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

FORM 10-K

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

For the fiscal year ended December 31, 2008

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

(215) 488-9300

(Registrant's telephone number, including area code)

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

None

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

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

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

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

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

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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	o

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on The Nasdaq Global Market under the symbol DSCO on June 29, 2008, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $159 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, if any, that has informed the registrant by March 11, 2009 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 4, 2009, 102,551,774 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 2009 definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2008 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, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations; plans regarding our efforts to gain U.S. regulatory approval for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL_4 Surfactant Technology and our capillary aerosolization systems, including our capillary aerosolization technology, including planning for and timing of any clinical trials and potential development milestones; our plans related to the establishment of our own commercial and medical affairs capabilities to support the launch of Surfaxin in the United States, if approved, and our other products; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our drug products; plans regarding potential strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our products.

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 the Complete Response that we submitted to the U. S. Food and Drug Administration (FDA) in October 2008 to respond to the May 2008 Approvable Letter for Surfaxin will not satisfy the FDA;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug or combination drug-device products that we may develop, whether independently, with development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our product candidates;
- 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 other efforts, and which may be subject to potentially significant delays or regulatory holds, or fail;
- risks relating to our ability to develop and manufacture drug products and capillary aerosolization systems, including systems based on our novel capillary aerosolization technology, for initiation and completion of our clinical studies, and, if approved, commercialization of our drug and combination drug-device products;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;
- the risk that we, our contract manufacturers or any of our third-party suppliers encounter problems or delays manufacturing or assembling drug products, drug substances, aerosolization devices and related components and other materials on a timely basis or in an amount sufficient to support our development efforts and, if our products are approved, commercialization;
- the risk that, if approved, we may be unable, for reasons related to market conditions, the competitive landscape or otherwise, to successfully launch and profitably sell our products;
- risks relating to our ability to develop a successful sales and marketing organization to market Surfaxin, if approved, and our other product candidates, 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 or that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- 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 we may not be able to raise additional capital or enter into collaboration agreements (including strategic alliances for development or commercialization of our KL_4 Surfactant and combination drug-device products);
- risks that financial market conditions may change, including that the ongoing credit crisis could adversely affect our ability to fund our activities, additional financings could result in equity dilution, or that 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 recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- the risks that we may be unable to maintain and protect the patents and licenses related to our products; other companies may develop competing therapies and/or technologies or health care reform may adversely affect us;
- the risk that we may become involved in securities, product liability and other litigation;
- risks relating to reimbursement and health care reform;
- 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. After gaining approval of a drug product, pharmaceutical companies face considerable challenges in marketing and distributing their products, and may never become profitable.

Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation 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

TO BE UPDATED

PART I

ITEM 1. BUSINESS.

COMPANY OVERVIEW

Discovery Laboratories, Inc. (referred 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) to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel proprietary technology (KL_4 Surfactant Technology) produces a synthetic, peptide-containing surfactant (KL_4 Surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol generating technology (Capillary Aerosolization Technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL_4 Surfactant to the deep lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are currently focused on developing our lead products, Surfaxin®, Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. Surfaxin, our first product based on our novel KL_4 Surfactant Technology, if approved, will represent the first synthetic, peptide-containing surfactant for use in pediatric medicine. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of this NDA and potentially grant marketing approval.

Aerosurf is our proprietary KL_4 Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. With Aerosurf, if approved, it will be possible to administer surfactant into the deep lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a potentially significant increase in the use of SRT in pediatric medicine.

We plan over time to develop our KL_4 Surfactant Technology into a robust pipeline of products that will potentially address a variety of debilitating respiratory conditions in a range of patient populations, from premature infants to adults, that suffer from severe and debilitating respiratory conditions for which there currently are few or no approved therapies. Our programs include development of Surfaxin to potentially address Bronchopulmonary Dysplasia (BPD) in premature infants and Acute Respiratory Failure (ARF) in children, and conducting research and development with our KL_4 Surfactant to potentially address Cystic Fibrosis (CF), Acute Lung Injury (ALI), and other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

BUSINESS STRATEGY

We received an Approvable Letter from the FDA with respect to Surfaxin for the prevention of RDS in premature infants in May 2008. During the preparation of our Complete Response to the Approvable Letter and the FDA's ongoing review period, our business strategy has been to conserve our financial resources and rigorously manage limited investments in research and development activities. The FDA has assigned April 17, 2009 as its action target date to complete its review of our NDA and potentially approve Surfaxin. Following the potential approval of Surfaxin by the FDA:

- We plan over the near- and long-term to expand and accelerate our proprietary KL_4 Surfactant Technology initiatives with pipeline programs intended to apply our synthetic, peptide-containing surfactant to a broad range of respiratory conditions. It is our goal, within existing financial and other constraints, to develop our pipeline as broadly and as quickly as reasonably possible;

- Initially, we plan to focus our development and commercial efforts on the management of RDS in premature infants. We believe that the RDS market represents a significant opportunity from both a medical and a business perspective.

    - Currently, the only available therapies for the treatment of RDS, which were approved in the early 1990's, are surfactants derived from bovine (cow lung) and porcine (pig lung) sources. The current annual market for these surfactants is estimated to be approximately $75 million in the United States and $200 million worldwide. Currently, surfactants are administered using endotracheal intubation (the invasive insertion of a breathing tube down the trachea) and conventional mechanical ventilation, which risk further serious lung injury and complications. As the medical community is focused on managing RDS patients without employing such invasive techniques, only a subset of premature infants at risk for RDS annually are treated with these surfactants.

    - Surfaxin, the first synthetic, peptide-containing surfactant that, if approved, will represent an alternative therapy to the currently-approved, animal-derived surfactants. We also are developing a lyophilized formulation, Surfaxin LS™, which, among other things, may potentially simplify storage and distribution requirements and methods of administering surfactant. We have a development program that is focused on gaining regulatory approval for Surfaxin LS in the United States, Europe and throughout the world. We believe that, over time, Surfaxin and Surfaxin LS, if approved, have the potential to displace the use of the animal-derived surfactants.

    - Aerosurf will potentially provide the neonatal medical community with the possibility of treating premature infants at risk for RDS without the risks associated with endotracheal intubation and mechanical ventilation. We plan on making significant investments in the development, regulatory, clinical and manufacturing activities necessary to gain regulatory approval for Aerosurf in the United States and worldwide. We believe that Aerosurf, if approved, will allow for a potentially significant increase in the number of infants receiving surfactant therapy, who currently are not treated because the benefits of surfactant therapy are believed to be outweighed by the risks of invasive administration.

    We believe that the combination of Surfaxin, Surfaxin LS and Aerosurf , if approved, have the potential, for the first time in years, to advance the treatment of RDS and make it possible for many more infants at risk for RDS to be treated with SRT. Our KL_4 Surfactant Technology also has the potential to address a range of other serious and debilitating neonatal and pediatric indications, many of which represent significant unmet medical needs, potentially redefining pediatric respiratory medicine.

- With our Surfaxin, Surfaxin LS and Aerosurf programs, we plan to build a fully-integrated pediatric franchise.

    - In the United States, we plan to establish our own specialty pulmonary commercial organization that will initially execute the launch of Surfaxin and specialize in neonatal and pediatric indications. To execute this strategy, we expect to incur expenses at an annual rate of approximately $20 - $25 million for sales, marketing and medical affairs capabilities. We believe that this strategy will provide us direct control over our U.S. sales and marketing activities, permit us to establish a strong presence in neonatal and pediatric intensive care units nationwide, and potentially optimize the economics of our business. If, however, we were presented with an alternative approach, through a strategic alliance or other collaboration arrangement, that would achieve the foregoing, and provide appropriate financial consideration and operational capabilities, we would consider such a potential transaction.

- For international markets, we plan to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications;

· We also plan to invest opportunistically in KL_4 Surfactant Technology pipeline programs that will target adult and other indications we believe represent potentially significant market opportunities. We plan to initially develop these programs through a proof-of-concept phase and, if successful, thereafter seek worldwide strategic alliances or collaboration arrangements for development and/or commercialization. There can be no assurance that we will succeed in demonstrating proof-of-concept or entering into any such alliance, but if we are successful, we believe that these programs could address significant unmet medical needs and potentially redefine respiratory medicine;

· We have, and will continue, to invest in maintaining and perfecting our potential competitive position by protecting our exclusive rights in and to our KL_4 Surfactant Technology, pipeline products and Capillary Aerosolization Technology through patents, patent extensions, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities such as new chemical entity designations and supplemental exclusivities. We believe that our development programs may also provide opportunities for new patent filings, which may potentially significantly extend the benefits of exclusivity into the future;

· We will continue to invest in our quality systems and manufacturing capabilities, including at our manufacturing operations in Totowa, New Jersey and our analytical laboratories in Warrington, Pennsylvania. We plan to manufacture sufficient drug product to meet our anticipated pre-clinical, clinical, formulation development and, if approved, potential future commercial requirements of Surfaxin, Aerosurf and other KL_4 Surfactant product candidates. During the period of formulation development for our lyophilized KL_4 Surfactant, including Surfaxin LS, we expect to enter into arrangements with one or more contract manufacturing organizations. For our capillary aerosolization systems, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our manufacturing requirements. Our long-term manufacturing plans include potentially expanding our existing facilities or building or acquiring additional manufacturing facilities and capabilities to support the production and development of our proprietary KL_4 Surfactant Technology pipeline products; and

· We will need significant additional capital to execute our business strategy. We plan to seek infusions of capital from a variety of potential sources, including strategic alliances, equity financings, debt financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific alliances or transactions.

Our estimates of market size and business opportunities included in this Business Section and elsewhere in this Annual Report on Form 10-K are based in part on our analysis of data derived from the following sources, among others: IMS Midas Data MAT, September 2008; Vermont Oxford Network Data, 2006; Annual Summary of Vital Statistics: 2006, Pediatrics, Martin et. al.; CDC National Vital Statistics, 2005; Management and Outcomes of Very Low Birth Weight, NEJM, 2008, Eichenwald, Stark; The Cystic Fibrosis Foundation; Discovery Labs Primary Market Research, 2007; as well as our analysis of the SELECT and STAR trials. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, economics and anticipated potential pharmaco-economic benefits of our drug products, if approved.

PROPRIETARY PLATFORM – SURFACTANT AND AEROSOL TECHNOLOGIES

Pulmonary surfactants are protein and phospholipids compositions that form naturally in the human lung and are critical to survival and normal respiratory function. They spread in a thin mono-layer to cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways that lead to the air sacs and facilitate breathing by continually modifying the surface tension of the fluid that lines the inside of the lungs. If the lungs have a surfactant deficiency, as frequently occurs in premature infants, or experience surfactant degradation, generally due to disease, lung insult or trauma, the air sacs in the lungs will tend to collapse and will not absorb sufficient oxygen, resulting in severe respiratory diseases and disorders. In addition to lowering alveolar surface tension, surfactants contribute in other important ways to 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. In our KL_4 Surfactant, KL_4 is our synthetic peptide that is designed to closely mimic the essential attributes of protein B (SP-B).

Many respiratory disorders are associated with surfactant deficiency or surfactant degradation. However, the use of surfactant therapy has limited application and is FDA-approved only for treating premature infants with RDS.
Currently available surfactants are derived from pig and cow lungs using a chemical extraction process. Although clinically effective, these surfactants have potential drawbacks and have not been developed to treat broader populations and other respiratory diseases.

We believe our KL_4 Surfactant and Capillary Aerosolization Technology will expand the therapeutic options to treat previously unaddressed respiratory problems in a range of patient populations from premature infants to adults. We also believe that potentially combining our aerosolized KL_4 Surfactant with other therapeutics could enable delivery of important therapeutics into the deep lung. We plan to develop our aerosolized KL_4 Surfactant initially for RDS in premature infants and thereafter for a wide range of indications in neonatal, pediatric and adult patient populations.

Our KL_4 Surfactant Technology

Our proprietary KL_4 Surfactant Technology produces a synthetic surfactant that is structurally similar to human pulmonary surfactant and contains a proprietary synthetic peptide, KL_4 (sinapultide). KL_4 is a 21 amino acid protein-like substance that closely mimics the essential attributes of human surfactant protein B (SP-B), which is the surfactant protein most important for the proper functioning of the respiratory system. Our synthetic surfactant may be manufactured to precise specifications and formulated as liquid instillate, lyophilized (dry powder), or aerosolized liquid. We acquired exclusive worldwide rights to this technology, which was invented at The Scripps Research Institute and exclusively licensed to and further developed by Johnson & Johnson, Inc. (Johnson & Johnson), in October 1996.

Our KL_4 Surfactant is a synthetic surfactant that can be manufactured consistently and with minimal variability. We also believe that our synthetic surfactant might possess pharmaceutical benefits not currently exhibited by the animal-derived surfactants. Our synthetic KL_4 Surfactant has also demonstrated in preclinical studies unique characteristics, including anti-inflammatory, antimicrobial and nonimmunogenic properties. We believe these characteristics will be important attributes as we develop our KL_4 Surfactant Technology pipeline to potentially address a broad range of respiratory conditions that represent significant unmet medical needs.

In May 2008 at the *Pediatric Academic Societies* Annual Meeting (PAS), data were presented from an animal study that assessed the effect of Surfaxin on biomarkers of lung inflammation and lung structure as compared to those treated with Survanta® (beractant), a currently available surfactant derived from cow lung and the most prescribed surfactant in the United States, Curosurf® (poractant alfa), a currently available surfactant derived from pig lung and the most prescribed surfactant in Europe, or no surfactant replacement therapy. The chosen animal model was selected because it closely resembles RDS in human lungs and is regarded as the most relevant system to study the pathophysiology and treatment of RDS. The results of the study showed that animals treated with Surfaxin had better lung function compared with those treated with Survanta, Curosurf, or no surfactant replacement. In addition, animals treated with Surfaxin had better structural integrity, as assessed by evaluation of lung tissue, and lower levels of lung tissue and blood inflammatory mediators, compared with animals treated with Survanta or no surfactant replacement therapy.

A study that assessed the impact of exogenous surfactants, including Surfaxin, on hyperoxic-induced lung injury in an *in-vitro* cell-culture model and concluded that our KL_4 Surfactant reduced inflammation and cell injury, resulting in improved cell survival and function compared with both Survanta and a saline control was published in *Pediatric Research*, a prominent peer-reviewed journal, in July 2008.

In May 2007, a study was presented at PAS, the objective of which 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 developing our KL_4 Surfactant Technology to potentially treat diseases in which respiratory inflammation plays in integral part, such as BPD, ARF, ALI and CF.

A study presented at PAS in May 2008 investigated the antimicrobial properties of Surfaxin. In that study, gram-positive and gram-negative bacterial broth was mixed with Surfaxin and Survanta, as well as with saline, a negative control, and ciprofloxacin, an antibiotic that served as a positive control. While both Surfaxin and Survanta suppressed gram-positive bacterial growth, only Surfaxin suppressed gram-negative bacterial growth.

Also at PAS in May 2008, a study was presented that assessed the potential for KL_4 to induce an immune response known as anaphylaxis. Anaphylaxis, a potentially life-threatening allergic reaction, can occur in humans after exposure to medications that contain a foreign protein. In this study, a well-established animal model was used to test whether KL_4 would trigger anaphylaxis. Supporting our belief that our KL_4 Surfactant has nonimmunogenic properties, this study concluded that KL_4 did not induce active or passive anaphylaxis, even when the immune system was potentiated and sensitized.

All of the foregoing preclinical studies demonstrate promising novel properties and attributes of our KL_4 Surfactant that potentially may be of benefit in addressing various respiratory diseases and disorders in broad patient populations. However, the clinical relevance of such attributes has not been adequately established and warrants further study.

In the clinical environment, our synthetic, peptide-containing surfactant has demonstrated attributes that are uniquely beneficial in the treatment of premature infants.

Our two Phase 3 clinical studies, SELECT and STAR, have demonstrated that Surfaxin is safe and efficacious when used for the prevention of RDS in premature infants. Data taken together from the SELECT and STAR studies 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 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.

We have also demonstrated that we can aerosolize our KL_4 Surfactant and have achieved the following important development objectives through research and feasibility studies:

- 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; and
- drug particle size believed to be suitable for deposition in the deep-lungs.

The initial formulation of our KL_4 Surfactant Technology is a liquid instillate, administered using the same method of administration as the currently available animal-derived surfactants; that is, intratracheally via an endotracheal tube. Our KL_4 Surfactant Technology also can be produced as a lyophilized formulation, our novel KL_4 Surfactant in a dry powder form that is then reconstituted just prior to administration. We have conducted several experiments that establish that our lyophilized KL_4 Surfactant retains the key characteristics of our liquid KL_4 Surfactant. We are currently conducting additional experiments and preclinical studies to fully characterize this new formulation and assess safety and efficacy. We believe that our lyophilized formulation may provide benefits in a clinical setting relative to liquid instillate surfactants, including:

- Lower viscosity, which may aid and/or improve the distribution of the surfactant through the lung and potentially reduce the frequency of transient peridosing events typically observed with the intratracheal administration of surfactants;

- Improve ease of administration and time of drug product preparation;

- Potentially eliminating continuous cold chain storage and refrigeration; and

- Potentially eliminating the need for warming.

