has charge of the stock ledger of the Corporation, or the transfer agent of the Corporation's stock, if there be one then acting, shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting, either at a place within the city where the meeting is to be held, at the place where the meeting is to be held or at the office of the transfer agent. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

Section 12. Inspectors. The Board may, in advance of any meeting of stockholders, appoint one or more inspectors to act at such meeting or any adjournment thereof. If the inspectors shall not be so appointed or if any of them shall fail to appear or act, the chairman of the meeting may, and on the request of any stockholder entitled to vote thereat shall, appoint inspectors. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector at such meeting with strict impartiality and according to the best of his ability. The inspectors shall determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, the validity and effect of proxies, and shall receive votes, ballots or consents, hear and determine all challenges and questions arising in connection with the right to vote, count and tabulate all votes, ballots or consents, determine the result, and do such acts as are proper to conduct the election or vote with fairness to all stockholders. Upon the request of the chairman of the meeting or any stockholder entitled to vote thereat, the inspectors shall make a report in writing of any challenge, request or matter determined by them and shall execute a certificate of any fact found by them. No director or candidate for the office of director shall act as inspector of an election of directors. Inspectors need not be stockholders.

Section 13. Consent of Stockholders in Lieu of Meeting. Unless otherwise provided in the Certificate of Incorporation, any action required by Subchapter VII of the General Corporation Law of the State of Delaware, to be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the corporation by delivery to its registered office in this State, its principal place of business, or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be by hand or by certified or registered mail, return receipt requested.

ARTICLE II

Board Of Directors

Section 1. General Powers. The business and affairs of the Corporation shall be managed by the Board. The Board may exercise all such authority and powers of the Corporation and do all such lawful acts and things as are not by statute or the Certificate of Incorporation or by these By-Laws directed or required to be exercised or done by the stockholders.

Section 2. Number, Qualifications, Elections and Term of Office. The number of directors of the Corporation ("Directors") shall be fixed from time to time by the vote of a majority of the entire Board then in office and the number thereof may thereafter by like vote be increased or decreased to such greater or lesser number (not less than three) as may be so provided, subject to the provisions of Section 11 of this Article II. All of the Directors shall be of full age and need not be stockholders. Except as otherwise provided by statute or these By-Laws, the Directors shall be elected at the annual meeting of the Stockholders for the election of Directors at which a quorum is present, and the persons receiving a plurality of the votes cast at such meeting shall be elected. Each Director shall hold office until the next annual meeting of the stockholders and until his successors shall have been duly elected and qualified, or until such Director's death, or until such Director shall have resigned, or have been removed, as hereinafter provided in these By-Laws, or as otherwise provided by statute or the Certificate of Incorporation.

Section 3. Place of Meetings. Meetings of the Board may be held at such place, within or without the State of Delaware, as the Board may from time to time determine or as shall be specified in the notice or waiver of notice of such meeting.

Section 4. Annual Meeting. The Board shall meet for the purpose of organization, the election or appointment of officers and the transaction of other business, as soon as practicable after each annual meeting of the stockholders, on the same day and at the same place where such annual meeting shall be held. Notice of such meeting need not be given. Such meeting may be held at any other time or place (within or without the State of Delaware) which shall be specified in a notice thereof given as hereinafter provided in Section 7 of this Article II.

Section 5. Regular Meetings. Regular meetings of the Board shall be held at such time and place as the Board may from time to time determine. If any day fixed for a regular meeting shall be a legal holiday at the place where the meeting is to be held, then the meeting which would otherwise be held on that day shall be held at the same hour on the next succeeding business day. Notice of regular meetings of the Board need not be given except as otherwise required by statute or these By-Laws.

Section 6. Special Meetings. Special meetings of the Board may be called by the Chairman of the Board, two or more directors or the President of the Corporation.

Section 7. Notice of Meetings. Notice of each special meeting of the Board (and of each regular meeting for which notice shall be required) shall be given by the Secretary as hereinafter provided in this Section 7 of Article II, in which notice shall be stated the time and place (within or without the State of Delaware) of the meeting. Notice of each such meeting shall be delivered to each Director either personally or by telephone, telegraph, cable or wireless, at least 24 hours before the time at which such meeting is to be held or by first-class mail, postage prepaid, addressed to him at his residence, or usual place of business, at least three days before the day on which such meeting is to be held. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail. Notice of any such meeting need not be given to any director who shall, either before or after the meeting, submit a signed waiver of notice or who shall attend such meeting without protesting, prior to or at its commencement, the lack of notice to him. Except as otherwise specifically required by these By-Laws, a notice or waiver of notice of any regular or special meeting need not state the purposes of such meeting.

Section 8. Quorum and Manner of Acting. A majority of the entire Board shall be present in person at any meeting of the Board in order to constitute a quorum for the transaction of business at such meeting, and, except as otherwise expressly required by statute or the Certificate of Incorporation, the act of a majority of the Directors present at any meeting at which a quorum is present shall be the act of the Board. Any one or more members of the Board or any committee thereof may participate in a meeting of the Board or such committee by means of a conference telephone or similar communications equipment allowing all participants in the meeting to hear each other at the same time and participation by such means shall constitute presence in person at a meeting. In the absence of a quorum at any meeting of the Board, a majority of the directors present thereat, or if no director be present, the Secretary, may adjourn such meeting to another time and place, or such meeting, unless it be the annual meeting of the Board, need not be held. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called. Except as provided in Article III of these By-Laws, the directors shall act only as a Board and the individual directors shall have no power as such.

Section 9. Organization. At each meeting of the Board, the Chairman of the Board (or, in his or her absence or inability to act, the President, or, in his or her absence or inability to act, another Director chosen by a majority of the Directors present) shall act as chairman of the meeting and preside thereat. The Secretary (or, in his or her absence or inability to act, any person appointed by the chairman of the meeting) shall act as secretary of the meeting and keep the minutes thereof.

Section 10. Resignations. Any Director may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 11. Vacancies. Vacancies, including newly created directorships, may be filled by the decision of majority of the Directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section for the filling of other vacancies.

Section 12. Removal of Directors. Except as otherwise provided in the Certificate of Incorporation or in these By-Laws, any Director may be removed, either with or without cause, at any time, by the affirmative vote of a majority of the votes of the issued and outstanding shares of stock entitled to vote for the election of the stockholders called and held for that purpose, or by a majority vote of the Board at a meeting called for such purpose, and the vacancy in the Board caused by any such removal may be filled by such stockholders or Directors, as the case may be, at such meeting, and if the stockholders shall fail to fill such vacancy, such vacancy shall be filled in the manner as provided by these By-Laws.