Our Capillary Aerosolization Technology

In December 2005, we entered into a strategic alliance with Philip Morris USA Inc. (PMUSA) d/b/a/ Chrysalis Technologies (Chrysalis) through which we gained worldwide exclusive rights to our Capillary Aerosolization Technology. Following a restructuring in March 2008, we now hold exclusive worldwide licenses to the Capillary Aerosolization Technology for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions. In addition, we hold in the United States exclusive rights to the Capillary Aerosolization Technology for use with other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. *See* "Business – Business Operations – Strategic Alliances and Collaboration Agreements – Philip Morris USA Inc., d/b/a Chrysalis Technologies."

Our proprietary Capillary Aerosolization Technology has the potential to enable targeted upper respiratory, airway, or alveolar delivery of therapies for either local or system wide pulmonary applications and has been initially designed to produce high-quality, low-velocity aerosols for possible deep lung aerosol delivery. Aerosol is created by pumping KL_4 Surfactant drug formulation through a heated capillary wherein the excipient system is 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. With this technology, we believe that the particle size may be controlled and adjusted through device modifications and drug formulation changes. In addition, because our KL_4 Surfactant Technology produces a surfactant that is designed to functionally coat the entire surface area of the distal respiratory tree, we believe that our aerosolized KL_4 Surfactant may be used in combination with other drugs (small or large molecule) to enhance a desired therapeutic effect by improving efficiency and delivering the combined drug more effectively into the deep lung than would be possible without our KL_4 Surfactant.

In studies conducted with our initial prototype capillary aerosolization system, which consists of a base unit and disposable dose packets, patient interface and other components, to date, with our KL4 surfactant, we have generated an aerosol that:

- retains the surface-tension lowering properties of a functioning surfactant;

- retains the surfactant composition of our liquid KL4 Surfactant;

- has a drug particle size believed to be suitable for deposition in the deep-lungs; and

- is produced at rates that can deliver therapeutic dosages in a reasonable time period, with consistent reproducible output. Preclinical studies presented at PAS in 2007 comparing our Capillary Aerosolization Technology to commercially-available aerosol devices, indicated that the capillary aerosolization system generated as much as a 10-fold higher aerosol output rate compared with the other devices studied.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

The only surfactants available today are animal-derived, were introduced in the United States in the 1990's, and are approved only for RDS in premature infants. These products have not been approved for other respiratory indications. We believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of products targeted to treat a wide range of respiratory problems, including those for which there are currently few or no approved therapies. Our programs are:

Respiratory Distress Syndrome in Premature Infants (RDS)

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in Neonatal Intensive Care Units (NICUs). One of the most common respiratory problems is RDS. RDS is a condition in which premature infants are born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen. Premature infants born prior to 32 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. 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. RDS can result in long-term respiratory and developmental problems, including cerebral palsy and death.

Premature babies with RDS often require endotracheal intubation to administer one of the currently available animal-derived surfactants (usually within the first hours of birth), and to provide respiratory support via mechanical ventilation. Unfortunately, many infants relapse following initial therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, which increases their risk of developing further serious respiratory complications. Neonatologists generally try to avoid mechanically ventilating infants due to perceived risks associated with intubation, such as the risk of trauma and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits of invasive surfactant administration clearly outweigh the associated risks. For all but the very low birth weight infants with severe RDS, a common ventilatory support treatment alternative to intubation and mechanical ventilation is nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of infants do not adequately respond to nCPAP and require subsequent surfactant administration via intubation and mechanical ventilation. As neonatologists cannot ascertain in advance which patients will fail nCPAP, they are faced with a dilemma, because the outcome for those infants who fail nCPAP and receive delayed surfactant therapy is not as favorable as those who receive surfactant therapy in the first hours of life.

We estimate that approximately 360,000 low birth weight premature infants are born annually in the United States and at risk for RDS. Of this total, we estimate that approximately 130,000 are diagnosed with RDS and approximately 86,000 are treated with surfactant replacement therapy. We also estimate that approximately 240,000 infants receive early nCPAP (as an initial management strategy in lieu of intubation and mechanical ventilation), with approximately 30% failing therapy and experiencing potentially disadvantaged outcomes.

We believe that the neonatal medical community increasingly recognizes the potential benefits of (i) a synthetic, peptide-containing surfactant, such as Surfaxin and Surfaxin LS, and more importantly, (ii) a less-invasive method of delivering surfactant, such as Aerosurf, to treat premature infants suffering from respiratory disorders. While the current RDS market for surfactants is estimated to be approximately $75 million annually in the United States and $200 million annually worldwide, we believe that this market has been constrained by the lack of further development of animal-derived surfactants coupled with the risks associated with surfactant administration in its current form. We believe that Surfaxin, Surfaxin LS and Aerosurf have the potential, over time, to displace animal-derived products and support a greatly expanded RDS market.

Surfaxin for the Prevention of RDS in Premature Infants

Surfaxin is the first synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and mimics the surface-active properties of human surfactant. Surfaxin is a liquid instillate and is administered (usually within the first hours of birth) via endotracheal tube supported by mechanical ventilation for respiratory support. The FDA has established April 17, 2009 as its target action date to complete its review of our NDA and potentially approve Surfaxin. If approved, Surfaxin will provide neonatologist with an alternative SRT to the currently used animal derived products.

Our NDA for Surfaxin, which we filed in April 2004, is supported by a Phase 3 pivotal trial (SELECT) for the prevention of RDS in premature infants. 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 surfactant derived from cow lung 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.

Data from the SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS, death due to RDS, and the development of certain severe respiratory problems versus the primary comparator Exosurf. Although the Survanta reference arm was not the primary focus of comparison, significantly fewer infants treated with Surfaxin died due to RDS compared with infants treated with Survanta.

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 surfactant derived from pig lung and the leading surfactant used in Europe. The STAR trial demonstrated the overall safety and non-inferiority of Surfaxin compared to Curosurf.

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.

Important new analysis of our SELECT and STAR Phase 3 clinical studies reveals that premature infants with RDS who were extubated after treatment with surfactant and then subsequently required reintubation had a significantly higher rate of mortality than those infants who did not require reintubation. The data also indicate that premature infants treated with Surfaxin required less reintubation compared to those treated with Survanta and Curosurf. Although the data indicated that the Surfaxin-treated infants were observed to have a statistically significant lower incidence of invasive reintubation than those infants treated with comparator surfactants, the clinical relevance of this finding has not been adequately established and warrants further study.

On May 1, 2008, we received a third Approvable Letter for this NDA. As was the case with the previous approvable letters, which had focused primarily on the Chemistry, Manufacturing and Controls (CMC) section of our NDA, this Approvable Letter did not contain a requirement for additional clinical trials. To gain clarification of certain items identified in this Approvable Letter and prior to submitting a response to the FDA, we submitted an information package to the FDA and requested a meeting, which occurred by teleconference on June 18, 2008. On October 17, 2008, we submitted our Complete Response to this Approvable Letter. The FDA accepted our Complete Response and established April 17, 2009 as its target action date to complete its review of this NDA and potentially approve Surfaxin.

The May 2008 Approvable Letter included, among other things, requests (i) to further tighten or justify one acceptance criterion for the biological activity test that we previously had implemented for Surfaxin release and stability testing (Biological Activity Test), (ii) to further tighten or justify acceptance criteria for lipid drug substance impurities, (iii) to further tighten or justify two of the 21 physical and chemical drug product acceptance criteria that we had proposed in our October 2007 Complete Response to an April 2006 Approvable Letter, and (iv) to submit certain specified equipment and aseptic process-related validation reports.

Based on our assessment of the May 2008 Approvable Letter, consultation with our regulatory experts, and our June 2008 teleconference with the FDA, with the exception of two items, we believed that we could respond to the Approvable Letter relying on readily available data. With respect to the two remaining items, we agreed with the FDA to provide additional confirmatory data and related information as follows:

(i) Surfaxin Biological Activity Test

A few years ago, based on discussions with the FDA, we qualified and validated the Biological Activity Test as a quality control in accordance with current Good Manufacturing Practices (cGMP) and implemented it for Surfaxin release and stability testing. In addition, as agreed at a December 2006 clarification meeting with the FDA, we replicated previously conducted studies in an RDS animal model using the same dose level that was used in the Surfaxin Phase 3 clinical trials (the 2007 RDS Animal Study). We believe that the Biological Activity Test data and the 2007 RDS Animal Study results support the comparability of Surfaxin drug product used in our Surfaxin Phase 3 clinical trials to the Surfaxin drug product to be manufactured for commercial use. In addition, these data were used to propose final acceptance criteria for the Biological Activity Test and were provided to, and reviewed by, the FDA prior to the May 2008 Approvable Letter.

At the June 18, 2008 meeting with the FDA, to further support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product, we agreed to conduct an additional test with respect to the Biological Activity Test using the same dose level that was used in the Surfaxin Phase 3 clinical trials (which was a different dose level than we had previously qualified and validated for quality control testing). In addition, also using the same dose level that was used in the clinical trials, we conducted a side-by-side study using the same RDS animal model used in the 2007 RDS Animal Study.

We believe that the data generated supports determination of final acceptance criteria for the Biological Activity Test, the proposed shelf life for Surfaxin and further confirms the comparability of Surfaxin drug product used in our Surfaxin Phase 3 clinical trials to the Surfaxin drug product to be manufactured for commercial use.

(ii) Specifications for Lipid-Related Impurities in Surfaxin Active Pharmaceutical Ingredients

Surfaxin is comprised of four active pharmaceutical ingredients (APIs): our novel KL_4 peptide, a fatty acid and two phospholipids. The FDA indicated that our proposed specifications for lipid-related impurities in the two individual phospholipids must satisfy guidance issued by the International Conference of Harmonization (ICH). The ICH generally designates threshold limits for impurities present in an API and also provides guidance for justifying specifications that exceed the designated threshold limits.

After discussing with the FDA potentially justifying impurity levels for certain lipid-related impurities that exceeded the ICH designated threshold limits based upon their being present in the human lung at levels equal to or greater than those that exist in Surfaxin, we agreed to review the scientific literature to ascertain the levels of these lipid-related impurities specific to the neonatal lung. We also consulted with lipid-experts and our phospholipids suppliers to assess whether the lipid-related impurities in question could be reduced. As a result of these efforts, we were able to include in the Complete Response data and other information demonstrating that the two phospholipids can be produced with lipid-related impurities at levels that satisfy ICH guidelines.

Prior to receiving the May 2008 Approvable Letter, we believe that we had made significant progress towards gaining approval for Surfaxin. As of March 2008, we had submitted to the FDA 12-month stability data on our Surfaxin process validation batches and the FDA had completed a pre-approval inspection (PAI) of our manufacturing operations at Totowa, New Jersey, and thereafter issued an Establishment Inspection Report (EIR) indicating an approval recommendation. Also, notably, on April 30, 2008, as part of our NDA review, we had completed labeling discussions with the FDA and had agreed to a proposed form of Surfaxin package insert setting forth prescribing information, although the package insert will not be considered final until the FDA approves our NDA. We believe that we are on track to potentially gain approval for Surfaxin in April 2009, although there can be no assurance that the FDA will meet its target action date or that it will approve Surfaxin.

We believe that, after a period devoted to gaining hospital formulary acceptance, Surfaxin, if approved, has the potential to command a substantial market share in the United States.

Surfaxin LS™ – Lyophilized Surfaxin for RDS in Premature Infants

Surfaxin LS is our lyophilized formulation of Surfaxin, which is manufactured as a dry powder form and reconstituted as a liquid just prior to administration. We believe that Surfaxin LS has the potential to increase ease of administration by reducing the preparation time, as well as potentially eliminating the need for continuous cold chain storage and refrigeration in the NICU. In addition, we believe that Surfaxin LS may demonstrate characteristics that could provide other clinical benefits.

Following the potential approval of Surfaxin liquid instillate, in anticipation of filing an Investigational New Drug (IND) Application to gain regulatory approval for Surfaxin LS in the United States, we plan to request a pre-IND meeting with the FDA with a view to agreeing upon and potentially initiating a clinical trial with Surfaxin LS in 2010. Similarly, to gain regulatory approval for Surfaxin LS in Europe, we plan to request a scientific advice meeting with the EMEA with a view to agreeing upon and potentially initiating a clinical trial in 2010. If the two regulatory agencies require a similar clinical trial design, we anticipate conducting a single clinical trial to gain regulatory approval for Surfaxin LS in the United States and Europe.

In October 2004, we filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) for clearance to market in Europe Surfaxin for the prevention and rescue treatment of RDS in premature infants. In June 2006, after ongoing analysis of Surfaxin process validation batches that had been manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria, we determined that we could not resolve the related 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. As we now plan to focus our efforts on gaining approval for Surfaxin LS in Europe, we do not plan to refile the MAA for Surfaxin.

We believe that Surfaxin LS, if approved, has the potential over time to displace the animal-derived surfactants and potentially significantly increase the market opportunity for use of liquid instillate surfactants from the current estimate of approximately $200 million worldwide.

Aerosurf for RDS in Premature Infants

Aerosurf is our aerosolized KL_4 Surfactant that is administered through less-invasive means and is being developed to potentially obviate the need for intubation and conventional mechanical ventilation. We believe that Aerosurf, if approved, holds the promise to significantly expand the use of our KL_4 Surfactant in pediatric respiratory medicine by providing neonatologists with a means of delivering our KL_4 Surfactant and potentially avoiding the risks (including serious lung injury and other complications) associated with invasive endotracheal intubation and mechanical ventilation.

As a precursor to the initiation of our Aerosurf program, we completed and announced in 2005 the results of our first pilot Phase 2 clinical study of aerosolized KL_4 Surfactant 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 within 30 minutes of birth over a three hour duration. The study showed that it is feasible to deliver our aerosolized KL_4 Surfactant via nCPAP and that the treatment was generally safe and well tolerated.

Preclinical developmental studies using the RDS animal model were presented at the 2007 Annual *Hot Topics in Neonatology* meeting held in Washington, DC, and demonstrated that Aerosurf (using our Capillary Aerosolization Technology) improves lung function and reduces inflammatory markers associated with lung injury and chronic lung disease.

We estimate that approximately 360,000 low birth weight premature infants are born annually in the United States and at risk for RDS. As discussed above (*see* “Respiratory Distress Syndrome in Premature Infants (RDS)”), of this total, we estimate that approximately 130,000 are diagnosed with RDS and approximately 86,000 are treated with surfactant replacement therapy. We also estimate that approximately 240,000 infants receive early nCPAP and approximately 30% fail therapy and experience potentially disadvantaged outcomes. We believe that Aerosurf, which can be administered via nCPAP, potentially obviating the need for intubation and mechanical ventilation, represents a significant market opportunity and has the potential to significantly expand the use of surfactants worldwide.

We are currently developing Aerosurf using our Capillary Aerosolization Technology. *See* “Business – Proprietary Platform –Surfactant and Aerosol Technologies – Our Capillary Aerosolization Technology.” We originally expected to initiate our Phase 2 clinical program utilizing this novel capillary aerosolization system in 2008. However, as these activities require significant investments in research, engineering, device development and device manufacturing capabilities, we found it necessary to re-prioritize certain of our development priorities as we focused our efforts on gaining regulatory approval for Surfaxin while conserving our cash resources.
If Surfaxin is approved and our resources permit, we expect to accelerate investment in our Capillary Aerosolization Technology with a view to potentially finalizing our regulatory package and initiating a Phase 2 clinical program in late 2009. In that regard, we have met with and received guidance from the FDA with respect to the design of our proposed Phase 2 clinical program. We are currently conducting certain developmental and pre-clinical activities to support our regulatory package.

In addition, we have also engaged in development activities for the next-generation capillary aerosolization system for use in potential Phase 2/3 clinical trials for Aerosurf and, if approved, future commercial activities. For this phase of our program, prior to receipt of the May 2008 Approvable Letter, we worked with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, both in the United States and international markets. Since receipt of the May 2008 Approvable Letter, our engineering team has also continued to make progress in developing the next-generation capillary aerosolization systems and, resources permitting, plans to reengage with the engineering and design firm following the potential approval of Surfaxin.

We believe that Aerosurf is a highly promising program. With the knowledge that we gain from our development activities to treat premature infants with RDS, we plan to leverage our technology platform to potentially address several respiratory conditions affecting pediatric and adult patient populations. *See* "Business – Business Strategy" and "– Business Operations –Strategic Alliances and Collaboration Arrangements – Philip Morris USA Inc., d/b/a Chrysalis Technologies."