Section 13. Compensation. The Board shall have authority to fix the compensation, including fees and reimbursement of expenses, of Directors for services to the Corporation in any capacity, provided no such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

Section 14. Action by the Board. To the extent permitted under the laws of the State of Delaware, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of the proceedings of the Board or committee.

ARTICLE III

Executive and Other Committees

Section 1. Executive and Other Committees. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of two or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the Committee. Any such committee, to the extent provided in the resolution, shall have and may exercise the powers of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it, provided, however, that in the absence or disqualification of any member of such committee or committees, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Each committee shall keep minutes of its proceedings and shall, report such minutes to the Board when required. All such proceedings shall be subject to revision or alteration by the Board; provided, however, that third parties shall not be prejudiced by such revision or alteration.

Section 2. General. A majority of any committee may determine its action and fix the time and place of its meetings, unless the Board shall otherwise provide. Notice of such meetings shall be given to each member of the committee in the manner provided for in Article II, Section 7. The Board shall have the power at any time to fill vacancies in, to change the membership of, or to dissolve any such committee. Nothing herein shall be deemed to prevent the Board from appointing one or more committees consisting in whole or in part of persons who are directors of the Corporation; provided, however, that no such committee shall have or may exercise any authority of the Board.

ARTICLE IV

Officers

Section 1. Number and Qualifications. The officers of the Corporation shall include the Chairman of the Board, the President, one or more Vice Presidents (one or more of whom may be designated an Executive Vice President or a Senior Vice President), the Treasurer and the Secretary. Any two or more offices may be held by the same person. Such officers shall be elected or appointed from time to time by the Board, each to hold office until the meeting of the Board following the next annual meeting of the stockholders, or until his or her successor shall have been duly elected or appointed and shall have qualified, or until such Officer's death, or until such Officer shall have resigned, or have been removed, as hereinafter provided in these By-Laws. The Board may from time to time elect a Vice Chairman of the Board, and the Board may from time to time elect, or the Chairman of the Board, or the President may appoint, such other officers (including one or more Assistant Vice Presidents, Assistant Secretaries and Assistant Treasurers), as may be necessary or desirable for the business of the Corporation. Such other officers and agents shall have such duties and shall hold their offices for such terms as may be prescribed by the Board or by the appointing.

Section 2. Resignation. Any officer of the Corporation may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 3. Removal. Any officer or agent of the Corporation may be removed, either with or without cause, at any time, by the vote of the majority of the entire Board at any meeting of the Board or, except in the case of an officer or agent elected or appointed by the Board, by the Chairman of the Board or the President. Such removal shall be without prejudice to the contractual rights, if any, of the person so removed.

Section 4. Vacancies. A vacancy in any office, whether arising from death, disability, resignation, removal or any other cause, may be filled for the unexpired portion of the term of the office which shall be vacant, in the manner prescribed in these By-Laws for the regular election or appointment to such office.

Section 5. a. The Chairman of the Board. The Chairman of the Board, if one be elected, shall, if present, preside at each meeting of the stockholders and of the Board and shall be an ex officio member of all committees of the Board. He shall perform all duties incident to the office of Chairman of the Board and such other duties as may from time to time be assigned to him by the Board.

b. The Vice Chairman of the Board. The Vice Chairman of the Board, if one be elected, shall have such powers and perform all such duties as from time to time may be assigned to him by the Board or the Chairman of the Board and, unless otherwise provided by the Board, shall in the case of the absence or inability to act of the Chairman of the Board, perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board.

Section 6. The President. The President shall be the chief executive officer of the Corporation and shall have general and active supervision and direction over the business and affairs of the Corporation and over its several officers, subject, however, to the direction of the Chairman of the Board and the control of the Board. If no Chairman of the Board is elected or at the request of the Chairman of the Board, or in the case of his absence or inability to act, unless there be a Vice Chairman of the Board so designated to act, the President shall perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board. He shall perform all duties incident to the office of President and such other duties as from time to time may be assigned to him by the Board or the Chairman of the Board.

Section 7. Vice Presidents. Each Executive Vice President, each Senior Vice President and each Vice President shall have such powers and perform all such duties as from time to time may be assigned to such person by the Board, the Chairman of the Board or the President. They shall in the order of their seniority, have the power and may perform the duties of the Chairman of the Board and the President.

Section 8. The Treasurer. The Treasurer shall exercise general supervision over the receipt, custody and disbursement of corporate funds. He or she shall have such further powers and duties as may be conferred upon him from time to time by the President or the Board of Directors. He or she shall perform the duties of controller if no one is elected to that office.

Section 9. The Secretary. The Secretary shall:

(a) keep or cause to be kept in one or more books provided for the purpose, the minutes of all meetings of the Board, the committees of the Board and the stockholders;

(b) see that all notices are duly given in accordance with the provisions of these By-Laws and as required by law;

(c) be custodian of the records and the seal of the Corporation and affix and attest the seal to all stock certificates of the Corporation (unless the seal be a facsimile, as hereinafter provided) and affix and attest the seal to all other documents to be executed on behalf of the Corporation under its seal;

(d) see that the books, reports, statements, certificates and other documents and records required by law to be kept and filed are properly kept and filed; and

(e) in general, perform all the duties incident to the office of Secretary and such other duties as from time to time may be assigned to him by the Board, the Chairman of the Board, or the President.

Section 10. Officer's Bonds or Other Security. If required by the Board, any officer of the Corporation may be required to give a bond or other security for the faithful performance of his duties, in such amount and with such surety or sureties as the Board may require.

Section 11. Compensation. The compensation of the officers of the Corporation for their services as such officers shall be fixed from time to time by the Board; provided, however, that the Board may delegate to the Chairman of the Board or the President the power to fix the compensation of officers and agents appointed by the Chairman of the Board or the President, as the case may be. An officer of the Corporation shall not be prevented from receiving compensation by reason of the fact that he is also a director of the Corporation, but any such officer who shall also be a Director shall not have any vote in the determination of the amount of compensation paid to him.

ARTICLE V

Indemnification

The Corporation shall, to the fullest extent permitted by the laws of the state of Delaware, indemnify any and all persons whom it shall have power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by them by reason of having been officers or Directors of the Corporation, any subsidiary of the Corporation or of any other corporation for which such person acted as officer or director at the request of the Corporation.

ARTICLE VI

Contracts, Checks, Drafts, Bank Account, Etc.

Section 1. Execution of Contracts. Except as otherwise required by statute, the Certificate of Incorporation or these By-Laws, any contracts or other instruments may be executed and delivered in the name and on behalf of the Corporation by such officer or officers (including any assistant officer) of the Corporation as the Board may, from time to time, direct. Such authority may be general or confined to specific instances as the Board may determine. Unless authorized by the Board or expressly permitted by these By-Laws, an officer or agent or employee shall not have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it pecuniarily liable for any purpose or to any amount.

Section 2. Loans. Unless the Board shall otherwise determine, either (a) the Chairman of the Board, the Vice Chairman of the Board or the President, singly, or (b) a Vice President, together with the Treasurer, may effect loans and advances at any time for the Corporation or guarantee any loans and advances to any subsidiary of the Corporation, from any bank, trust company or other institution, or from any firm, corporation or individual, and for such loans and advances way make, execute and deliver promissory notes, bonds or other certificates or evidences of indebtedness of the Corporation, or guarantee of indebtedness of subsidiaries of the Corporation, but no officer or officers shall mortgage, pledge, hypothecate or transfer any securities or other property of the Corporation, except when authorized by the Board.

Section 3. Checks, Drafts, Etc. All checks, drafts, bills of exchange or other orders for the payment of money out of the funds of the Corporation, and all notes or other evidences of indebtedness of the Corporation, shall be signed in the name and on behalf of the Corporation by such persons and in such manner as shall from time to time be authorized by the Board.

Section 4. Deposits. All funds of the Corporation not otherwise employed shall be deposited from time to time to the credit of the Corporation in such banks, trust companies or other depositories as the Board may from time to time designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. For the purpose of deposit and for the purpose of collection for the account of the Corporation, checks, drafts and other orders for the payment of money which are payable to the order of the Corporation my be endorsed, assigned and delivered by any officer or agent of the Corporation, or in such manner as the Board may determine by resolution.

Section 5. General and Special Bank Accounts. The Board may, from time to time, authorize the opening and keeping of general and special bank accounts with such banks, trust companies or other depositories as the Board may designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. The Board may make such special rules and regulations with respect to such bank accounts, not inconsistent with the provisions of these By-Laws, as it may deem expedient.

Section 6. Proxies in Respect of Securities of Other Corporations. Unless otherwise provided by resolution adopted by the Board, the Chairman of the Board, the President or a Vice President may from time to time appoint an attorney or attorneys or agent or agents of the Corporation, in the name and on behalf of the Corporation, to cast the votes which the Corporation may be entitled to cast as the holder of stock or other securities in any other corporation, any of whose stock or other securities may be held by the Corporation, at meetings of the holders of the stock or other securities of such other corporation, or to consent in writing, in the name of the Corporation as such holder, to any action by such other corporation, and may instruct the person or persons so appointed as to the manner of casting such votes or giving such consent, and may execute or cause to be executed, in the name and on behalf of the Corporation, and under its corporate seal, or otherwise, all such written proxies or other instruments as he or she may deem necessary or proper in the premises.

ARTICLE VII

Shares, Etc.

Section 1. Stock Certificates. Shares of stock of the Corporation shall be represented by certificates, or shall be uncertificated shares that may be evidenced by a book-entry system maintained by the registrar of such stock, or a combination of both. To the extent that shares are represented by certificates, such certificates shall be in a form approved by the Board. Each certificate shall be signed in the name of the Corporation by (A) the Chairman or Vice Chairman of the Board or the President or a Vice President, and (B) the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer, and sealed with the seal of the Corporation (which seal may be a facsimile, engraved or printed); provided, however, that where any such certificate is countersigned by a transfer agent other than the Corporation or one of its employees, or is registered by a registrar other than the Corporation or one of its employees, the signature of the officers of the Corporation upon such certificates may be facsimiles, engraved or printed. In case any officer who shall have signed or whose facsimile signature has been placed upon such certificates shall have ceased to be such officer before such certificates shall be issued, they may nevertheless be issued by the Corporation with the same effect as if such officer were still in office at the date of their issue.

Section 2. Books of Account and Record of Shareholders. The books and records of the Corporation may be kept at such places within or without the state of incorporation as the Board of Directors may from time to time determine. The stock record books and the blank stock certificate books shall be kept by the Secretary or by any other officer or agent designated by the Board of Directors.

Section 3. Transfer of Shares. Subject to any restrictions on transfer and unless otherwise provided by the Board, shares of stock may be transferred only on the books of the Corporation by the surrender to the Corporation or its transfer agent of the shares in certificated form, properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, or upon proper instructions from the holder of uncertificated shares, in each case with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require. Except as otherwise provided by applicable law, the Corporation shall be entitled to recognize the exclusive right of a person in whose name any share or shares stand on the record of stockholders as the owner of such share or shares for all purposes, including, without limitation, the rights to receive dividends or other distributions and to vote as such owner, and the Corporation may hold any such stockholder of record liable for calls and assessments and the Corporation shall not be bound to recognize any equitable or legal claim to or interest in any such share or shares on the part of any other person whether or not it shall have express or other notice thereof. Whenever any transfers of shares shall be made for collateral security and not absolutely, and both the transferor and transferee request the Corporation to do so, such fact shall be stated in the entry of the transfer.

Section 4. Regulations. The Board may make such additional rules and regulations, not inconsistent with these By-Laws, as it may deem expedient concerning the issue, transfer and registration of certificates for shares of stock of the Corporation. It may appoint, or authorize any officer or officers to appoint, one or more transfer agents or one or more transfer clerks and one or more registrars and may require all certificates for shares of stock to bear the signature or signatures of any of them.

Section 5. Lost, Destroyed or Mutilated Certificates. The holder of any certificate representing shares of stock of the Corporation shall immediately notify the Corporation of any loss, destruction or mutilation of such certificate, and the Corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it which the owner thereof shall allege to have been lost, stolen or destroyed or which shall have been mutilated, and the Board may, in its discretion, require such owner or his legal representative to give the Corporation a bond in such sum, limited or unlimited, and in such form and with such surety or sureties as the Board in its absolute discretion shall determine, to indemnify the Corporation against any claim that way be made against it on account of the alleged loss, theft or destruction of any such certificate, or the issuance of a new certificate. Anything herein to the contrary notwithstanding, the Board, in its absolute discretion, may refuse to issue any such new certificate, except pursuant to legal proceedings under the laws of the State of Delaware.