Bronchopulmonary Dysplasia (BPD)

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. BPD is diagnosed when premature infants require mechanical ventilation or supplemental oxygen either at the 28^{th} day of life or 36 weeks post-menstrual age. Premature babies are often born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen, resulting in RDS. These infants often require endotracheal intubation to administer one of the currently available animal-derived surfactants (usually within the first hours of birth), and to provide respiratory support via mechanical ventilation. Unfortunately, many infants relapse following initial therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, which increases their risk of developing BPD. We believe that treatment with repeated doses of our KL_4 Surfactant after the initial RDS treatment (on day one or two of life) may prevent BPD and improve the clinical outcome of these infants.

There are presently no approved drugs for the treatment of BPD. Infants diagnosed with BPD suffer from abnormal lung development and typically have a need for respiratory assistance, often for many months, as well as comprehensive continuing care potentially spanning years. It is estimated that the cost of treating an infant with BPD in the United States can approach $250,000 during the initial inpatient stay alone. We estimate that 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. The results of this trial suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD. The results of this study were published in *Pediatrics* in January 2009.

We 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 LS or Aerosurf for the prevention of BPD. We also may consider a strategic alliance and/or other collaborative arrangement prior to further developing our KL_4 Surfactant to address this disease. We currently expect to consider potential alternatives only after we have successfully gained FDA approval of Surfaxin for the prevention of RDS in premature infants.

Acute Respiratory Failure (ARF)

ARF occurs when lung tissue is significantly damaged, leading to an impairment in lung function and the need 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). We estimate that 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.

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Surfaxin for 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 stay in the NICU or pediatric intensive care unit (PICU) 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 compares Surfaxin to standard of care masked by a sham air control. Approximately 170 children (subject to sample size adjustment under the protocol) 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 is being conducted at approximately 35-40 sites 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. Following conclusion of the viral season in the Northern Hemisphere later in the first half of 2009, we plan to assess the status of patient enrollment in this trial (in accordance with the protocol) and determine at that time whether adjustments to our timeline, which is heavily dependent upon the virulence of the viral seasons, are required.

Because of the relative weight difference between RDS and ARF patient populations and volumetric dosing associated with our KL_4 Surfactant, children with ARF who are treated with Surfaxin in our Phase 2 clinical trial are expected to receive a dose volume that is approximately 5 times greater than the average dose volume administered to premature infants with RDS.

Cystic Fibrosis (CF)

CF is a life-threatening genetic disease affecting the respiratory and other body systems. CF is characterized by a genetic mutation that produces thick, viscous mucus that is difficult to clear from the airways of the lung and typically leads to life-threatening respiratory infections. Preclinical and exploratory clinical studies suggest that therapeutic surfactants may improve lung function by loosening mucus plugs and enhancing mucociliary clearance.

CF is the most common, life-threatening genetic disorder in the United States, occurring in approximately one in every 3,500 Caucasian live births. CF affects approximately 30,000 patients in the United States and nearly 70,000 worldwide. To date, treatment of pulmonary conditions in CF primarily includes antibiotics to address lung infection and airway clearance therapies to break down and remove mucus. Life expectancy for CF has more than doubled in the past 25 years to age 37, due to significant advances in research and care.

In September 2008, our aerosolized KL_4 Surfactant was selected for a Phase 2a clinical trial in patients with CF that is being conducted as an investigator-initiated study at The University of North Carolina and is funded primarily through a grant provided by the Cystic Fibrosis Foundation. The trial is designed as a double-blind, randomized study to evaluate whether our aerosolized KL_4 Surfactant is safe and well tolerated in patients with mild to moderate CF lung disease, and to assess the short-term effectiveness of our aerosolized KL_4 Surfactant. We anticipate the results from this trial in late 2009.

We believe that our novel synthetic, peptide-containing surfactant has unique attributes, including potentially nonimmunogenic, anti-inflammatory and anti-microbial properties, that when combined with a potential ability to enhance mucociliary clearance in CF lung disease, may advance the treatment of CF and improve treatment outcomes for these very ill patients. We plan on advancing this development program in collaboration with a potential strategic partner, although there can be no assurance that we will be successful in entering into such an arrangement.

Serious Respiratory Indications Associated with Inflammation of the Lungs

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

We are also evaluating the potential of developing our proprietary aerosolized KL_4 Surfactant Technology to address debilitating respiratory disorders, such as ALI, asthma, and COPD. As resources permit, we will consider investing in these indications through a proof-of-concept phase and, if successful, plan on advancing these programs in collaboration with potential strategic partners, although there can be no assurance that we will be successful in entering into such an arrangement. We believe that these investments could potentially address significant unmet medical needs and redefine respiratory medicine.

Acute Lung Injury (ALI)

ALI is associated with conditions that either directly or indirectly injure the air sacs of the lung. ALI is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer. Among the causes of ALI are complications typically associated with certain major surgeries, mechanical ventilator induced lung injury (often referred to as VILI), smoke inhalation, pneumonia and sepsis. There are a significant number of patients at risk in the United States for Acute Lung Injury annually and there are no currently-approved therapies.

We believe that our aerosolized KL_4 Surfactant may potentially be effective as a preventive measure to treat patients at risk for ALI. This prophylactic approach may reduce the number of patients requiring costly intensive care therapy, eliminate long periods of therapy and generate cost savings in the hospital setting.

Asthma

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the bronchial airway system occurs when the airway muscles tighten, while inflammation is a swelling of the airways usually due to an inflammatory reaction caused by an irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma – airway narrowing occurs with concomitant surfactant dysfunction in the airways of the deep lung that develops during an asthma attack. We believe that our proprietary aerosolized KL_4 Surfactant has the potential to relieve the narrowing in the airways associated with asthma.

Asthma may require life-long therapy to prevent or treat episodes. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available asthma medications include inhaled and oral steroids, bronchodilators and leukotriene antagonists. Bronchodilators alone cannot be used to control severe episodes or chronic, severe asthma. Oral steroids can cause serious side effects when used for prolonged periods and, thus, are typically limited to severe asthmatic episodes and chronic, severe asthma. We believe that our aerosolized KL_4 Surfactant may relieve airway obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

Chronic Obstructive Pulmonary Disease (COPD)

COPD is an incurable, chronic respiratory disorder that includes both emphysema and chronic bronchitis and is characterized by obstruction to airflow that interferes with normal breathing, inflammation, mucus plugs formation infection and disruption of the normal lung architecture.

We believe that our novel synthetic, peptide-containing surfactant has unique attributes, including potential anti-inflammatory and anti-microbial properties, that, when combined with a potential ability to enhance mucus clearance (*see* "Cystic Fibrosis (CF)", above) may be an effective treatment for COPD, potentially improving outcomes for these very ill patients. We plan on advancing this development program in collaboration with a potential strategic partner, although there can be no assurance that we will be successful in entering into such an arrangement.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are initially focused primarily on developing from our proprietary KL_4 Surfactant Technology and Capillary Aerosolization Technology a series of pipeline programs intended to support a significant pediatric franchise. 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. In connection with our evaluations, we modify and adapt our research and development plans from time to time and anticipate that we will continue to do so.

We also plan to invest opportunistically in KL_4 Surfactant Technology pipeline programs that will target adult and other indications, which we believe represent potentially significant market opportunities. We plan to initially develop these programs through a proof-of-concept phase and, if successful, thereafter seek worldwide strategic alliances or collaboration arrangements for development and/or commercialization. There can be no assurance that we will succeed in demonstrating proof of concept or entering into any such alliance, however.

To support our research and development activities, we have:

- a medical staff with expertise in pediatric and pulmonary medicine and extensive contacts in the neonatoal medical community;
- expertise in the design and implementation of pre-clinical experiments and studies to support drug development. We conduct certain development-related experiments and bench studies in-house and also engage professional research laboratories as well as academic and education centers to conduct animal studies and experiments requiring specialized equipment and expertise;
- expertise in the design, development and management of clinical trials. Our own expertise includes scientific, medical, statistical and trial management capabilities. We also rely on scientific advisory committees and other medical and consulting experts to assist in the design and ongoing monitoring of our clinical trials. We generally manage our own clinical trials operations and also will rely on contract research organizations (CROs) to support operations of our multi-center trials in certain countries. We anticipate using CROs to assist in our future clinical trials;
- data management and biostatistics expertise to analyze and report on our clinical trial data, supported by third-party technology systems and independent consultants;
- regulatory personnel with significant expertise in the FDA regulatory approval process. We also consult with independent FDA and international regulatory experts;
- medical affairs expertise. Our medical affairs team includes experienced medical science liaisons who provide scientific and medical education to the pediatric medical community, including at medical meetings and symposia, concerning our KL_4 Surfactant Technology and Capillary Aerosolization Technology and related scientific articles and publications;
- engineering expertise, to support development of our aerosolized KL_4 Surfactant. In addition to our own design engineering team, we plan to work with design engineers, medical device experts and other third-party collaborators to advance the development of our Capillary Aerosolization Technology;
- quality operations capabilities to assure compliance with applicable regulations;
- manufacturing operations capabilities to generate test articles for use in pre-clinical and clinical studies; and
- research, analytical and manufacturing facilities and capabilities, including our new analytical and development laboratories that support our drug and device development activities. We also rely on third party laboratories to support our ongoing efforts and provide certain laboratory services.

Research and development costs are charged to operations as incurred. During the years ended December 31, 2008, 2007 and 2006, we recorded research and development expenses of $26.6 million, $26.2 million and $23.7 million, respectively.

Manufacturing and Distribution

Manufacturing – Precision-Engineered Surfactant

Our KL_4 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, Avanti Polar Lipids, Inc. and Nippon Fine Chemical and its affiliate, Inabata America Corporation. Suppliers of our containers, closures and excipients used in our manufacturing process include 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, located in Totowa, New Jersey, consists of pharmaceutical manufacturing and development space that is designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP. *See* "Properties." These operations, which we acquired from our then-contract manufacturer in December 2005, are an integral part of our long-term manufacturing strategy for the continued development of our KL_4 Surfactant Technology, including life-cycle management of Surfaxin, new formulations development and formulation enhancements, and expansion of our aerosolized KL_4 Surfactant products, beginning with Aerosurf. Owning our own manufacturing operations has provided us with direct operational control and, we believe, potentially improved economics for the production of pre-clinical, clinical and potential commercial supply of our lead product, Surfaxin, and our other KL_4 Surfactant Technology pipeline products.

In April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. After a comprehensive formal investigation and implementation of a corrective action and preventative action (CAPA) plan, we completed manufacture of three new Surfaxin process validation batches in February 2007. In March 2008, we submitted to the FDA 12-month stability data on these new Surfaxin process validation batches. We believe that our success at 12 months validated our CAPA plan and demonstrated that our manufacturing problems are resolved. In October 2008, as part of our Complete Response to the May 2008 Approvable Letter, we included 18-month stability data on these new process validation lots. We believe stability data for these and subsequent lots continue to support at least a 12-month shelf life for Surfaxin.

Also in March 2008, the FDA completed a pre-approval inspection (PAI) of our Totowa facility and issued an Establishment Inspection Report (EIR) indicating an approval recommendation for our Surfaxin NDA. *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, this could potentially cause us to delay development or clinical programs or, following approval, product launch, or cause us to experience shortages of products inventories."

Our manufacturing strategy includes investing in our analytical and quality systems. In October 2007, we completed construction of a new analytical and development laboratory in our headquarters in Warrington, Pennsylvania and have consolidated at this location the analytical, quality and development activities previously located in Doylestown, Pennsylvania and Mountain View, California. The activities conducted in our new laboratory include release and stability testing of raw materials as well as clinical and, if approved, commercial drug product supply. We also perform development work with respect to our aerosolized KL_4 Surfactant and novel formulations of our KL_4 Surfactant Technology. The laboratory has expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics. In addition, in 2007, we built a microbiology laboratory at our manufacturing facility in Totowa, NJ to support production of our drug product candidates.

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, 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. As this early termination option could require us to move out of our Totowa facility as early as March 2011, we are developing a long-term manufacturing strategy that includes (i) potentially renegotiating our current lease to amend the termination and other provisions, (ii) building or acquiring additional manufacturing capabilities to support product development and, if approved, commercial production of our KL_4 Surfactant product candidates, and (iii) potentially using contract manufacturers.

We plan to have manufacturing capabilities, primarily at our Totowa manufacturing operations, to produce sufficient commercial supplies of Surfaxin, if approved, and to meet our anticipated pre-clinical, clinical, formulation development and, if approved, potential future commercial requirements of Surfaxin, Aerosurf and other KL_4 Surfactant product candidates. During the period of formulation development for our lyophilized KL_4 Surfactant, including Surfaxin LS, we expect to enter into arrangements with one or more contract manufacturing organizations.

Manufacturing –Aerosol Devices and Related Componentry

We are developing and will potentially commercialize our aerosolized KL_4 Surfactant to address a broad range of serious respiratory conditions, starting with Aerosurf for RDS in premature infants. *See* "Business – Business Operations – Strategic Alliances and Collaboration Arrangements – Philip Morris USA Inc., d/b/a Chrysalis Technologies."

To manufacture capillary aerosolization devices and related components for our Phase 2 Aerosurf 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 capillary aerosolization systems, including the aerosol-generating device, disposable dose delivery packets, which must be assembled in a clean room environment, and patient interface systems to administer our aerosolized KL_4 Surfactant. 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 assembled capillary 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 capillary aerosolization systems that we plan to use in our planned Phase 2 clinical trials. *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, this could potentially cause us to delay development or clinical programs or, following approval, product launch, or cause us to experience shortages of products inventories."

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 KL_4 Surfactant products 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.

Sales and Marketing

To prepare for the potential U.S. launch of Surfaxin for the prevention of RDS in premature infants, we plan to establish our own specialty pulmonary commercial organization that will initially specialize in the development of a significant pediatric franchise. We believe that this strategy will provide us direct control over our U.S. sales and marketing activities, permit us to establish a strong presence in neonatal and pediatric intensive care units nationwide, and potentially optimize the economics of our business. If, however, we were presented with an alternative approach, through a strategic alliance or other collaboration arrangement, that would achieve the foregoing, and provide appropriate financial consideration and operational capabilities, we would consider such a potential transaction.

Our commercial activities will initially focus on RDS in premature infants. We believe that Aerosurf, if approved, will provide the neonatal medical community with a portfolio of treatment options, all based on our proprietary synthetic, peptide-containing surfactant to address this serious respiratory disorder in an expanded number of treatment-eligible premature infants. Our commercial organization will focus on meeting the demands of this potentially expanding market for the treatment of RDS and potentially other serious and debilitating neonatal and pediatric indications, many of which represent significant unmet medical needs. *See* "Business – Surfactant Replacement Therapy for Respiratory Medicine – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS)."

To execute this strategy, we expect to incur expenses at an annual rate of approximately $20 - $25 million for sales, marketing and medical affairs capabilities. We have made limited investments pending the potential approval of Surfaxin. Our pre-approval preparations have included the hiring of certain experienced management personnel. We plan to hire our sales representatives only after we have received approval to market Surfaxin. For international markets, we plan to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications.

General and Administrative

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

Strategic Alliances and Collaboration Arrangements

Philip Morris USA Inc., d/b/a Chrysalis Technologies

In March 2008, we restructured our December 2005 Strategic Alliance Agreement (Original Alliance Agreement) with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility for the further development of the Capillary Aerosolization Technology, including finalizing design development for the initial prototype aerosolization device platform and disposable dose packets. In connection with the restructuring, we entered into an Amended and Restated License Agreement dated March 28, 2008 (U.S. License Agreement) with PMUSA to amend and restate the Original Alliance Agreement in the United States. As PMUSA assigned to Philip Morris Products S.A. (PMPSA) all rights in and to the Capillary Aerosolization Technology outside of the United States (International Rights), effective the same date, we entered into a License Agreement with PMPSA with respect to the International Rights (International License Agreement) on substantially the same terms and conditions as the U.S. License Agreement. We currently hold exclusive licenses to the Capillary Aerosolization Technology both in and outside of the United States for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, Exclusive Field). In addition, under the U.S. License Agreement, our license to use the Capillary Aerosolization Technology includes other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions.

In connection with the restructuring, Chrysalis completed a technology transfer, provided development support to us through June 30, 2008, and also paid us $4.5 million to support our future development activities, of which $2.0 million was paid upon execution of the license agreements in March 2008 and $2.5 million was paid upon completion of the technology transfer in June 2008. We are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field in the territories. In connection with exclusive undertakings of PMUSA and PMPSA not to exploit the Capillary Aerosolization Technology for all licensed uses, we are obligated to pay royalties on all product sales, including sales of aerosol devices and related components that are not based on the Capillary Aerosolization Technology; provided, however, that no royalties are payable to the extent that we exercise our right to terminate the license with respect to a specific indication. We also agreed in the future to pay minimum royalties, but are entitled to a reduction of future royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned in prior periods.