Section 6. Fixing of Record Date. In order that the Corporation may determine the stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix in advance a record date, which shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action. A determination of stockholders of record entitled to notice of, or to vote at, a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

ARTICLE VIII

Offices

Section 1. Principal or Registered Office. The principal registered office of the Corporation shall be at such place as may be specified in the Certificate of Incorporation or other certificate filed pursuant to law, or if none be so specified, at such place as may from time to time be fixed by the Board.

Section 2. Other Offices. The Corporation also may have an office or offices other than said principal or registered office, at such place or places either within or without the State of Delaware.

ARTICLE IX

Fiscal Year

The fiscal year of the Corporation shall be determined by the Board.

ARTICLE X

Seal

The Board shall provide a corporate seal which shall contain the name of the Corporation, the words "Corporate Seal" and the year and State of Delaware.

ARTICLE XI

Amendments

Section 1. Stockholders. These By-Laws may be amended or repealed, or new By-Laws may be adopted, at any annual or special meeting of the stockholders, by a majority of the total votes of the stockholders or when stockholders are required to vote by class by a majority of the appropriate class, in person or represented by proxy and entitled to vote on such action; provided, however, that the notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of these By-Laws, or the adoption of new By-Laws, is one of the purposes of such meeting.

Section 2. Board of Directors. These By-Laws may also be amended or repealed or new By-Laws may be adopted by the Board at any meeting of the Board; provided, however, that notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of the By-Laws, or the adoption of new By-Laws, is one of the purposes of such meetings. By-Laws adopted by the Board may be amended or repealed by the stockholders as provided in Section 1 of this Article XI.

ARTICLE XII

Miscellaneous

Section 1. Interested Directors. No contract or other transaction between the Corporation and any other corporation shall be affected and invalidated solely by the fact that any one or more of the Directors of the Corporation is or are interested in or is a director or officer or are directors or officers of such other corporation, and any Director or Directors, individually or jointly, may be a party or parties to or may be interested in any contract or transaction of the Corporation or in which the Corporation is interested; and no contract, act or transaction of the Corporation with any person or persons, firm or corporation shall be affected or invalidated by the fact that any Director of the Corporation is a party or are parties to or interested in such contract, act or transaction, or in any way connected with such person or persons, firms or associations, and each and every person who may become a Director of the Corporation is hereby relieved from any liability that might otherwise exist from contracting with the Corporation for the benefit of himself or herself, any firm, association or corporation in which such Director may be in any way interested.

Section 2. Ratification. Any transaction questioned in any stockholders derivative suit on the grounds of lack of authority, defective or irregular execution, adverse interest of director, officer or stockholder, nondisclosure, miscomputation, or the application of improper principles or practices of accounting, may be ratified before or after judgment, by the Board or, by the stockholders in case less than a quorum of Directors are qualified, and, if so ratified, shall have the same force and effect as if the questioned transaction had been originally duly authorized, and said ratification shall be binding upon the Corporation and its stockholders, and shall constitute a bar to any claim or execution of any judgment, in respect of such questioned transaction.

Exhibit 10.35

MASTER SERVICES AGREEMENT

This Master Services Agreement ("**Agreement**"), is entered into as of August 10, 2007 ("**Effective Date**"), by and between Discovery Laboratories, Inc., a Delaware corporation with a principal place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976 ("**Discovery Labs**") and Kloehn Ltd., a Nevada corporation having its principal place of business at 1000 Banburry Cross Drive, Las Vegas, NV 89144 ("**Kloehn**").

Whereas, Discovery Labs has entered into a strategic alliance dated December 9, 2005 (the "**Chrysalis Alliance**") with Philip Morris USA Inc., d/b/a Chrysalis Technologies ("**Chrysalis**") providing for the development and licensing of combination drug-device surfactant products ("**Aerosol Devices**") based on Discovery Labs' aerosolized surfactant replacement therapy ("**aSRT**"), consisting of devices (the "**Base Units**") and related disposable delivery packets (the "**DDPs**"); and

Whereas, Chrysalis has entered into an agreement with Kloehn pursuant to which Kloehn is assisting Chrysalis in the engineering and development of the Base Units and DDPs, particularly in the field of manufacture and assembly of fluidic components and systems; and

Whereas, Kloehn and Discovery Labs have collaborated on the manufacture of Base Units and DDPs to be used in engineering confidence testing and in the initial Phase 2 clinical trials planned by Discovery Labs and Discovery Labs wishes to enter into an arrangement with Kloehn pursuant to which Kloehn will manufacture for Discovery certain sub-components of, and integrate those sub-components along with others that may be provided by third parties into, Base Units and DDPs in connection with Discovery Labs' new drug application with respect to Surfaxin for the prevention of respiratory distress syndrome (RDS) in premature infants, to be filed with the United States Food and Drug Administration (the **"FDA")** and, potentially, foreign regulators (the "**aSRT Project**"), and Kloehn is willing to provide such services (the "**Services**"), upon the terms and conditions contained herein;

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth below, and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereby agree as follow:

1. **Services.**

1.1 As agreed upon by both parties, Kloehn will perform the Services related to the aSRT Project on an as-needed basis and as requested by Discovery Labs from time to time, as more particularly described in this Agreement and in applicable project work orders. The Services shall be provided on a project-by-project basis in accordance with the specifications and terms of individual project work orders (each, a "**PWO**"). Each PWO shall: (i) describe the activities required for the assembly of sub-components that comprise the key components of the Base Units, the DDPs, and the patient interface), the technical specifications for assembling the Devices, cost analyses and fees, performance milestones and reporting requirements, timelines and other criteria for the assembly and delivery of the Base Units and the DDPs; (ii) set forth Kloehn's compensation for the Services; (iii) provide that the Base Units, the DDPs and related systems shall be subject to quality control testing and approval by or on behalf of Discovery prior to release for clinical trial use as set forth in the Quality Agreement between the parties dated even date herewith (the "**Quality Agreement**"); (iv) be signed by both parties prior to commencing work on any project; and (v) be governed by this Agreement and made a part hereof. Any proposed change to the scope of the project or estimated total project costs set forth in any PWO shall not be deemed effective unless and until such change has been agreed to in writing by the parties hereto. In the event of a conflict between the provisions of this Agreement and the provisions of a PWO or any other attachment, the terms of this Agreement shall prevail. A form of PWO is attached hereto as Attachment A.