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of a broad portfolio of potential Surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Esteve will pay us a transfer price on sales of Surfaxin and other KL_4 Surfactant products. 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 territory. Esteve is obligated 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 territory. As part of a restructuring of this alliance in December 2004, we regained full commercialization rights to our KL_4 Surfactant Technology in portions of the original territory licensed to Esteve, including key European markets, Central America, and South America (Former Esteve Territories) and 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 strategic collaborations for the development and commercialization of certain of our KL_4 Surfactant products, including Surfaxin and Aerosurf, in the Former Esteve Territories.

Potential Alliances and Collaboration Arrangements

We intend to seek investments of additional capital and potentially enter into strategic alliances and collaboration arrangements for the development and commercialization of our KL_4 Surfactant product candidates. 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 there can be no assurance that we will enter into any specific alliances or transactions. *See* “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Financings Pursuant to Common Stock Offerings”

LICENSING, PATENTS AND OTHER PROPRIETARY RIGHTS AND REGULATORY DESIGNATIONS

We continue, to invest in maintaining and perfecting our potential competitive position through a number of means: (i) by protecting our exclusive rights in our KL_4 Surfactant Technology and Capillary Aerosolization Technology through patents and patent extensions, (ii) by seeking regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities such as new chemical entity designations and supplemental exclusivities, and (iii) through protecting our trade secrets and proprietary methodologies that support our manufacturing and analytical processes.

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 synthetic 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 (Scripps) 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, 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 No. 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 No. 5,748,891; U.S. Patent No. 6,013,764; U.S. Patent No. 6,120,795; and U.S. Patent No. 6,492,490 (along with certain corresponding issued and pending foreign counterparts).

All such patents, which include important KL_4 composition of matter claims and relevant European patents, expire on various dates beginning in November 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.

Capillary Aerosolization Technology Patents and Patent Rights

Under our license agreements with PMUSA and PMPSA, we hold exclusive licenses to the Capillary 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 2023, or, in some cases, possibly later. The license agreements provide for monitoring inventions and seeking patent protection for innovations related to both Capillary Aerosolization Technology and our surfactant technology. Our license rights extend to innovations to the Capillary Aerosolization Technology that are made under the license agreements. With these proprietary rights, we believe that our aerosolized KL_4 Surfactant can be developed to potentially address a broad range of serious respiratory conditions. *See* "Business – Business Operations – Strategic Alliances and Collaboration Agreements – Philip Morris USA Inc., d/b/a Chrysalis Technologies."

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 or they may expire 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."

Other Regulatory Designations

New Drug Product Exclusivity

KL_4 (sinapultide), our proprietary peptide that serves as the important base of our precision-engineered surfactant platform technology, including Surfaxin, is a new chemical entity. Upon approval, Surfaxin is expected to receive either five years or three years of marketing exclusivity depending on FDA's determination whether Surfaxin drug product qualifies for new chemical entity exclusivity or supplemental exclusivity, respectively.

Orphan Drug and Orphan Medicinal Product Designations

"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 FDA has granted Orphan Drug designation for Surfaxin as a treatment for RDS in premature infants. However, as our Surfaxin NDA is for the prevention, rather than treatment, of RDS, it is not certain whether the FDA will provide this benefit to Surfaxin. As we believe that prevention and treatment are identical in the context of neonatal RDS, we plan to request a meeting with the FDA following approval of Surfaxin, if approved, to clarify the application of this designation to Surfaxin. The FDA has also granted Orphan Drug designation to (i) Surfaxin for the prevention of BPD in premature infants, (ii) Surfaxin for the treatment of BPD in premature infants, (iii) Surfaxin for the treatment of Meconium Aspiration Syndrome (MAS), and (iv) our KL_4 Surfactant for the treatment of ARDS in adults.

Similarly, the Commission of the European Communities grants "Orphan Medicinal Product" designation, which provides for exclusive marketing rights for indications in Europe for 10 years (subject to revision after six years) following marketing approval by the EMEA. In addition, the designation would enables us to receive regulatory assistance in the further development process, and to access reduced regulatory fees throughout its marketing life.
has designated. We have received Orphan Medicinal Product designation for (i) Surfaxin for the prevention and treatment of RDS in premature infants (ii) Surfaxin for the treatment of MAS, and (ii) our KL_4 Surfactant for the treatment of ALI in adults (which in this circumstance encompasses ARDS).

Fast Track Designations

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.

The FDA has granted "Fast Track" designation for (i) Surfaxin for the treatment and prevention of BPD in premature infants, and (ii) our KL_4 Surfactant for the treatment of ARDS in adults.

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. The most commonly used of these approved surfactants are Curosurf, which is derived from a chemical extraction porcine (pig) lung, and Survanta, which is derived from a chemical extraction process of bovine (cow) lung. Curosurf is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta is marketed by the Abbott Nutritionals, Inc. Forest Laboratories, Inc., markets Infasurf®, a surfactant derived from calf lung surfactant extract in the United States. The only approved synthetic surfactant available in the United States was Exosurf; however, this product does not contain any surfactant proteins and the manufacturer, GlaxoSmithKline, plc., has discontinued marketing this product.

GOVERNMENT REGULATION

The development, manufacture, distribution, marketing and advertising 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. Gaining regulatory approval of a drug product candidate requires the expenditure of substantial resources over an extended period of time. As a result, larger companies with greater financial resources will likely have a competitive advantage over us.

Development Activities: To gain regulatory approval of our KL_4 Surfactant Technology pipeline products, we must demonstrate, through experiments, preclinical studies and clinical trials that each of our drug product candidates meets the safety and efficacy standards established by the FDA and other international regulatory authorities. In addition, we and our suppliers and contract manufacturers must demonstrate that all development-related laboratory, clinical and manufacturing practices comply with regulations of the FDA, other international regulators and local regulators. Regulations establish standards for such things as drug substances, materials and excipients; medical device components, subassemblies and device manufacture; drug manufacturing operations and facilities and analytical laboratories processes and environments; in each instance, in connection with research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion, and distribution of product candidates, on a product-by-product basis. *See* "Risk Factors – 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."

Pre-clinical Studies and Clinical Trials: Development testing generally begins with laboratory testing and experiments, as well as research studies using animal models to obtain preliminary information on a product's efficacy and to identify any safety issues. The results of these studies are compiled along with other information in an investigational new drug (IND) application, which is filed with the FDA. After resolving any questions raised by the FDA, which may involve additional testing and animal studies, clinical trials may begin. Regulatory agencies in other countries generally require a Clinical Trial Application (CTA) to be submitted and approved before each trial can commence in each country.

Clinical trials normally are conducted in three sequential phases and may take a number of years 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.

The conduct of clinical trials are subject to stringent medical and regulatory requirements. The time and expense required to establish clinical sites, provide training and materials, establish communications channels and monitor a trial over a long period of time is substantial. The conduct of clinical trials at institutions located around the world is subject to foreign regulatory requirements governing human clinical trials, which vary widely from country to country. Delays or terminations of clinical trials 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. Clinical trials are monitored by the regulatory agencies as well as medical advisory and standards boards, which could determine at any time to reevaluate, alter, suspend, or terminate a trial based upon accumulated data, including data concerning the occurrence of adverse health events during or related to the treatment of patients enrolled in the trial, and the regulator's or monitor's risk/benefit assessment with respect to patients enrolled in the trial. If they occur, such delays or suspensions could have a material impact on our KL_4 Surfactant Technology development programs. *See* "Risk Factors – Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes", and "– Our ongoing clinical trials may be delayed, or fail, which will harm our business."

Regulatory Review: The results of preclinical and clinical trials are submitted to the FDA in an NDA, with comparable filings submitted to other international regulators. After the initial submission, the FDA has a period of time in which it must determine if the NDA is complete. If an NDA is accepted for filing, following the FDA's review, the FDA may grant marketing approval, request additional information, or deny the application if it determines that the application does not provide an adequate basis for approval. If the FDA grants approval, the approval may be conditioned upon the conduct of postmarketing clinical trials or other studies to confirm the product's safety and efficacy for its intended use. Until the FDA has issued its approval, no marketing activities can be conducted in the United States. Similar regulations apply in other countries.

After an NDA is submitted, although the statutory period provided for the FDA's review is less than one year, dealing with questions or concerns of the agency and, taking into account the statutory timelines governing such communications, may result in review periods that can take several years. For example, the FDA has issued to us three approvable letters, indicating that our Surfaxin drug product may be approved if we satisfy certain conditions. Although in many cases applicants are required to consider additional clinical trials, which may have the effect of termination a development program, the approvable letters that we received did not require additional clinical trials. We were delayed, however, as we were required in certain instances to develop additional data to respond to the matters raised by the FDA.

Manufacturing Standards: The FDA and other international regulators establish standards and routinely inspect facilities and equipment, analytical and quality laboratories and processes used in the manufacturing and monitoring of products. Prior to granting approval of a drug product, the agency will conduct a pre-approval inspection of the manufacturing facilities, and the facilities of suppliers, to determine that the drug product is manufactured in accordance with cGMP regulations and product specifications. Following approval, the FDA will conduct periodic inspections. If, in connection with a facility inspection, the FDA determines that a manufacturer does not comply with cGMP, the FDA will issue an inspection report citing the potential violations and may seek a range of remedies, from administrative sanctions, including the suspension of our manufacturing operations, to seeking civil or criminal penalties. *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, this could potentially cause us to delay development or clinical programs or, following approval, product launch, or cause us to experience shortages of products inventories."

International Approvals: If we succeed in gaining regulatory approval to market our products in the United States, we will still need to apply for approval with other international regulators. Regulatory requirements and approval processes are similar in approach to that of the United States. With certain exceptions, where the approval of the FDA carries considerable weight, international regulators are not bound the findings of the FDA, such that there is a risk that foreign regulators will not accept a clinical trial design or may require additional data or other information not requested by the FDA. In Europe, there is a centralized procedure under which the EMEA will conduct the application review and recommend marketing approval to the European Commission, or not, for the sale of drug products in the EU countries.

Post-approval Regulation: Following the grant of marketing approval, the FDA regulates the marketing and promotion of drug products. Promotional claims are generally limited to the information provided in the product package insert for each drug product, which is negotiated with the FDA during the NDA review process. In addition, the FDA enforces regulations designed to guard against conflicts of interest, misleading advertising and improper compensation of prescribing physicians. The FDA will review, among other things, direct-to-consumer advertising, prescriber-directed advertising and promotional materials, sales representative communications to healthcare professionals, promotional programming and promotional activities on the Internet. The FDA will also monitor scientific and educational activities. If the FDA determines that a company has promoted a product for an unapproved use ("off-label"), or engaged in other violations, it may issue a regulatory letter and may require corrective advertising or other corrective communications to healthcare professionals. Enforcement actions may also potentially include product seizures, injunctions and civil or criminal penalties. The consequences of such an action and the related adverse publicity could have a material adverse effect on a developer's ability to market its drug and its business as a whole.

Following approval the FDA and other international regulators will continue to monitor data to assess the safety and efficacy of an approved drug. 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 a recall or withdrawal of the product from the market, as well as possible civil or criminal sanctions. Similar oversight is provided by international regulators.

Combination drug-device products. Combination drug products, such as our aerosolized KL_4 Surfactant, which consists of our proprietary KL_4 Surfactant administered through our novel capillary aerosolization systems, 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 regulatory authorities having different expertise and may involve more complicated and time-consuming regulatory coordination, approvals and clearances than a drug product alone. In the United States, our aerosolized KL_4 Surfactant combination drug-device product will be reviewed by the Center for Drug Evaluation and Research (CDER) of the FDA, with input from the division that approves medical devices. 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 strategic alliance 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 KL_4 Surfactant Technology and Capillary Aerosolization Technology"; " – Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes", "– Our ongoing clinical trials may be delayed, or fail, which will harm our business", "– If the FDA and foreign regulators do not approve our products, we will not be able to market our products," 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."

Certain of our product candidates may qualify for Fast Track and/or Orphan Drug designation. Fast Track designation 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. Orphan Drug designation is granted to pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States and provides certain advantages to the Orphan Drugs sponsors, 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 drugs. *See* "Risk Factors – Even though some of our product candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other product candidates that do not qualify for expedited review, and "Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Other Regulatory Designations."

EMPLOYEES

As of February 5, 2009, we have approximately 118 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". 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 prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you could lose all or part of your investment.

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 our products under development, including Surfaxin, we must receive regulatory approvals for each product. The FDA and foreign regulators, such as the EMEA, extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes (i) preclinical studies and clinical trials of each drug product candidate and active pharmaceutical ingredients to establish the safety and effectiveness of each product, and (ii) 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 data are generated by clinical trials, the FDA or foreign regulator may not accept or approve an NDA or MAA filed by a pharmaceutical or biotechnology company for such drug product. 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 filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. On May 1, 2008, the FDA issued a third Approvable Letter to us with respect to this NDA. On October 17, 2008, we filed our Complete Response to this Approvable Letter. The FDA has established April 17, 2009 as its target action date to complete its review of our NDA. The FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business. *See* also "Risk Factors – 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 prevent our commercializing this product in the United States and adversely impact our ability to commercialize this product elsewhere."

In October 2004, we filed an MAA with the EMEA for clearance to market in Europe Surfaxin for the prevention and rescue treatment of RDS in premature infants. In June 2006, after ongoing analysis of Surfaxin process validation batches that had been manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria, we determined that we could not resolve the related 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. As we now plan to focus our efforts on gaining approval for Surfaxin LS in Europe, we do not plan to refile the MAA for Surfaxin.

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 previously unidentified 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 secure 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 prevent our commercializing this product in the United States and adversely impact our ability to commercialize this product elsewhere.

Receipt of the May 2008 Approvable Letter delayed the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. On June 18, 2008, we held a telephonic meeting with the FDA to confirm our approach to responding to certain items identified in this Approvable Letter. We filed our Complete Response on October 17, 2008 and the FDA established April 17, 2009 as its target action date to complete its review of our NDA. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to secure 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 product candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other product candidates that do not qualify for expedited review.

The FDA has notified us that two of our intended indications of our KL_4 Surfactant Technology pipeline, 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 KL_4 Surfactant Technology pipeline may also qualify for Fast Track designation. 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 product 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, drug substances and materials suppliers and third-party contract manufacturers, will be able to:

- complete our pre-clinical and clinical trials of our KL_4 Surfactant product candidates with scientific results that are sufficient to support further development and 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 drug substances, medical device components and related services necessary to manufacture our KL_4 Surfactant product candidates, including Surfaxin, Surfaxin LS and Aerosurf;
- resolve to the FDA's satisfaction the matters identified in the May 2008 Approvable Letter for Surfaxin for the prevention of RDS in premature infants;
- provide for sufficient manufacturing capabilities, at our manufacturing operations in Totowa and with third-party contract manufacturers, to produce sufficient drug product, including Surfaxin, Surfaxin LS and capillary aerosolization systems to meet our pre-clinical and clinical development requirements;
- successfully implement a strategy for the manufacture of capillary 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 impact 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 complementary technologies;
- failure of a drug 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 KL_4 Surfactant 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 likely 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, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials, we may suffer significant setbacks in late-stage 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 KL_4 Surfactant Technology pipeline, including planned Phase 2 clinical trials with respect to Aerosurf for RDS in premature infants. 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.

Receipt of the May 2008 Approvable Letter has caused us to refocus our efforts and conserve our financial resources, which may subject us to unanticipated risks and uncertainties.

As a result of the May 2008 Approvable Letter and the delay with respect to the timing of potentially gaining approval for Surfaxin for the prevention of RDS in premature infants, we have adopted a strategy of focusing our efforts primarily on responding to the Approvable Letter and conserving our financial resources to potentially gain approval for Surfaxin in 2009. This caused us to reassess the level of investment and the pace of our research and development programs, including for Aerosurf, BPD, ARF and new formulations of our KL_4 Surfactant, including Surfaxin LS. Reductions in investment will cause us to experience delays in the progress of some of our programs. While we remain reasonably confident that we can achieve our goals, we will continue to reassess the business environment, the competitive landscape, our position within the biotechnology industry and the adequacy of our financial resources. As a consequence of our reassessment, at any time we may implement additional and potentially significant changes to our development plans and our operations as we seek to strengthen our financial and operational position. Such changes, if adopted, could prove to be disruptive and detrimental to our development programs. Moreover, consideration and planning of such strategic changes diverts management’s attention and other resources from day-to-day operations, which may subject us to further risks and uncertainties.