1.2 All Services rendered under this Agreement will be performed by Kloehn: (i) with due care; (ii) in accordance with generally prevailing industry standards; (iii) in full compliance with current good clinical practices ("**cGCP**") and current good manufacturing practices ("**cGMP**") as specified in regulations promulgated from time to time by the FDA; (iv) in the manner and as provided in the Quality Agreement between the parties; (v) in accordance with standard operating procedures ("**SOPs**") and policies that are acceptable to Discovery Labs, in its sole discretion, from time to time; and (vi) in compliance with all applicable laws and government regulatory requirements.

1.3 During the course of the aSRT Project, Kloehn shall be responsible for and use its best efforts with respect to the control of access to and utilization of all aSRT Project materials, including sub-components. Materials and sub-components vendors shall be selected as set forth in the Quality Agreement. Inventory of all aSRT Project materials and sub-components shall be tracked by Kloehn in accordance with cGMP.

1.4 Kloehn shall provide to Discovery Labs, at such intervals as Discovery Labs may reasonably request, periodic operating reports, including, but not limited to, with respect to manufacturing processes and events, inventory purchasing, storage, utilization and Base Units and DDPs inventory, in a format that is reasonably acceptable to Discovery.

1.5 Kloehn shall provide to Discovery Labs quarterly periodic financial reports, in such detail and format as is reasonably acceptable to Discovery Labs.

2. **Compensation and Payment.**

2.1 **Fees.** In consideration for the Services rendered by Kloehn to Discovery Labs, Discovery Labs will pay Kloehn per the budget set forth in each PWO.

2.2 **Invoices.** Invoices submitted pursuant to a PWO should be submitted to:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622
Attention: Accounts Payable

Discovery Labs shall pay Kloehn as promptly as practicable following receipt of Kloehn's invoices, provided Kloehn has complied in all material respects with the terms of this Agreement. If any portion of an invoice is disputed, then Discovery Labs shall pay the undisputed amounts as set forth in the preceding sentence and the parties shall use good faith efforts to reconcile the disputed amount as soon as possible. In the event of any overpayment by Discovery Labs, Kloehn shall promptly refund to Discovery Labs the amount of such overpayment or, if acceptable to Discovery Labs, credit the amount of such overpayment on the next invoice.

3. **Term and Termination.**

3.1 This Agreement will commence on the Effective Date and shall continue to March 31, 2009 (the "**Term**"). The Term of this Agreement may be extended upon the mutual written agreement of the parties.

3.2 Notwithstanding the preceding paragraph, if Discovery Labs shall determine in the exercise of its reasonable judgment to terminate this Agreement (which judgment may be based upon, but not be limited to, economic or regulatory events or developments, inconclusive clinical trial results or commercial feasibility concerns, or the occurrence of events described in Section 5), Discovery Labs shall give Kloehn written notice of termination and, within sixty (60) days, Discovery Labs and Kloehn shall cooperate to develop a plan for the orderly wind-down and transfer of any Services being performed, including, without limitation, technology and inventory and related materials and property, if any, owned by Discovery Labs, all of which potential transfer activities shall be set forth in each PWO.

3.3 Upon any material breach of this Agreement by either party, the non-breaching party may terminate this Agreement upon thirty (30) days written notice to the breaching party, in accordance with the provisions of Section 3.2. The notice shall become effective at the end of the thirty (30) day period unless the breaching party cures such breach within such period. For purposes of this Agreement, material breach includes, but is not limited to, nonperformance and breach of confidential information.

3.4 Neither expiration nor termination of this Agreement shall relieve either party of its rights or obligations under Sections 3.4, 4, 6.4, 6.5, 6.6, and 6.8 through 6.12.

4. **Proprietary Information, Intellectual Property, and Records.**

4.1 **Proprietary Information.**

i) The parties hereto shall use their best efforts and shall keep confidential and not disclose to third parties or use any of the disclosing party's Proprietary Information (as hereafter defined), except as may be required in providing the Services. Each party hereto will return any Proprietary Information belonging to the disclosing party upon the first to occur of: a) written request of the disclosing party, b) expiration of this Agreement, or c) termination of this Agreement. Proprietary Information will not include any information or material which:

a) is now in the public domain or which becomes generally available to the public other than as a result of a disclosure by the receiving party; or

b) was already known to or in the possession of receiving party prior to disclosure as can be demonstrated by documentary evidence; or

c) was disclosed on a non-confidential basis by a third party, provided that such party is not prohibited by a confidentiality agreement with or other contractual, legal or fiduciary obligation of nondisclosure to the disclosing party.

ii) "Discovery Proprietary Information" includes (i) all proprietary information and/or material owned by Discovery Labs, and now or hereafter included in Discovery Labs' intellectual property portfolio including, but not limited to: Surfaxin® (KL_4-Surfactant, sinapultide, lucinactant) and/or surfactant lavage techniques used to treat pulmonary diseases, and shall further include all data, materials, products, technology, computer programs, specifications, manuals, business plans, software, marketing plans, and financial information, (ii) all proprietary information, intellectual property and/or material licensed to Discovery Labs, including, without limitation, that certain license granted to Discovery Labs pursuant to the Chrysalis Alliance, (iii) the Base Units and DDPs, (iv) all trade secrets owned, licensed or otherwise developed and controlled by Discovery Labs, including without limitation trade secrets related to the manufacture, release and quality control activities of Discovery Labs' surfactant replacement therapy platform and aSRT product candidates and delivered to Kloehn as part of a technology transfer, and (v) any information or material learned from or developed by Discovery Labs in the course of the aSRT Project or for Discovery Labs by Kloehn in connection with the Services hereunder.

iii) "Kloehn Proprietary Information" includes all proprietary information owned or licensed by Kloehn relating to the pumping mechanism and syringe subcomponents and shall further include all of Kloehn's data, materials, products, technology, computer programs, specifications, manuals, business plans, software, marketing plans, and financial information, to the extent that the foregoing is owned, licensed or developed by Kloehn or otherwise made available to Kloehn by a third party on a confidential basis, as may be disclosed to Discovery Labs as a result of providing the Services hereunder.

iv) The confidentiality obligations of this Section 4 shall survive the expiration or termination of this Agreement for a period of five (5) years thereafter.