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 potentially cause us to delay development or clinical programs or, following approval, product launch, or 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 current good manufacturing procedures (cGMP) or other similar requirements that the FDA or foreign regulators establish. Our KL_4 Surfactant 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 manufacturing and completing all required release testing on a timely basis to meet demand;
- 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 drug substances and materials suppliers. Such problems 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 our manufacturing operations in Totowa, New Jersey in December 2005, we have manufactured our drug products. This is the only facility at which we produce our drug product. We currently do not have a back-up facility. Any interruption in manufacturing operations at this location could result in shortage of drug supply 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 do not have fully-redundant systems and equipment to respond promptly in the event of a significant loss at our manufacturing operations. We may under certain conditions be unable to produce Surfaxin and our other KL_4 Surfactant product candidates at the required volumes or to appropriate standards, if at all. If we are unable to successfully develop and maintain our manufacturing capabilities and at all times comply with cGMP, it will adversely affect our clinical development activities and, potentially, the sales of our products, if approved.

If we fail to maintain relationships with our manufacturers, assemblers and integrator of our capillary aerosolization systems, or if we fail to identify additional, qualified replacement manufacturers, assemblers and integrators to manufacture subcomponents and integrate our initial prototype capillary aerosolization system or anticipated later-development versions, 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 KL_4 Surfactant Technology, including Aerosurf, we currently plan to rely on third-party contract manufacturers to manufacture, assemble and integrate the subcomponents of our capillary aerosolization technology 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 drug 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 specification. In the United States, the device manufacturer must be registered with the FDA (in Europe, the device manufacture and critical suppliers must be registered with the appropriate regulatory authority) 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 our initial prototype capillary aerosolization system that we plan to use in Phase 2 clinical trials. However, as with many device development initiatives, there is a risk that these manufacturers and integrator may not be able to manufacture and integrate the subcomponents of our capillary aerosolization systems to our specified standards. In addition, we may not be able to identify qualified additional or replacement manufacturers and integrators to manufacture subcomponents and integrate our current prototype or next generation and later development versions of our capillary 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. If we do not successfully identify and enter into a contractual agreements with manufacturers, assemblers and integrators that have the required expertise, it will adversely affect our timeline for the development and, if approved, commercialization of Aerosurf.

If the parties we depend on for supplying our active drug substances, materials and excipient products as well as 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 manufacture drug product that meets appropriate content, quality and stability standards for use in clinical trials and, if approved, for commercial distribution. Our ability to manufacture depends upon receiving adequate supplies and relate services, which may be difficult or uneconomical to procure. 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, or manufacture materials and excipient products or our drug product, or capillary aerosolization systems subcomponent parts or integrated devices, to appropriate standards for use in clinical studies, (ii) comply with manufacturing specifications under any definitive manufacturing, supply or services agreements with us, or (iii) maintain relationships with our suppliers and service providers for a sufficient time to successfully produce and market our product candidates.

In some cases, we are dependent upon a single supplier to provide all of our requirements for one or more of our drug substances, materials and excipient products or one or more of our drug product device subcomponents, components and subassemblies. If we do not maintain important manufacturing and service relationships, we may be not be able to identify 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, upon approval, 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.

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. Following receipt of the May 2008 Approvable Letter and submission of our Complete Response in October 2008, the FDA established April 17, 2009 as its target action date to complete review of our NDA. Pending the potential approval of Surfaxin, we have made limited investments towards establishing our own specialty pulmonary commercial organization to execute the launch of Surfaxin in the United States. Our pre-approval preparations have included the hiring of certain experienced management personnel and investment in our medical affairs capabilities to provide for increased scientific and medical education activities.

Following the potential approval of Surfaxin we expect to incur expenses at an annual rate of approximately $20 - $25 million for sales, marketing and medical affairs capabilities. We plan to hire our sales representatives to market Surfaxin in the United States only after we have received approval to market Surfaxin. If, however, we were presented with an alternative approach, through a strategic alliance or other collaboration arrangement, that would achieve the foregoing, and provide appropriate financial consideration and operational capabilities, we would consider such a potential transaction.

For international markets, we plan to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications. 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.

We expect to rely primarily on our marketing and sales team to market Surfaxin, Surfaxin LS and Aerosurf, if approved, in the United States. 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 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. Even if we successfully develop and gain regulatory approval for our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

To date, we have generated revenues primarily from investments, research grants and collaboration 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, 2008, we have an accumulated deficit of approximately $327.4 million and we expect to continue to incur significant increasing operating losses over the next several years. As a result of our financial position as of December 31, 2008, the audit opinion we received from our independent auditors, which is included in our financial statements in this report, contained a notation related to our ability to continue as a going concern.

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 sufficient revenues to support continued commercialization of 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.

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 commercial requirements to meet changing customer demand is difficult to predict. If we are successful in gaining regulatory approval of our products, we may not be able to accurately forecast customer demand for our drug product candidates, including Surfaxin, or respond effectively to unanticipated increases in demand. This could have an adverse effect on our business. If we overestimate customer demand, or attempt 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 drug product candidates, we may never require the production capacity that we expect to have available.

Our preferred strategy with respect to development and marketing of our products, in many cases, is to enter into strategic partnerships and/or collaboration agreements 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, may depend upon strategic partnerships and collaboration arrangements 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 strategic partners' or collaborators' expertise and dedication of sufficient resources to develop and commercialize covered products. In addition, if any of our strategic partnerships and collaboration arrangements fail to timely meet their stated objectives, our success may depend upon our identifying and obtaining additional strategic partnerships and collaboration arrangements.

Our collaboration arrangement with Esteve for Surfaxin and certain other of our drug 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.

In March 2008, we restructured a strategic alliance with Philip Morris USA, Inc. (PMUSA) d/b/a/ Chrysalis and assumed full responsibility for development of the Capillary Aerosolization Technology, including finalizing design development for the initial prototype aerosolization device platform and disposable dose packets. We currently plan to rely on our own engineering expertise as well as design engineers, medical device experts and other third-party collaborators to advance the development of our Capillary Aerosolization Technology. If we are unable to identify design engineers and medical device experts to support our development efforts, including of the initial prototype aerosolization system and the next generation versions of the capillary aerosolization systems, it would impair our ability to commercialize or develop our aerosolized KL_4 Surfactant products, which would have a material adverse effect on our development activities and our business.

We may, in the future, grant to strategic partners and collaboration partners rights to license, develop and commercialize our products. Under such arrangements, our partners may control key decisions relating to the development and commercialization of the covered products. By granting such rights, 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 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 potential commercialization of Surfaxin and our other KL_4 Surfactant product candidates. *See* "Risk Factors – Our limited sales and marketing experience may restrict our success in commercializing our drug product candidates."

Under our restructured license agreement with PMUSA, we now have rights to develop the Capillary Aerosolization Technology, which will require us to build internal development capabilities or enter into future collaboration or other arrangements to gain the engineering expertise required to support our development activities.

Under our restructured arrangement with PMUSA, we now have rights to develop the Capillary Aerosolization Technology and have not had development support from PMUSA since June 30, 2008. Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not be able to complete the development of the initial prototype capillary aerosolization system, if at all, on a timely basis and such inability may delay or prevent initiation of our planned Phase 2 clinical trials;

- To continue the development of the Capillary Aerosolization Technology, we will require access to sophisticated engineering capabilities. To meet that requirement, we are developing our own internal medical device engineering expertise and plan to work with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries. There is no assurance that our efforts will be successful, however.

- If we are unable to successfully develop the initial prototype capillary aerosolization system and/or the next generation capillary aerosolization system, we may seek a potential strategic partner or third-party collaborator that has the necessary medical device development expertise to advance the development of our Capillary Aerosolization Technology. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop our aerosolized KL_4 Surfactant; and

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 drug product candidates.

We may rely on third-party distributors to distribute, 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 drug product candidates and could increase our costs of commercialization. Our dependence on distribution arrangements and marketing alliances to commercialize our drug product candidates will subject us to a number of risks, including:

- we may be required to relinquish important rights to our products or drug 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 drug 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 such 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 expense.

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 distributors and 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 approved, through one or more strategic partners. We currently have such an alliance with Esteve for distribution of our KL_4 Surfactant products in Andorra, Greece, Italy, Portugal and Spain. We have limited influence over the decisions made by Esteve or its sublicensees or the resources that they may devote to the marketing and distribution of Surfaxin products in their licensed territory, and Esteve or its 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 drug product candidates.

In light of the delayed timeline for the anticipated approval for Surfaxin, we will have to raise significant additional capital to continue our existing planned research and development activities. Moreover, such additional financing could result in equity dilution.

We anticipate the potential approval of Surfaxin in April 2009. Until such time as we are able to commercialize our Surfaxin drug product, if approved, and generate revenues, we will need substantial additional funding to conduct our ongoing research and product development activities. Our operating plans require that expenditures will only be committed if we achieve important development and regulatory milestones and have the necessary working capital resources. Accordingly, as we attempt to conserve our resources, we expect to experience delays in certain of our development programs. If we are unable to raise substantial additional funds through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we may be forced to further limit many, if not all, of our programs and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would develop ourselves. If we are unable to raise required capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations.

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 strategic alliances and collaborative ventures 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.

In addition, the continued credit crisis and related instability in the global financial system may have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve, including an inability to access the capital markets at a time when we would like or require, and an increased cost of capital. Except for the CEFFs with Kingsbridge, we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain, only available on unattractive terms or could 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 common stock on The Nasdaq Global Market. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could require the delay of new product development and clinical trial plans. *See also* "Risk Factors – Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders."

To meet our capital requirements, 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 there can be no assurance 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 from PharmaBio Development, Inc. (PharmaBio), a Strategic Investment Group of Quintiles Transnational Corp., 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 have financed certain acquisitions of personal property, machinery and equipment through an equipment financing facility with GE Business Financial Services Inc. under a Credit and Security Agreement that we executed with GE in May 2007. Our ability to draw under this facility expired in November 2008. In September 2008, we received a loan from the Commonwealth of Pennsylvania, Department of Community and Economic Development, Machinery and Equipment Loan Fund (MELF), in the amount of $500,000 to fund the purchase and installation of new machinery and equipment and the upgrade of existing machinery and equipment at our new analytical and development laboratory in Warrington, Pennsylvania. The loan is secured by the machinery and equipment and is payable in equal monthly installments over a period of seven years. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities."

If we require additional funds to support our capital programs, there can be no assurance that GE or any other lender will be willing to provide us funding or that we will be able to secure additional funding through the MELF or other program of the Commonwealth. 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.

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

We currently have three CEFFs with Kingsbridge, dated in April 2006 (the 2006 CEFF), May 2008 (the May 2008 CEFF) and December 2008 (the December 2008 CEFF). The issuance of shares of our common stock under the CEFFS and upon exercise of the related 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 CEFFs, we will issue shares of our common stock to Kingsbridge at a discount (6% to 10% for the 2006 CEFF, 6% to 12% for the May 2008 CEFF and 6% to 15% for the December 2008 CEFF) to the daily volume weighted average price of our common stock during the six or eight trading-day period, as appropriate, after we access a CEFF. Issuing shares at a discount will further dilute the interests of other stockholders. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Committed Equity Financing Facility".

To the extent that Kingsbridge sells to third parties the shares of our common stock that we sell to Kingsbridge under the CEFFs, 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 CEFFs, we will not be able to issue any portion of the shares potentially available for issuance under the CEFFs and therefore may not be able to use the CEFFs to fund our activities and the CEFFs could expire without having been utilized. Moreover, Kingsbridge has the right under certain circumstances to terminate the CEFFs, including in the event of a material adverse event. In addition, even if we meet all the conditions provided under the CEFFs, we are dependent upon the financial ability of Kingsbridge to perform its obligations and purchase shares of our common stock under the CEFFs. Any inability on our part to use at least one of the CEFFs or any failure by Kingsbridge to perform its obligations under the CEFFs 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, 2008, the price of our common stock ranged from $3.02 to $0.77. 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, 2008, the average daily trading volume in our common stock was approximately 972,387 shares and the average number of transactions per day was approximately 2,276. 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, if we fail to adhere to the strict listing criteria of The Nasdaq Global Market, our stock may be delisted. During approximately two weeks in the fourth quarter of 2008, our stock traded below $1.00 per share. If our stock had continued to trade below $1.00 per share for 30 consecutive days, it may have been subject to delisting under one of the regulatory listing requirements. However, in response to the ongoing financial crisis and markets disruptions, Nasdaq temporarily suspended this listing requirement through April 20, 2009. If our 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 Pink OTC Markets Inc.) or on the OTC Bulletin Board® of the Financial Industry Regulatory Authority, Inc. (FINRA). 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. We recently won dismissal of such an action, which was brought against us and certain of our former and current executive officers. Even if securities class actions that we may face in the future are ultimately determined to be meritless or unsuccessful, they involve substantial costs and a diversion of management attention and resources, which could 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 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. *See also*, “Risk Factors – Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders.” As of March 04, 2009, we had 102,551,774 shares of common stock issued and outstanding.

We have a universal shelf registration statement on Form S-3 (File No. 333-151654), filed with the SEC on June 13, 2008, for the proposed offering from time to time of up to $150 million of the Company’s securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing. We may issue securities pursuant to this shelf registration statement from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

In addition, as of December 31, 2008, there are approximately (i) 7.8 million shares of our common stock reserved for potential issuance upon the exercise of outstanding warrants, (ii) 18.5 million shares of our common stock reserved for issuance pursuant to our equity incentive plans, and (iii) 324,339 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, 2008, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 18 percent (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 (5%) 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 KL_4 Surfactant Technology and Capillary Aerosolization Technology.

Our technology platform is based on the scientific rationale of using our KL_4 Surfactant Technology and Capillary Aerosolization Technology to treat life-threatening respiratory disorders and to serve as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our drug product candidates and our drug-device combination products based on these technologies. Any material problems with our technology platforms 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 product 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 our proprietary rights;
- protect trade secrets; and
- operate without infringing the proprietary rights of others, both in the United States and in other countries.

The patent position of companies 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 secure rights to products or processes that 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 were to 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 for our KL_4 Surfactant Technology 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 KL_4 Surfactant products. These patents, which include important KL_4 composition of matter claims and relevant European patents, expire on various dates beginning in November 2009 and ending in 2017 or, in some cases, possibly later. For our aerosolized KL_4 Surfactant, we hold exclusive licenses in the United States and outside the United States to PMUSA's Capillary Aerosolization Technology for use with pulmonary surfactants for all respiratory diseases. Our exclusive license in the United States also extends to other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. The Capillary Aerosolization Technology patents expire on various dates beginning in May 2016 and ending in 2023, 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. In certain cases, 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, PMUSA and PMPSA. 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 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 take what we believe to be 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. We generally seek to enter into these types of agreements with consultants, advisors and research collaborators; however, 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. Such disputes often involve significant expense and yield unpredictable results. 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 with us for many years, have played integral roles in our progress and we believe that they 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.

In 2006, we entered into amended and new employment agreements without executives that generally include provisions such as a stated term and enhanced severance benefits in the event of a change of control. We also provide our key employees equity incentives in the form of stock and option grants. As of December 31, 2008, we had employment agreements with 14 officers that expire in May 2010. These agreements provide for automatic one-year renewal at the end of each term, unless otherwise terminated by either party. 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 drug 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 frequently aggressively seek 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, if approved, 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 locally-authorized 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 drug 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 drug product candidates;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our drug 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 increasingly challenge 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 our drugs, 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 drug products, 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 Restated Certificate of Incorporation, as amended, our Amended and Restated By-Laws, our 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 Amended and Restated By-Laws, 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 may be subject to claims asserting violations of securities laws. Even if such actions are found to be without merit, the potential impact of such actions, which generally seek unquantified damages and attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any future proceeding 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. 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 in certain cases 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 applied for and issued, the risk increases that our patents or patent applications for our SRT 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 to invalidate our patents, obtain substantial damages or 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 $0.9 million. 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.

In October 2007, we completed construction of a new analytical and development laboratory within our Warrington, Pennsylvania headquarters location. We consolidated into this new laboratory all analytical, quality and development activities that were previously 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 perform at this location development work with respect to our aerosolized KL_4 Surfactant and novel formulations of our product candidates.

We lease approximately 21,000 square feet of space for our manufacturing operations in Totowa, New Jersey, at an annual rent of $150,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. This lease expires in December 2014, subject to a right in the landlord, under certain conditions and upon two years' prior notice, to terminate the lease early. *See also*, "Business – Business Operations – Manufacturing and Distribution – Manufacturing – Precision-Engineered Surfactant."

Under a lease agreement that expired June 30, 2008, we leased 16,800 square feet at our research facility in Mountain View, California, at an annual rent of approximately $275,000. Under a lease that was terminated effective July 31, 2008, we leased 5,600 square feet of office and analytical laboratory space in Doylestown, Pennsylvania. The activities previously conducted at these locations have been relocated to our new laboratory in Warrington, Pennsylvania.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

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 our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

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 2008.