4.2 **Intellectual Property.**

i) Kloehn acknowledges and agrees that, as between Discovery Labs and Kloehn, all ownership, copy, patent, trade secrecy, trademark, service mark, trade name and other rights in any and all work product created hereunder (hereinafter "**Intellectual Property**"), which Intellectual Property shall include, without limitation, all inventions, discoveries, designs, programs, improvements, developments, new concepts, methods, agents, materials, and ideas, whether patentable or not, and products, processes and know-how related to the use or production thereof made or conceived by Kloehn for the aSRT Project pursuant to this Agreement and on behalf of Discovery Labs, during the term of this Agreement or within six (6) months thereafter, that relate to or results from any work performed by Kloehn for Discovery Labs or that make use of Discovery Labs' equipment, supplies, facilities, technology or trade secrets shall be the sole property of Discovery Labs, including without limitation the information and/or material licensed to Discovery Labs pursuant to the Chrysalis Alliance, whether developed independently by Kloehn or jointly with others and whether Discovery Labs uses, registers or markets the same. For the purposes of this Agreement, "**Intellectual Property**" does not include any fluidic pump technology and trade secrets that are owned, and were developed by, Kloehn prior to and independently of the Services provided under this Agreement.

ii) Kloehn does hereby agree to promptly disclose all Intellectual Property to Discovery Labs in writing, sign all papers, execute all oaths and do everything necessary to assign to Discovery Labs, and does hereby assign to Discovery Labs, all rights in and to the Intellectual Property. For these purposes Kloehn agrees to make, constitute and appoint Discovery Labs, irrevocably and coupled with an interest, Kloehn's true and lawful attorney in fact, in Kloehn's name, place and stead, to sign, execute, acknowledge, deliver and record all documents and instruments, at any time and in any manner, which Discovery Labs may deem necessary or desirable to grant and assign to Discovery Labs all rights of any nature whatsoever (including, but not limited to the exclusive global copyrights, patents, trademarks and service marks) in and to the Intellectual Property. Such documents and instruments shall include but not be limited to all documents required in applying for and obtaining registration of all priority rights in the Intellectual Property and all documents necessary to assign to Discovery Labs all rights thereto. As necessary and upon request, during and after the term of this Agreement, Kloehn agrees to further assist Discovery Labs to evidence, perfect, register or enforce any and all rights set forth in this Section 4.

iii) Kloehn acknowledges and agrees that should Kloehn's services hereunder result in the creation of copyrightable Intellectual Property, said Intellectual Property is a work made for hire as the term is used in the United States Copyright Laws in that it was prepared within the scope of Discovery Labs' engagement of Kloehn's services and it constitutes a work specially ordered by Discovery Labs.

iv) Kloehn may develop innovative fluidic pump technology pursuant to this Agreement and wishes to retain rights to any such technology for all uses other than with respect to respiratory medical devices ("Non-medical Fluidics"). Such Non-medical Fluidics may constitute "Chrysalis Technology Improvements", which is defined under the Chrysalis Alliance to include, among other things, inventions created or reduced to practice by or on behalf of Discovery Labs and its subcontractors in the performance of the Chrysalis Alliance, which inventions relate primarily to Chrysalis' proprietary Aerosol Technology (which includes, without limitation, technologies, devices, processes, equipment, materials and know-how relating to the aerosolization of liquid forms of drug products and the Base Units and DDPs). Under the Chrysalis Alliance, such Chrysalis Technology Improvements are the property of Chrysalis. Accordingly, Discovery Labs is unable to agree to the retention of rights by Kloehn in Non-medical Fluidics. Nevertheless, Discovery Labs acknowledges and agrees that Kloehn may negotiate with Chrysalis for rights to Non-medical Fluidics and, to the extent that an agreement is reached between Kloehn and Chrysalis and provided that such rights are beyond the scope of the rights granted to Discovery Labs under the Chrysalis Alliance, Discovery Labs will execute such agreements as may reasonably be required to transfer and vest such rights to Kloehn.

4.3 **Records and Materials.** Kloehn agrees to keep, separate and segregate from other work, all documents, records, notebooks, correspondence, processes, techniques, methods, agents, know-how and other material which directly relate to Kloehn's performance under this Agreement. At Discovery Labs' request, Kloehn shall afford Discovery Labs access to said records relating to this Agreement. Discovery Labs shall own all right for, title to and interest in such items, whether prepared or acquired by Kloehn or provided to Kloehn by Discovery Labs or other party. Upon expiration or termination of this Agreement or upon earlier request by Discovery Labs, Kloehn shall immediately assemble all tangible items of work in process, notes, plans and other materials related in any way to Kloehn's performance under this Agreement and all documents, records, notebooks and similar repositories of or containing confidential information, including copies thereof, then in Kloehn's possession or subject to Kloehn's control, whether prepared by Kloehn or others, and will promptly (not to exceed five (5) business days after termination) deliver such items to Discovery Labs or, at Discovery Labs' instructions, destroy them and certify such destruction in writing to Discovery Labs.

4.4 **Audits**. During the term of this Agreement and for a period of 5 (five) years thereafter, Kloehn agrees to permit Discovery Labs (or its designee) to examine with prior notice at any reasonable time during normal business hours: (a) the facilities where the Services are being performed, and (b) reports, databases and any other relevant information necessary to confirm that the Services are being conducted in conformance with this Agreement and in compliance with applicable laws and regulations. Kloehn agrees to cooperate with Discovery Labs (or its designee) and provide all requested documentation. Kloehn agrees to take or cause to be taken any reasonable actions requested by the Company to cure deficiencies noted during an audit or inspection.

5. **Future Transactions**

5.1 The parties contemplate that Kloehn's satisfactory performance of the Services, when combined with the achievement, as determined in the sole and unfettered discretion of Discovery Labs, of satisfactory developmental, clinical, marketing, business and financial results with respect to the aSRT Project, provide the basis for future agreements between Discovery Labs and Kloehn. Specifically, (a) Kloehn must timely perform the Services according to the standards set forth in this Agreement and the Quality Agreement, (b) Kloehn must establish and maintain the technology necessary to support any future iteration of the aSRT Project, and (c) Kloehn must maintain a competitive Services pricing structure. For the avoidance of doubt, assuming that the expectations and business needs of the parties and all applicable technical and regulatory requirements are satisfied at all times, and subject to the contingencies noted in Section 5.2, the parties anticipate, and agree to negotiate in good faith to enter into, future agreements associated with the aSRT Project, with specific reference, but potentially not limited to, the core business of Kloehn, fluidic pump technology.