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 March 4, 2009, the number of stockholders of record of shares of our common stock was 158 and the number of beneficial owners of shares of our common stock was approximately 17,100. As of March 4, 2009, there were 102,551,774 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 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	$ 1.75	$ 2.63
Second Quarter 2008	$ 1.29	$ 3.02
Third Quarter 2008	$ 1.48	$ 2.19
Fourth Quarter 2008	$ 0.77	$ 2.00

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

Sales of Unregistered Securities

During the 12 months ended December 31, 2008, 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, 2008.

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, 2008, 2007 and 2006 and with respect to the Consolidated Balance Sheets as of December 31, 2008 and 2007 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, 2005 and 2004 and the balance sheet data as of December 31, 2006 and 2005 and 2004 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,				
	2008	**2007**	**2006**	**2005**	**2004**
Revenues from collaborative agreements	$ 4,600	$ -	$ -	$ 134	$ 1,209
Operating Expenses:					
Research and development	26,566	26,200	23,716	24,137	25,793
General and administrative	16,428	13,747	18,386	18,505	13,322
Restructuring charges	–	–	4,805	–	8,126
In-process research and development	–	–	–	16,787	–
Total expenses[(1)]	42,994	39,947	46,907	59,429	47,241
Operating loss	(38,394)	(39,947)	(46,907)	(59,295)	(46,032)
Other income / (expense)	(712)	(58)	574	391	(171)
Net loss	$ (39,106)	$ (40,005)	$ (46,333)	$ (58,904)	$ (46,203)
Net loss per common share - basic and diluted	$ (0.40)	$ (0.49)	$ (0.74)	$ (1.09)	$ (1.00)
Weighted average number of common shares outstanding	98,116	81,731	62,767	54,094	46,179

(1) Included in the net loss for the years ended December 31, 2008, 2007 and 2006 were non-cash charges for stock-based compensation for employees in accordance with SFAS No. 123(R) of $4.6 million, $5.2 million and $5.5 million, respectively.

Consolidated Balance Sheet Data:
(in thousands)

	For the year ended December 31,				
	2008	**2007**	**2006**	**2005**	**2004**
Cash and investments	$ 24,792	$ 53,007	$ 26,402	$ 50,908	$ 32,654
Working capital	15,551	43,149	18,999	33,860	24,519
Total assets	32,889	62,744	34,400	56,008	37,637
Long-term obligations, less current potion	12,090	13,494	12,110	3,562	7,583
Total stockholder’s equity	$ 10,933	$ 38,781	$ 14,322	$ 34,838	$ 21,097

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

INTRODUCTION

Management's discussion and analysis of financial condition and results of operations (MD&A) is provided as a supplement to the accompanying consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our Consolidated Financial Statements. *See* "Exhibits and Financial Statement Schedules." Our discussion is organized as follows:

- **Company Overview and Business Strategy**: this section provides a general description of our company and business plans.

- **Critical Accounting Policies:** this section contains a discussion of the accounting policies that we believe are important to our financial condition and results of operations and that require the exercise of judgment and use of estimates on the part of management in their application. In addition, all of our significant accounting policies, including the critical accounting policies and estimates, are discussed in Note 3 to the accompanying consolidated financial statements.

- **Results of Operations**: this section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations, including comparisons of the results for the years ended December 31, 2008, 2007 and 2006.

- **Liquidity and Capital Resources**: this section provides a discussion on our capital resources, future capital requirements, cash flows, committed equity financing facilities, historical financing transactions, outstanding debt arrangements and commitments.

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company developing Surfactant Replacement Therapies (SRT) to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel proprietary technology (KL_4 Surfactant Technology) produces a synthetic, peptide-containing surfactant (KL_4 Surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol generating technology (Capillary Aerosolization Technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL_4 Surfactant to the deep lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are currently focused on developing our lead products, Surfaxin®, Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. Surfaxin, our first product based on our novel KL_4 Surfactant Technology, if approved, will represent the first synthetic, peptide-containing surfactant for use in pediatric medicine. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of this NDA and potentially grant marketing approval.

Aerosurf is our proprietary KL_4 Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. With Aerosurf, if approved, it will be possible to administer surfactant into the deep lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a potentially significant increase in the use of SRT in pediatric medicine.

We plan over time to develop our KL_4 Surfactant Technology into a robust pipeline of products that will potentially address a variety of debilitating respiratory conditions in a range of patient populations, from premature infants to adults, that suffer from severe and debilitating respiratory conditions for which there currently are few or no approved therapies. Our programs include development of Surfaxin to potentially address Bronchopulmonary Dysplasia (BPD) in premature infants and Acute Respiratory Failure (ARF) in children, and conducting research and development with our KL_4 Surfactant to potentially address Cystic Fibrosis (CF), Acute Lung Injury (ALI), and other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

BUSINESS STRATEGY

We received an Approvable Letter from the FDA with respect to Surfaxin for the prevention of RDS in premature infants in May 2008. During the preparation of our Complete Response to the Approvable Letter and the FDA's ongoing review period, our business strategy has been to conserve our financial resources and rigorously manage limited investments in research and development activities. The FDA has assigned April 17, 2009 as its action target date to complete its review of our NDA and potentially approve Surfaxin. Following the potential approval of Surfaxin by the FDA:

- We plan over the near- and long-term to expand and accelerate our proprietary KL_4 Surfactant Technology initiatives with pipeline programs intended to apply our synthetic, peptide-containing surfactant to a broad range of respiratory conditions. It is our goal, within existing financial and other constraints, to develop our pipeline as broadly and as quickly as reasonably possible;

- Initially, we plan to focus our development and commercial efforts on the management of RDS in premature infants. We believe that the RDS market represents a significant opportunity from both a medical and a business perspective.

    - Currently, the only available therapies for the treatment of RDS, which were approved in the early 1990's, are surfactants derived from bovine (cow lung) and porcine (pig lung) sources. The current annual market for these surfactants is estimated to be approximately $75 million in the United States and $200 million worldwide. Currently, surfactants are administered using endotracheal intubation (the invasive insertion of a breathing tube down the trachea) and conventional mechanical ventilation, which risk further serious lung injury and complications. As the medical community is focused on managing RDS patients without employing such invasive techniques, only a subset of premature infants at risk for RDS annually are treated with these surfactants.

    - Surfaxin, the first synthetic, peptide-containing surfactant that, if approved, will represent an alternative therapy to the currently-approved, animal-derived surfactants. We also are developing a lyophilized formulation, Surfaxin LS™, which, among other things, may potentially simplify storage and distribution requirements and methods of administering surfactant. We have a development program that is focused on gaining regulatory approval for Surfaxin LS in the United States, Europe and throughout the world. We believe that, over time, Surfaxin and Surfaxin LS, if approved, have the potential to displace the use of the animal-derived surfactants.

    - Aerosurf will potentially provide the neonatal medical community with the possibility of treating premature infants at risk for RDS without the risks associated with endotracheal intubation and mechanical ventilation. We plan on making significant investments in the development, regulatory, clinical and manufacturing activities necessary to gain regulatory approval for Aerosurf in the United States and worldwide. We believe that Aerosurf, if approved, will allow for a potentially significant increase in the number of infants receiving surfactant therapy, who currently are not treated because the benefits of surfactant therapy are believed to be outweighed by the risks of invasive administration.

We believe that the combination of Surfaxin, Surfaxin LS and Aerosurf , if approved, have the potential, for the first time in years, to advance the treatment of RDS and make it possible for many more infants at risk for RDS to be treated with SRT. Our KL_4 Surfactant Technology also has the potential to address a range of other serious and debilitating neonatal and pediatric indications, many of which represent significant unmet medical needs, potentially redefining pediatric respiratory medicine.

- With our Surfaxin, Surfaxin LS and Aerosurf programs, we plan to build a fully-integrated pediatric franchise.

    - In the United States, we plan to establish our own specialty pulmonary commercial organization that will initially execute the launch of Surfaxin and specialize in neonatal and pediatric indications. To execute this strategy, we expect to incur expenses at an annual rate of approximately $20 - $25 million for sales, marketing and medical affairs capabilities. We believe that this strategy will provide us direct control over our U.S. sales and marketing activities, permit us to establish a strong presence in neonatal and pediatric intensive care units nationwide, and potentially optimize the economics of our business. If, however, we were presented with an alternative approach, through a strategic alliance or other collaboration arrangement, that would achieve the foregoing, and provide appropriate financial consideration and operational capabilities, we would consider such a potential transaction.

    - For international markets, we plan to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications;

- We also plan to invest opportunistically in KL_4 Surfactant Technology pipeline programs that will target adult and other indications we believe represent potentially significant market opportunities. We plan to initially develop these programs through a proof-of-concept phase and, if successful, thereafter seek worldwide strategic alliances or collaboration arrangements for development and/or commercialization. There can be no assurance that we will succeed in demonstrating proof-of-concept or entering into any such alliance, but if we are successful, we believe that these programs could address significant unmet medical needs and potentially redefine respiratory medicine;

- We have, and will continue, to invest in maintaining and perfecting our potential competitive position by protecting our exclusive rights in and to our KL_4 Surfactant Technology, pipeline products and Capillary Aerosolization Technology through patents, patent extensions, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities such as new chemical entity designations and supplemental exclusivities. We believe that our development programs may also provide opportunities for new patent filings, which may potentially significantly extend the benefits of exclusivity into the future;

- We will continue to invest in our quality systems and manufacturing capabilities, including at our manufacturing operations in Totowa, New Jersey and our analytical laboratories in Warrington, Pennsylvania. We plan to manufacture sufficient drug product to meet our anticipated pre-clinical, clinical, formulation development and, if approved, potential future commercial requirements of Surfaxin, Aerosurf and other KL_4 Surfactant product candidates. During the period of formulation development for our lyophilized KL_4 Surfactant, including Surfaxin LS, we expect to enter into arrangements with one or more contract manufacturing organizations. For our capillary aerosolization systems, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our manufacturing requirements. Our long-term manufacturing plans include potentially expanding our existing facilities or building or acquiring additional manufacturing facilities and capabilities to support the production and development of our proprietary KL_4 Surfactant Technology pipeline products; and

- We will need significant additional capital to execute our business strategy. We plan to seek infusions of capital from a variety of potential sources, including strategic alliances, equity financings, debt financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific alliances or transactions.

Our estimates of market size and business opportunities included in this Overview Section and elsewhere in this Annual Report on Form 10-K are based in part on our analysis of data derived from the following sources, among others: IMS Midas Data MAT, September 2008; Vermont Oxford Network Data, 2006; Annual Summary of Vital Statistics: 2006, Pediatrics, Martin et. al.; CDC National Vital Statistics, 2005; Management and Outcomes of Very Low Birth Weight, NEJM, 2008, Eichenwald, Stark; The Cystic Fibrosis Foundation; Discovery Labs Primary Market Research, 2007; as well as our analysis of the SELECT and STAR trials. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, economics and anticipated potential pharmaco-economic benefits of our drug products, if approved.

As of December 31, 2008, we had cash and marketable securities of $24.8 million and three Committed Equity Financing Facilities (CEFFs) under which we may, at our discretion (subject to certain conditions, including minimum purchase price and volume limitations), to raise in the aggregate up to $114.2 million capital to support our business plans, although the 2006 CEFF, which currently has available up to approximately $34.3 million, will expire in May 2009. (*See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources"). Our capital requirements will depend upon many factors, including the success of our product development and, if our products are approved, commercialization plans. However, there is no assurance that our research and development projects will be successful, that products developed (including Surfaxin for the prevention of RDS) will obtain regulatory approval in the United States, that any approved product, including Surfaxin, will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates, judgments 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 believe the following accounting policies are the most critical for an understanding of our financial condition and results of operations. For further discussion of our accounting policies *see* Note 3 - "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements.

Revenue recognition – research and development – strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. Funds received from these agreements are recorded as deferred revenue and are recognized over the performance period as specified in the agreements when all performance obligations are satisfied. Grant revenue is recorded upon receipt of funds.

Research and development expenses

Research and development costs consist primarily of expenses associated with our personnel, facilities, manufacturing operations, formulation development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

RESULTS OF OPERATIONS

The net loss for the years ended December 31, 2008, 2007 and 2006 was $39.1 million (or $0.40 per share), $40.0 million (or $0.49 per share), $46.3 million (or $0.74 per share), respectively. Included in the net loss for the years ended December 31, 2008, 2007 and 2006 were stock-based compensation expenses of $4.6 million (or $0.05 per share), $5.2 million (or $0.06 per share), and $5.5 million (or $0.09 per share), respectively. Additionally, for the year ended December 31, 2006, the net loss included a restructuring charge of $4.8 million (or $0.08 per share). *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – 2006 Restructuring Charge."

Revenue

In March 2008, we restructured our strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis) and assumed full responsibility for the development of the Capillary Aerosolization Technology. As part of the restructuring, Chrysalis completed a technology transfer of the Capillary Aerosolization Technology and paid us $4.5 million to support our further development activities. We currently hold exclusive licenses to the Capillary Aerosolization Technology both in and outside of the United States for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions. In addition, under the U.S. License Agreement, our license to use the Capillary Aerosolization Technology includes other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. We are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold. We also agreed in the future to pay minimum royalties, but are entitled to a reduction of future royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned in prior periods. *See* "Business – Business Operations – Strategic Alliances and Collaboration Arrangements." We did not earn revenue during the years ended December 31, 2007 and 2006.

We expect the FDA to complete its review of our NDA in April 2009. If Surfaxin is approved, we expect our first revenues from product sales in late-2009. As Surfaxin is a hospital-based indication, before we can make any sales at a particular hospital, we will need to comply with that hospital's formulary acceptance requirements, which can be a time-consuming process. As a result, we expect our product revenues to build slowly beginning in 2009 and 2010 and become more meaningful in 2011 and beyond.

We plan to focus our resources on developing a strong pediatric franchise in the United States. To develop a pediatric franchise in international markets, we plan to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications.

In addition, we plan to invest opportunistically in KL_4 Surfactant Technology pipeline programs that will target adult and other indications that we believe represent potentially significant market opportunities, including potentially CF and ALI. Initially, we plan to take these programs through a proof-of-concept phase, and, if successful, to seek potential worldwide strategic alliances or collaboration arrangements for development and/or commercialization of these pipeline programs. Although there can be no assurance that we will succeed in entering into any such arrangements, they would potentially include revenues from up-front and milestone payments, as well as financial support for research and development activities.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2008, 2007 and 2006 were $26.6 million, $26.2 million and $23.7 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands)	Year Ended December 31,		
Research and Development Expenses:	**2008**	**2007**	**2006**
Manufacturing development	$ 15,711	$ 14,774	$ 11,994
Development operations	7,567	7,310	8,351
Direct pre-clinical and clinical programs	3,288	4,116	3,371
Total Research and Development Expenses [(1)]	$ 26,566	$ 26,200	$ 23,716

(1) Included in research and development expenses for the year ended December 31, 2008, 2007 and 2006 is a charge of $1.5 million, $1.7 million and $1.6 million, respectively, associated with stock-based employee compensation in accordance with the provisions of FASB Statement of Financial Accounting Standards No. 123(R) (SFAS No. 123(R)).

For a description of the clinical programs included in research and development, *see* "Business – Surfactant Replacement Therapy for Respiratory Medicine."

Manufacturing Development

Manufacturing development includes: (i) manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and potential commercial drug supply for our KL_4 Surfactant products, in conformance with current good manufacturing practices (cGMP) (these costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities and analytical services, etc.); (ii) design and development for the manufacture of our novel capillary aerosolization systems, including an aerosol generating device, the disposable dose delivery packets and patient interface system necessary to administer Aerosurf for our anticipated Phase 2 clinical trials; (iii) pharmaceutical development activities, including development of a lyophilized formulation of our KL_4 Surfactant; (iv) activities to address issues identified in the May 2008 Approvable Letter; and (v) our comprehensive investigation and remediation of manufacturing issues following the occurrence of process validation stability failures in April 2006, as well as activities related to preparation of the Complete Response to the April 2006 Approvable Letter for Surfaxin that we received from FDA.

The increase in manufacturing development expenses in 2008 as compared to 2007 is primarily due to: (i) purchases of the active ingredients for the production of Surfaxin, and (ii) activities related to preparation of the Complete Response to the May 2008 Approvable Letter. The increase in manufacturing development expenses in 2007 as compared to 2006 is primarily due to: (i) activities related to preparation of the Complete Response (submitted in November 2007) to the April 2006 Approvable Letter; (ii) investments and enhancements to our quality assurance and analytical chemistry capabilities to support our manufacturing requirements; and (iii) device development activities for our Aerosurf program.

Manufacturing development expenses included charges of $0.8 million, $0.7 million and $0.5 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123(R) for the years ended December 31, 2008, 2007, and 2006, respectively.

Development Operations

Development operations includes medical, scientific, clinical, regulatory, data management and biostatistics activities for the execution of our product development programs. Development operations also includes medical affairs activities, including medical science liaisons, to provide scientific and medical education support in connection with our KL_4 Surfactant Technology pipeline programs, including the potential approval of Surfaxin in the United States. These costs include personnel, specialized consultants, outside services to support regulatory and data management activities, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The increase in development operations expenses in 2008 as compared to 2007 is primarily due to investment in our medical affairs capabilities in anticipation of the potential approval of Surfaxin in the United States. The decrease in development operations expenses in 2007 as compared to 2006 is primarily due to staff reductions that were implemented following receipt of the April 2006 Approvable Letter and the occurrence of Surfaxin process validation batch stability failures in April 2006. (*See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – 2006 Restructuring Charge").

Development operations expenses included charges of $0.7 million, $0.9 million and $1.1 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123(R) for the years ended December 31, 2008, 2007, and 2006, respectively.

Direct Pre-Clinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) pre-clinical activities, including toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, clinical drug supply and related external costs such as contract research consultant fees and expenses; and (iii) activities related to preparation of the Complete Responses (submitted in November 2007 and October 2008, respectively) to the April 2006 Approvable Letter and the May 2008 Approvable Letter.

Direct pre-clinical and clinical programs expenses in 2008 and 2007 included: (i) costs associated with preparation of the Complete Responses to the May 2008 Approvable Letter and the April 2006 Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF; and (iii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for RDS in premature infants. The decrease in expenses in 2008 as compared to 2007 is primarily due to our efforts to conserve financial resources by limiting our investment in research and development programs while we focus on potentially gaining regulatory approval for Surfaxin in the United States.

Direct pre-clinical and clinical programs expenses in 2006 were primarily associated with: (i) regulatory activities related to our efforts to gain regulatory approval for Surfaxin in the United States, (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 our Aerosurf program. The increase in expenses in 2007 as compared to 2006 is primarily due to expenses in 2007 associated with pre-clinical activities for the development of Aerosurf and the ongoing Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF.

We will continue to conserve financial resources by limiting our investment in research and development programs while we focus on potentially gaining regulatory approval for Surfaxin in the United States. Following the potential approval of Surfaxin, if resources permit, we plan to accelerate investment in our KL_4 Surfactant pipeline programs and expect our research and development expenses to increase in 2009, primarily associated with development and clinical activities for our lyophilized KL_4 Surfactant and our Aerosurf program.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs of executive management, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

General and administrative expenses for the years ended December 31, 2008, 2007, and 2006 were $16.4 million, $13.7 million, and $18.4 million, respectively. General and administrative expenses included charges of $3.1 million, $3.5 million and $3.8 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123(R) for the years ended December 31, 2008, 2007, and 2006, respectively.

A significant component of general and administrative expenses is pre-launch commercial activities associated with preparing for the potential approval and commercial launch of Surfaxin, including hiring of certain experienced management personnel to develop and implement our commercialization strategy, investments to support our presence at key neonatal medical meetings, market research activities, and other preparatory sales and marketing activities.

Expenses for pre-launch commercial activities were $5.0 million, $2.2 million and $5.9 million for the years ended December 31, 2008, 2007 and 2006, respectively. The expenses in 2008 were incurred in anticipation of the potential approval and commercial launch of Surfaxin in May 2008. Following receipt of the May 2008 Approvable Letter, we scaled back our pre-launch commercial activities while we focused on preparation of the Complete Response to the May 2008 Approvable Letter and potentially gaining approval of Surfaxin. The expenses in 2006 were incurred in anticipation of the potential approval and commercial launch of Surfaxin in April 2006. Following receipt of the April 2006 approvable Letter and the April 2006 Surfaxin process validation batch stability failures, we restructured the company, reduced our commercial workforce and terminated certain pre-launch commercial programs. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – 2006 Restructuring Charge."

Following the potential approval of Surfaxin, we plan to establish our own specialty pulmonary commercial organization in the United States that will initially execute the launch of Surfaxin and, with the introduction of Surfaxin LS and Aerosurf, if approved, focus on developing a significant pediatric franchise. We believe that this strategy will provide us direct control over our U.S. sales and marketing activities, permit us to establish a strong presence in neonatal and pediatric intensive care units nationwide, and potentially optimize the economics of our business. Our pre-approval preparations have included the hiring of certain experienced management personnel. We plan to hire our sales representatives only after we have received approval to market Surfaxin. If, however, we were presented with an alternative approach, through a strategic alliance or other collaboration arrangement, that would achieve the foregoing, and provide appropriate financial consideration and operational capabilities, we would consider such a potential transaction.

We believe our existing general and administrative resources, including legal, finance, business development, information technologies, human resources and general management capabilities, are sufficient to support the potential launch of Surfaxin in the United States. We anticipate making additional investments in the future to enhance these capabilities as and when required to meet the needs of our research and development programs and commercial organization.

We also plan additional investments to sustain and perfect our potential competitive position by maintaining our existing patent portfolio, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities, and by investing in new patents, patent extensions, new trademarks, and regulatory exclusivity designations, when available. *See* "Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

2006 Restructuring Charge

In April 2006, after ongoing analysis of Surfaxin process validation batches that had been manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria, we reduced staff levels and reorganized management to lower our cost structure and re-align our operations with changed business priorities. The reduction in workforce totaled 52 employees, including three senior executives, and represented approximately 33% of our workforce, primarily from our commercial group. All affected employees were eligible for severance payments and continuation of benefits.

We incurred a restructuring charge of $4.8 million in the second quarter 2006 associated with the staff reductions and discontinued commercial programs, which was accounted for in accordance with Statement of Financial Accounting Standards No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* (SFAS No. 146) 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 associated with discontinued commercial programs. As of December 31, 2008, payments totaling $4.5 million had been made related to these items and $0.3 million were unpaid and included in accounts payable and accrued expenses.

Other Income / (Expense)

Other income / (expenses), net was ($0.7) million, ($0.1) million and $0.6 million for the years ended December 31, 2008, 2007 and 2006, respectively, as summarized in the chart below:

(Dollars in thousands)	Year Ended December 31, 2008	2007	2006
Interest income	$ 842	$ 1,794	$ 1,495
Interest expense	(1,614)	(1,906)	(1,453)
Other income / (expense)	60	54	532
Other income / (expense), net	$ (712)	$ (58)	$ 574

Interest income consists of interest earned on our cash and marketable securities. The decrease in interest income in 2008 is due to a general decline in market interest rates and in our average cash and marketable securities balance. The increase in interest income in 2007 is due to an increase in our average cash and marketable securities balance.

Interest expense consists of interest accrued on the outstanding balance of our loan with PharmaBio Development Inc. ("PharmaBio"), the strategic investment group of Quintiles Transnational Corp., and under our equipment financing facilities. In addition, interest expense includes $0.5 million, $0.5 million and $0.1 million for the years ended December 31, 2008, 2007 and 2006, respectively, associated with the amortization of deferred financing costs for warrants issued to PharmaBio in October 2006 as consideration for a restructuring of our loan in 2006. The decrease in interest expense in 2008 is due to a decline in the variable interest rate on our PharmaBio loan, which is equal to the U.S. prime rate. The increase in interest expense in 2007 is due to a full year of amortization of deferred financing costs for warrants issued in October 2006 in connection with the restructuring of our loan with PharmaBio.

Other income / (expenses) primarily consists of proceeds from the sale of our Commonwealth of Pennsylvania research and development tax credits ($0.1 million, $0.2 million, and $0.6 million in 2008, 2007 and 2006, respectively). The decrease in proceeds from the sale of these tax credits is due to more credits being available for sale in 2006 as compared to 2007 and 2008.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our CEFFs, capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through a combination of these sources, as well as sales revenue from our product candidates, beginning with Surfaxin for RDS, if approved.

Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. We are currently focused on developing our lead KL_4 Surfactant products, Surfaxin, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting pediatric populations. The FDA has established April 17, 2009 as its target action date to complete its review of our Surfaxin NDA. (*See* "Business – Surfactant Replacement Therapy (SRT) for Respiratory Medicine.") As of December 31, 2008, we had $24.8 million in cash and marketable securities and three CEFFs, under which we may potentially raise (subject to certain conditions, including stock price and volume limitations) up to an aggregate of $114.2 million, although the 2006 CEFF, which currently has available up to approximately $34.3 million, will expire in May 2009. (*See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities"). However, there can be no assurance that our research and development projects will be successful, that products developed (including Surfaxin) will obtain necessary regulatory approval, that any approved product will be commercially viable, that any of the three CEFFs will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

To meet our capital requirements, 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 there can be no assurance that we will take any further specific actions or enter into any transactions. *See* "Risk Factors – In light of the delayed timeline for the anticipated approval for Surfaxin, we will have to raise significant additional capital to continue our existing planned research and development activities. Moreover, such additional financing could result in equity dilution, " "–The terms of our indebtedness may impair our ability to conduct our business," " – Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders," and "– 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."

Cash Flows

We had cash, cash equivalents and marketable securities of $24.8 million, $53.0 million and $26.4 million as of December 31, 2008, 2007 and 2006, respectively. The decrease of $28.2 million in 2008 is primarily due to $35.4 million used in operating activities, capital expenditures and principal payments on equipment loans, partially offset by proceeds of $6.3 million from financings under our CEFFs and $0.9 million from our equipment financing facilities. The increase of $26.6 million in 2007 is primarily due to $35.6 million used in operating activities and capital expenditures and principal payments on equipment loans, partially offset by: (i) $51.7 million of net proceeds from two registered direct offerings of our common stock; (ii) $7.0 million of proceeds from financings under our CEFFs; and (iii) $2.9 million from our equipment financing facilities.

Cash Flows Used in Operating Activities

Cash flows used in operating activities were $31.8 million, $29.4 million and $39.8 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Our cash flows used in operating activities are a result of our net operating losses adjusted for non-cash expenses associated with stock-based compensation, depreciation and changes in our accounts payable and accrued liabilities. (For a discussion on our net operating losses, *see* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations"). Cash flows from operating activities in 2008 also include $4.5 million received from Chrysalis to support development of our capillary aerosolization technology.

Cash Flows Used in Investing Activities

Cash flows used in investing activities include capital expenditures of $0.6 million, $3.8 million and $1.4 million for the years ended December 31, 2008, 2007 and 2006, respectively. Capital expenditures were primarily for laboratory and manufacturing equipment to support analytical, quality, manufacturing and development activities. In 2007, we completed construction of a new analytical and development laboratory in our headquarters in Warrington, Pennsylvania, for a total cost of approximately $3.0 million and consolidated at this location the analytical, quality and development activities previously located in Doylestown, Pennsylvania and Mountain View, California. The laboratory has expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics. The leases for our Doylestown, Pennsylvania and Mountain View, California locations either expired or were terminated. (*See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations") In 2006, capital expenditures primarily consisted of laboratory equipment for our analytical activities.

Cash flows from / (used in) investing activities also include cash used to purchase short-term marketable securities and cash received from the sale and/or maturity of short-term marketable securities. When assessing our cash position and managing our liquidity and capital resources, we do not consider cash flows between cash and marketable securities to be meaningful. Cash used to purchase marketable securities is subject to an investment policy that is approved by the Board of Directors and that provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs. As of December 31, 2008, available-for-sale marketable securities consist of United States treasury notes, certificates of deposits, and high-quality commercial paper with a maturity of greater than three months.

Cash Flows from Financing Activities

Cash flows from financing activities were $4.2 million, $59.7 million and $17.4 million for the years ended December 31, 2008, 2007 and 2006, respectively, as summarized in the chart below:

(In millions)	Year Ended December 31,		
	2008	**2007**	**2006**
Financings under CEFFs	$ 6.3	$ 7.0	$ 7.4
Financings pursuant to common stock offerings	–	51.7	9.5
Proceeds from equipment financing facilities	0.9	2.9	1.5
Proceeds from exercise of stock options and warrants	–	–	0.7
Debt service payments	(3.0)	(1.9)	(1.7)
Cash flows from financing activities, net	$ 4.2	$ 59.7	$ 17.4

The following sections provide a more detailed discussion of our cash flows from financing activities.

Committed Equity Financing Facilities (CEFFs)

We have entered into four CEFFs with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in which Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allow us, at our discretion, to raise capital at the time and in amounts deemed suitable to us, to support our business plans. We are not obligated to utilize any of the funds available under the CEFFs. Should we choose to utilize any of the CEFFs, our ability to access the funds available under the CEFFs is subject to certain conditions, including stock price and volume limitations.

CEFF Terms and Conditions

As of December 31, 2008, we had three CEFFs available for financings: the CEFF dated December 12, 2008 (December 2008 CEFF), the CEFF dated May 22, 2008 (May 2008 CEFF), and the CEFF dated April 17, 2006 (2006 CEFF). The following table sets forth an overview of the "draw down" requirements and availability under each CEFF.

(in millions, except per share data and trading days)	Expiration	Minimum Price to Initiate Draw Down[1]	Minimum VWAP for Daily Pricing[2]	# of Trading Days In Each Draw Down[2]	Amount per Contract		Potential Availability at December 31, 2008	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
2006 CEFF	May 12, 2009	$ 2.00	85% of prior day closing price	8	11.7	$ 50.0	4.5	$ 34.3
May 2008 CEFF	June 18, 2011	$ 1.15	90% of prior day closing price	8	19.3	$ 60.0	15.6	$ 54.9
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60	90% of prior day closing price	6	15.0	$ 25.0	15.0	$ 25.0

(1) To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day of the draw down must be at least equal to the minimum price set forth above.

(2) If on any trading day, the daily volume-weighted average of our common stock (VWAP) is less than the minimum VWAP set forth above, no shares are purchased on that trading day and the aggregate amount of the draw down is reduced for each such day 1/8th (1/6th for the Dec. 2008 CEFF) of the amount that we originally designated. Unless we and Kingsbridge agree 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.

Each draw down is limited in amount as follows:

- 2006 CEFF – 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;
- May 2008 CEFF – the lesser of 3.0 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or $10 million; and
- December 2008 CEFF – the lesser of 1.5 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or $3 million.

The purchase price of shares sold to Kingsbridge under the CEFFs is at a discount to the VWAP (as defined in the applicable agreement) for each of the trading days following our initiation of a “draw down” under the CEFF, as follows:

Daily VWAP	% of VWAP	(Applicable Discount)
2006 CEFF		
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)%
May 2008 CEFF		
Greater than $7.25 per share	94%	(6)%
Less than or equal to $7.25 but greater than $3.85 per share	92%	(8)%
Less than or equal to $3.85 but greater than $1.75 per share	90%	(10)%
Less than or equal to $1.75 but greater than or equal to $1.15 per share	88%	(12)%
December 2008 CEFF		
Greater than $7.25 per share	94%	(6)%
Less than or equal to $7.25 but greater than $3.85 per share	92%	(8)%
Less than or equal to $3.85 but greater than $1.75 per share	90%	(10)%
Less than or equal to $1.75 but greater than or equal to $1.10 per share	88%	(12)%
Less than or equal to $1.10 but greater than or equal to $.60	85%	(15)%

In addition, Kingsbridge may terminate the CEFFs under certain circumstances, including if a material adverse event relating to our business continues for 10 trading days after notice of the material adverse event.

CEFF Financings

The financings that we have completed under the 2006 CEFF are:

In May 2006, we completed a financing under the 2006 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 2006 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 2006 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 2006 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 2006 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.

In September 2008, we completed a financing under the 2006 CEFF, resulting in proceeds of $1.3 million from the issuance of 676,360 shares of our common stock at an average price per share, after the applicable discount, of $1.85.

Also, 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, 2008, the Class C Investor Warrant had not been exercised.

The financings that we have completed under the May 2008 CEFF are:

On July 11, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.6 million from the issuance of 1,104,850 shares of our common stock at an average price per share, after the applicable discount, of $1.41.

On July 31, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.5 million from the issuance of 991,537 shares of our common stock at an average price per share, after the applicable discount, of $1.51.

On October 17, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.3 million from the issuance of 913,827 shares of our common stock at an average price per share, after the applicable discount, of $1.44.

On November 20, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $0.3 million from the issuance of 221,202 shares of our common stock at an average price per share, after the applicable discount, of $1.13.

On January 2, 2009, we completed a financing that was initiated in 2008 under the May 2008 CEFF, resulting in proceeds of $0.5 million from the issuance of 478,783 shares of our common stock at an average price per share, after the applicable discount, of $1.04.