5.2 Kloehn acknowledges that, to manufacture and market aSRT devices in accordance with cGMP and to assure a continuous supply of Base Units and DDPs at all times, Discovery Labs intends to work with more than one FDA-qualified manufacturer and integrator and, in order to secure the commitment of such manufacturers and integrators, Discovery Labs will likely be required to direct a minimal level of orders to such entities. Notwithstanding the foregoing, with respect to Kloehn's core business of developing and manufacturing pumping mechanisms and syringe subcomponents, in which Kloehn asserts a proprietary interest and related intellectual property (the "**Kloehn Subcomponents**"), Discovery Labs and Kloehn agree to negotiate in good faith to execute and deliver an agreement under which Kloehn will be the sole manufacturer of the Kloehn Subcomponents, provided that such agreement shall contain terms and conditions satisfactory to both parties providing for back-up inventories and, further providing for volume requirements, mechanisms to transfer manufacturing processes and know-how to one or more successor manufacturers designated by Discovery Labs in the event of a default or failure by Kloehn to manufacture to Discovery Labs' specifications. The foregoing assumes that the expectations and business needs of the parties and applicable technical and regulatory requirements are and will continue to be satisfied at all times.

5.3 Notwithstanding anything in this Agreement to the contrary, Kloehn acknowledges that Discovery Labs may enter into one or more agreements with other parties ("**Collaborators**") for the purpose of assigning or delegating to such Collaborators (pursuant to licensing or other arrangements) commercialization, manufacturing and assembly responsibilities for the Base Units, DDPs and related equipment. Such arrangements may provide, among other things, that Discovery Labs would no longer act as the procurer of Base Units, DDPs and related systems. In such event, Discovery Labs will not be obligated to require such Collaborators to comply with the undertakings of Discovery Labs under this Agreement, but will apprise such Collaborators of Kloehn's previous commitment to the aSRT Project and will discuss with such Collaborators Kloehn's historical performance under this Agreement and, to the extent practical, facilitate negotiations between such Collaborators and Kloehn, in particular with respect to the core business of Kloehn, fluidic pump technology. Kloehn acknowledges that Discovery Labs can not compel such Collaborators to agree to negotiate in good faith to enter into future agreements.

5.4 Notwithstanding the foregoing, the parties recognize that there can be no assurance that Discovery Labs, or any of its potential Collaborators, will deem it necessary or desirable to pursue the development of the aSRT Project, or that unforeseen developments, including, without limitation, actions of the FDA or other governmental agency, may not arise which would make the continuation of Kloehn's Services in the event of the ongoing development and ensuing commercialization of the aSRT Project undesirable or impractical.

6. **Miscellaneous Provisions.**

6.1 **Assignment.** Due to the specialized nature of the Services provided by Kloehn hereunder, Kloehn may not assign, transfer or convey this Agreement or any moneys due or to become due hereunder without the prior written consent of Discovery Labs, which consent shall not be unreasonably withheld. Discovery Labs may assign its rights and obligations under this Agreement without the consent of Kloehn.

6.2 **Notices.** All notices under this Agreement shall be given in writing and delivered personally (against receipt), sent by prepaid registered or certified mail, return receipt requested, or by prepaid overnight courier service or, to the extent receipt is confirmed, telecopy or other electronic transmission service, to the appropriate address or number as set forth below:

If to Discovery Labs:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622
Attention: Chuck Katzer, Senior Vice President, Manufacturing Operations
Fax: (215) 488-9530
E-mail: ckatzer@discoverylabs.com

With a copy to:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622
Attention: David Lopez, Executive Vice President, General Counsel
Fax: (215) 488-9557
E-mail: dlopez@discoverylabs.com

If to Kloehn:

Kloehn Ltd. USA
10000 Banburry Cross Drive
Las Vegas, NV 89144
Attention: Michael Marshall, Vice President, General Manager
Fax: (702) 243-7727
E-mail: mmarshall@kloehn.com

With a copy to:

Kenneth L. Sherman, Esq.
Myers Dawes Andras & Sherman, LLP
19900 MacArthur Boulevard, 11th Floor
Irvine, CA 92612
Fax: (949) 223-9610
E-mail: sherman@mdaslaw.com

or to such addresses either party may from time to time designate by written notice to the other, and shall be given by mail (postage prepaid), express courier (prepaid), fax or by personal delivery. The date of receipt by fax, personal delivery, express courier or mailing as the case may be, shall be deemed the date of delivery to a party.

6.3 **Representations and Warranties**. Kloehn represents and warrants that:

i) as of the Effective Date of this Agreement, Kloehn has no conflicting third party agreements, and Kloehn will not enter into any third party agreements during the Term of this Agreement that would prevent or interfere with Kloehn's performance of Kloehn's obligations hereunder; and

ii) if applicable, the person(s) responsible for providing the Services has not been debarred by the FDA under 21 U.S.C. 335a and that it will not subcontract any of the Services to any person who has been debarred.

6.4 **Indemnification.** Kloehn shall indemnify, defend and hold Discovery Labs harmless from and against any claim, loss, damage and expense including reasonable attorney's fees (the foregoing, individually and collectively, "**Claim**"), arising out of Kloehn's breach or alleged breach of any of the covenants, representations and warranties contained in this Agreement and arising out of Services performed and carried out pursuant to this Agreement; *provided, however*, that Kloehn shall have no obligation to indemnify Discovery Labs to the extent that it shall be finally determined by a court of competent jurisdiction that such claim, loss, damage and expense are the result of Discovery Labs' gross negligence or willful misconduct, and in such event, Discovery Labs shall be required to reimburse Kloehn for costs of defense incurred by Kloehn prior to such determination. The indemnity provided in this Agreement shall be in addition to, and not in substitution of, any indemnity provided in the Quality Agreement or other agreement between the parties. Discovery Labs acknowledges and agrees that the indemnity provided in this Section 6.4 is limited to the performance and undertakings of Kloehn under this Agreement. In the event any Claims arise out of or relate to the use of Base Units and Disposable Dose Packets to treat humans as part of a clinical trial, Discovery Labs acknowledges that Kloehn will be obligated to indemnify Discovery Labs pursuant to this Section 6.4 only if, and only to the extent that, Kloehn shall have breached this Agreement, for example, by manufacturing Base Units or Disposable Dose Packets that deviate from the specifications provided in an applicable PWO, and not in connection with Claims arising out of a defect in the design of the Base Units or Disposable Dose Packets or the improper use of the Base Units or Disposable Dose Packets by third parties.

6.5 **Independent Contractor.** The parties hereto are acting as independent contractors and shall not be deemed to be partners, joint ventures or each other's employees or agents. Neither party shall have the right to act on behalf of the other except as expressly set forth in this Agreement. Kloehn will be solely responsible for and will pay all taxes related to the receipt of payments hereunder and shall give reasonable proof and supporting documents, if reasonably requested, to verify the payment of such taxes.

6.6 **Insurance.** Throughout the term of this Agreement, Kloehn shall maintain, and shall provide to Discovery Labs, copies of insurance policies with the following minimum coverages and under which Discovery Labs shall be named an additional insured: (i) standard property insurance, in such form as is acceptable to Discovery Labs and covering all component materials, equipment, improvements and all devices (including all such materials, equipment, improvements and devices that are owned by Discovery Labs and in the possession of Kloehn at any time), in such amounts, and with such retentions, deductibles, limits and sub-limits as Discovery Labs and Kloehn shall agree, but in no event less than the estimated replacement cost of Kloehn's facility and all fixtures, equipment, inventory and other personal property located therein, and the cost of re-validating and qualifying the facility under the FDA regulations, (ii) standard general liability insurance including bodily injury, death, property damage in a minimum amount of $5,000,000 per occurrence and $10,000,000 in the aggregate; (iii) product liability insurance in a minimum amount of $5,000,000 per occurrence and $10,000,000 in the aggregate; (iv) workers compensation insurance; and (v) such other coverages as are normal and customary in the industry for similar contract manufacturers and integrators, in such amounts as are reasonably acceptable to both parties.

6.7 **Governing Law.** This Agreement will be governed by and construed in accordance with the laws of the State of Delaware, United States of America (regardless of its or any other jurisdiction's choice-of-law principles).

6.8 **Equitable Remedies.** Each of the parties agrees that money damages would not be a sufficient remedy for any breach of this Agreement by such party and that the other party will be entitled to seek specific performance and injunctive relief as remedies for any such breach. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.

6.9 **Waiver.** Failure by either party to insist on strict adherence to any one or more of the terms or conditions of this Agreement, or on one or more occasions, will not be construed as a waiver, nor deprive that party of the right to require strict compliance with the same thereafter.

6.10 **Business Identifiers; Publicity.** Neither party shall use the trade name, logos, or trademarks of the other party and/or its products or services without the other party's prior written consent. Neither party shall identify the other party as a prospective, current, or former client in any press release, publicity, advertising, or other disclosure without prior written consent of the other party. Notwithstanding the foregoing, Discovery Labs may disclose the existence of this Agreement, the identity of Kloehn and the nature of the Services provided hereunder, if in the reasonable exercise of its judgment, Discovery Labs concludes that disclosure is necessary or appropriate to comply with the requirements of the federal securities laws.

6.11 **Severability.** If any provision of this Agreement is for any reason declared invalid, void or unenforceable by a court of competent jurisdiction, the validity and binding effect of any remaining provisions will not be affected and the remaining portion of this Agreement will remain in full force and effect as if this Agreement had been executed with said provisions eliminated.

6.12 **Entire Agreement.** This Agreement, the Quality Agreement dated even date herewith, and the Confidentiality Agreement dated as of January 11, 2006, contain the entire agreement of the parties and supersedes and cancels all other agreements, discussions, representations or understandings between the parties with respect to the subject matter hereof, including the Interim Letter Agreement dated as of April 12, 2006 between the parties. No amendments hereto, or waivers or releases of obligations hereunder, shall be effective unless agreed to in writing by the parties hereto. This Agreement may be signed in counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

DISCOVERY LABORATORIES, INC.	KLOEHN LTD.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

Attachment A

Sample Project Work Order

Project Work Order pursuant to Master Services Agreement between Discovery Laboratories, Inc. and Kloehn Ltd., dated August 10, 2007 (the "Agreement").

1. Describe, in detail, the activities to be to be performed hereunder:

2. Specifications:

3. Budget:

4. Fees:

5. Milestone and other reporting requirements:

6. Timelines:

7. The Services to be performed pursuant to this PWO shall be subject to quality control testing and approval as set forth in the Quality Agreement between the parties dated April 20, 2007.

8. In the event of termination of the Agreement the following the respective responsibilities of the parties are as follows:

DISCOVERY LABORATORIES, INC.	KLOEHN LTD.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

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, Form S-3 No. 333-139173, Form S-3 No. 333-111360, Form S-3 No. 333-122887 and Form S-3 No. 333-38282) of Discovery Laboratories, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-148028) pertaining to the Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan

(3) 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, Form S-8 No. 333-138476, Form S-8 No. 333-67422, Form S-8 No. 333-55900 and Form S-8 No. 333-33900) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Discovery Laboratories, Inc.

(4) Registration Statement (Form S-8 No. 333-59945) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Discovery Laboratories, Inc., Discovery Laboratories, Inc. 1996 Stock Option/Stock Issuance Plan and Acute Therapeutics, Inc. 1996 Stock Option/ Stock Issuance Plan

(5) Registration Statement (Form S-8 No. 333-37975) pertaining to the Restated 1993 Stock Option Plan of Ansan Pharmaceuticals, Inc. and the 1995 Stock Option Plan of Ansan Pharmaceuticals, Inc.

of our report dated March 10, 2008, with respect to the consolidated financial statements of Discovery Laboratories, Inc. and subsidiary and of our report dated March 10, 2008, with respect to the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc. and subsidiary, included in this Annual Report (Form 10-K) of Discovery Laboratories, Inc. and subsidiary for the year ended December 31, 2007.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2008

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 our 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 14, 2008

/s/ Robert J. Capetola

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 our 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 14, 2008

/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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (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 14, 2008

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

/s/ John G. Cooper
John G. Cooper
Executive Vice President, 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.