Subsequently, in 2009, we initiated and completed additional financings under the May 2008 CEFF, as follows:

On January 16, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of $0.4 million from the issuance of 419,065 shares of our common stock at an average price per share, after the applicable discount, of $1.04.

On February 18, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.0 million from the issuance of 857,356 shares of our common stock at an average price per share, after the applicable discount, of $1.17.

Also, on May 22, 2008, in connection with the May 2008 CEFF, we issued a warrant to Kingsbridge to purchase up to 825,000 shares of our common stock at an exercise price of $2.506 per share, which expires in November 2013 and is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.1 million. As of December 31, 2008, the Investor Warrant had not been exercised.

No financings have been completed under the Dec 2008 CEFF. On December 22, 2008, in connection with the December 2008 CEFF, we issued a warrant to Kingsbridge to purchase up to 675,000 shares of our common stock at an exercise price of $1.5132 per share, which is fully exercisable for a five-year period beginning May 12, 2009. The warrant is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $1.0 million.

In connection with a CEFF that we entered in 2004, which has since been terminated, 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 expires in January 2010 and is exercisable, 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.

Financings Pursuant to Common Stock Offerings

Historically, we have, and expect to continue to, fund our business operations through various sources, including financings pursuant to common stock offerings.

2008 Universal Shelf

In June 2008, we filed a universal shelf registration statement on Form S-3 (No. 333-151654) (2008 Universal Shelf) with the SEC for the proposed offering from time to time of up to $150 million of our securities. Under the 2008 Universal Shelf, we have the flexibility to react to market opportunities as they arise and will be able to issue and sell a variety of securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at that time. We have not completed any financings under the June 2008 Universal Shelf.

October 2005 Universal Shelf

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 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.

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.

The October 2005 universal shelf registration statement expired in December 2008 and is no longer available for future financings.

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.

Debt

Historically, we have, and expect to continue to, fund our business operations through various sources, including debt arrangements such as credit facilities and equipment financing facilities.

Loan with PharmaBio

PharmaBio extended to us a secured, revolving credit facility of $8.5 to $10 million in 2001. Under an October 2006 restructuring, the outstanding principal balance of $8.5 million is due and payable on April 30, 2010 and, since October 1, 2006, interest has accrued at the prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, is 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, 2008, the outstanding balance under the loan was $10.1 million ($8.5 million of pre-restructured principal and $1.6 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

For the years ended December 31, 2008, 2007 and 2006, we incurred interest expense associated with the PharmaBio loan of $0.5 million, $0.7 million and $0.8 million, respectively. The decrease in interest expense in 2008 was due to a decline in the prime rate during 2008 from 7.25% to 3.25%. In addition, for the years ended December 31, 2008, 2007 and 2006, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to PharmaBio in October 2006 of $0.5 million, $0.5 million and $0.1 million, respectively.

Equipment Financing Facilities

We have, and expect to continue to, fund our purchases of capital expenditures through the use of equipment financing facilities. The outstanding principal balance of our equipment financing facilities as of December 31, 2008 and 2007 was as follows:

(in thousands)	As of December 31, 2008	2007
GE Business Financial Services, Inc.		
Short-term	$ 2,385	$ 2,625
Long-term	664	2,991
Total	3,049	5,616
Pennsylvania Machinery and Equipment Loan		
Short-term	57	–
Long-term	428	–
Total	485	–
Total Short-term	2,442	2,625
Total Long-term	1,092	2,991
Total	$ 3,534	$ 5,616

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide us a $12.5 million facility (Facility) to fund our capital programs. Upon execution of the Credit Agreement, we simultaneously drew down approximately $4.0 million to prepay our then-outstanding indebtedness under a previous facility. Over the term of the Facility, we received $7.2 million, $4.0 million of which was associated with the prepayment of a previous facility and $2.3 million of which was associated with construction and equipment for a new analytical and development laboratory built in our Warrington, Pennsylvania corporate headquarters in 2007. The right to draw under this Facility expired on November 30, 2008.

Proceeds received under the Facility were $0.4 million and $6.8 million for the years ended December 31, 2008 and 2007, respectively. Advances to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our previous facility is amortized over a period of 27 months. Interest on each advance accrues at a fixed rate per annum equal to one-month LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances are 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%.

Principal payments under the Facility were $3.0 million and $1.2 million for the years ended December 31, 2008 and 2007, respectively. Interest expense under the Facility was $0.5 million and $0.7 million for the years ended December 31, 2008 and 2007, respectively.

Our obligations under the Facility are secured by a security interest in (i) the financed property and equipment, and (ii) all of our intellectual property (Supplemental Collateral), subject to limited exceptions set forth in the Loan Agreement. The Supplemental Collateral will be released on the earlier to occur of (a) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (b) 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, GE and PharmaBio entered into an Intercreditor Agreement under which GE 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).

In September 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department) and executed a Promissory Note, pursuant to which the Department made a loan to us from the Machinery and Equipment Loan Fund in the amount of $500,000 (MELF Loan) to fund the purchase and installation of new machinery and equipment and the upgrade of existing machinery and equipment at our new analytical and development laboratory in Warrington, Pennsylvania. Principal and interest on the MELF Loan is payable in equal monthly installments over a period of seven years. Interest on the principal amount will accrue at a fixed rate per annum equal to 5.0%. We may prepay the MELF Loan at any time without penalty. Principal payments under the facility were $15,000 for the year ended December 31, 2008.

In addition to customary terms and conditions, the MELF Agreement provides that we must meet certain criteria regarding retention and creation of new jobs within a three-year period. In the event that we fail to comply with this requirement, the interest rate on the Promissory Note, except in limited circumstances, will be adjusted to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Contractual Obligations

Payments due under contractual debt obligations at December 31, 2008, including principal and interest, are as follows:

(in thousands)	**2009**	**2010**	**2011**	**2012**	**2013**	**Thereafter**	**Total**
Loan payable[(1)]	$ –	$ 10,573	$ –	$ –	$ –	$ –	$ 10,573
Equipment loan obligations[(1)]	2,946	722	152	85	85	155	4,145
Operating lease obligations	1,143	1,135	1,151	1,168	320	150	5,067
Total	$ 4,089	$ 12,430	$ 1,303	$ 1,253	$ 405	$ 305	$ 19,785

(1) *See*: *"Management's Discussion and Analysis of Financial Condition and Operations - Liquidity and Capital Resources - Debt."* For the purposes of this table, we have assumed that the PharmaBio Loan will accrue interest through maturity at an average rate that is equal to the current prime rate of 3.25%.

Operating Lease Agreements

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

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 an additional three years through February 2013 with additional payments of $3.0 million over the 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 manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires in December 2014, subject to a right of the landlord 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. The total aggregate payments over the term of the lease are $1.4 million. For a discussion of our manufacturing strategy, *see* "Business – Business Operations – Manufacturing and Distribution."

Our lease for 5,600 square feet of office and analytical laboratory space in Doylestown, Pennsylvania was terminated effective July 31, 2008 and all activities at this location have been consolidated into our new laboratory space in Warrington, Pennsylvania. Our lease for 16,800 square feet of office and laboratory space at our facility in Mountain View, California, expired without renewal or extension on June 30, 2008. In December 2007, we consolidated these activities into our new laboratory space in Warrington, Pennsylvania.

Rent expense under all of these leases for the years ended December 31, 2008, 2007, and 2006 was $1.2 million, $1.5 million and $1,4 million respectively.

Contractual Obligations

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

(a) Evaluation of disclosure controls and procedures

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

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

(b) Management's Report on 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, 2008. 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, 2008.

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 11, 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.

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, 2008, 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, 2008, 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, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008 of Discovery Laboratories, Inc. and subsidiary and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

March 11, 2009
Philadelphia, Pennsylvania

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 2008 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" 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 11, 2009

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 11, 2009
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer (Principal Accounting Officer)	March 11, 2009
/s/ W. Thomas Amick	W. Thomas Amick Chairman of the Board of Directors	March 11, 2009
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	March 11, 2009
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 11, 2009
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 11, 2009
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 11, 2009

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 Laboratories, Inc. (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.	Incorporated by reference to Exhibit 3.5 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as filed with the SEC on March 14, 2008.
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.
4.9	Warrant Agreement dated May 22, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on May 28, 2008.
4.10	Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
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	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.
10.3*	Restated 1993 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.4*	1995 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.5*	Amended and Restated 1998 Stock Incentive Plan of Discovery (amended as of May 13, 2005).	Incorporated by reference to Exhibit 4.1 to Discovery's Registration Statement on Form S-8, as filed with the SEC on August 23, 2005 (File No. 333-116268).
10.6*	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*	Discovery's 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.

Exhibit No.	Description	Method of Filing
10.8*	Form of 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.
10.9*	Form of Stock Issuance Agreement, dated as of October 30, 2007, between the Discovery 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.
10.10+	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	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.
10.13	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.
10.14	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.
10.15*	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*	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
10.17*	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.
10.18*	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

Exhibit No.	Description	Method of Filing
10.19*	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.
10.20*	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
10.21*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert Segal, M.D.	Incorporated by reference to Exhibit 10.4 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.22*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert Segal, M.D., F.A.C.P., and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 15, 2008
10.23*	Amendment dated December 12, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert Segal, M.D., F.A.C.P., and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 18, 2008
10.24*	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
10.25*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Charles F. Katzer and Discovery	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 15, 2008
10.26*	Amendment dated December 12, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Charles F. Katzer 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 December 18, 2008
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 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.

Exhibit No.	Description	Method of Filing
10.29	First Amendment to Credit and Security Agreement (the "Amendment") dated May 30, 2008, between the Company and GE Business Financial Services Inc. (formerly 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 June 2, 2008.
10.30	Master Services Agreement between Discovery and Kloehn Ltd., dated as of August 10, 2007	Incorporated by reference to Exhibit 10.35 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as filed with the SEC on March 14, 2008.
10.31 +	Amended and Restate License Agreement by and between Discovery and Philip Morris USA Inc., d/b/a/ Chrysalis Technologies, dated March 28, 2008	Incorporated by reference to Exhibit 10.4 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.32 +	License Agreement by and between and Philip Morris Products S.A., dated March 28, 2008	Incorporated by reference to Exhibit 10.5 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.33	Common Stock Purchase Agreement, dated as of May 22, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 27, 2008.
10.34	Registration Rights Agreement, dated as of December 12, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 27, 2008.
10.35	Common Stock Purchase Agreement, dated December 12, 2008, 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 December 15, 2008.
10.36	Registration Rights Agreement, dated as of December 12, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
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.

Exhibit No.	Description	Method of Filing
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.

* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report pursuant to Item 15(b) of Form 10-K

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

CONTENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. (the "Company") as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. 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 financial position of the Company at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses and has generated negative cash flows from operations since inception and expects such results to continue for the foreseeable future. In addition, there is uncertainty as to the Company's ability to raise additional capital sufficient to meet its obligations on a timely basis. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The December 31, 2008 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 3 to the consolidated financial statements, the Company changed its method of accounting for uncertainties in income taxes in 2007.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

March11, 2009
Philadelphia, PA

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,744	$ 36,929
Available-for-sale marketable securities	2,048	16,078
Prepaid expenses and other current assets	625	611
Total current assets	25,417	53,618
Property and equipment, net	5,965	7,069
Restricted cash	600	600
Deferred financing costs and other assets	907	1,457
Total assets	$ 32,889	$ 62,744
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,111	$ 758
Accrued expenses	5,313	7,086
Equipment loan, current portion	2,442	2,625
Total current liabilities	9,866	10,469
Loan payable, including accrued interest	10,128	9,633
Equipment loan, non-current portion	1,092	2,991
Other liabilities	870	870
Total liabilities	21,956	23,963
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized;101,588 and 96,953 shares issued, 101,275 and 96,640 shares outstanding at December 31, 2008 and December 31, 2007, respectively	102	97
Additional paid-in capital	341,293	329,999
Accumulated deficit	(327,409)	(288,303)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Accumulated other comprehensive income	1	42
Total stockholders' equity	10,933	38,781
Total Liabilities & Stockholders’ Equity	$ 32,889	$ 62,744

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,		
	2008	**2007**	**2006**
Revenues:	$ 4,600	$ –	$ –
Expenses:			
Research & development	26,566	26,200	23,716
General & administrative	16,428	13,747	18,386
Restructuring charges	–	–	4,805
Total expenses	42,994	39,947	46,907
Operating loss	(38,394)	(39,947)	(46,907)
Other income / (expense):			
Interest and other income	902	2,029	2,072
Interest and other expense	(1,614)	(2,087)	(1,498)
Other income / (expense), net	(712)	(58)	574
Net loss	$ (39,106)	$ (40,005)	$ (46,333)
Net loss per common share - basic and diluted	$ (0.40)	$ (0.49)	$ (0.74)
Weighted average number of common shares outstanding - basic and diluted	98,116	81,731	62,767

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2008, 2007 and 2006
(In thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Deficit	Treasury Stock Shares	Treasury Stock Amount	Accumulated Other Compre-hensive Income / (Loss)	Total
Balance – January 1, 2006	**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, Oct. 2006 loan restructuring	–	–	1,940	–	–	–	–	–	1,940
Issuance of common stock, Nov. 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**
Comprehensive loss:									
Net loss	–	–	–	–	(39,106)	–	–	–	(39,106)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	(41)	(41)
Total comprehensive loss	–	–	–	–	–	–	–	–	(39,147)
Issuance of common stock, stock option exercises	18	–	21	–	–	–	–	–	21
Issuance of common stock, 401(k) employer match	231	–	380	–	–	–	–	–	380
Issuance of common stock, CEFF financings	4,387	5	6,266	–	–	–	–	–	6,271
Stock-based compensation expense	–	–	4,627	–	–	–	–	–	4,627
Balance – December 31, 2008	**101,589**	**$ 102**	**$ 341,293**	**$ –**	**$ (327,409)**	**(313)**	**$ (3,054)**	**$ 1**	**$ 10,933**

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2008	**2007**	**2006**
Cash flow from operating activities:			
Net loss	$ (39,106)	$ (40,005)	$ (46,333)
Adjustments to reconcile net loss to net cash used In operating activities:			
Depreciation and amortization	2,215	2,062	1,058
Stock–based compensation and 401(k) match	5,007	5,613	6,326
Loss on disposal of property and equipment	110	18	48
Changes in:			
Prepaid expenses and other current assets	(56)	(89)	(5)
Accounts payable	1,353	(871)	(48)
Accrued expenses	(1,773)	2,762	(1,539)
Other assets	3	35	(17)
Other liabilities	495	1,080	684
Net cash used in operating activities	(31,752)	(29,395)	(39,826)
Cash flow from investing activities:			
Purchase of property and equipment	(632)	(3,765)	(1,448)
Purchase of marketable securities	(25,765)	(38,355)	(4,621)
Proceeds from sale or maturity of marketable securities	39,754	22,319	7,884
Net cash provided by / (used in) investing activities	13,357	(19,801)	1,815
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	6,292	58,809	17,549
Proceeds from equipment loans	896	2,862	1,509
Principal payments under equipment loan obligations	(2,978)	(1,948)	(1,692)
Net cash provided by financing activities	4,210	59,723	17,366
Net (decrease) / increase in cash and cash equivalents	(14,185)	10,527	(20,645)
Cash and cash equivalents – beginning of year	36,929	26,402	47,047
Cash and cash equivalents – end of year	$ 22,744	$ 36,929	$ 26,402
Supplementary disclosure of cash flows information:			
Interest paid	$ 529	$ 676	$ 1,102
Non-cash transactions:			
Unrealized gain / (loss) on marketable securities	(41)	42	2
Exchange of equipment loan obligation	–	3,968	–
Charge for warrant issuance related to loan restructuring	–	–	1,940

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company developing Surfactant Replacement Therapies (SRT) to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel proprietary technology (KL_4 Surfactant Technology) produces a synthetic, peptide-containing surfactant (KL_4 Surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol generating technology (Capillary Aerosolization Technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL_4 Surfactant to the deep lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are currently focused on developing our lead products, Surfaxin®, Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. Surfaxin, our first product based on our novel KL_4 Surfactant Technology, if approved, will represent the first synthetic, peptide-containing surfactant for use in pediatric medicine. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of this NDA and potentially grant marketing approval.

Aerosurf is our proprietary KL_4 Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. With Aerosurf, if approved, it will be possible to administer surfactant into the deep lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a potentially significant increase in the use of SRT in pediatric medicine.

We plan over time to develop our KL_4 Surfactant Technology into a robust pipeline of products that will potentially address a variety of debilitating respiratory conditions in a range of patient populations, from premature infants to adults, that suffer from severe and debilitating respiratory conditions for which there currently are few or no approved therapies. Our programs include development of Surfaxin to potentially address Bronchopulmonary Dysplasia (BPD) in premature infants and Acute Respiratory Failure (ARF) in children, and conducting research and development with our KL_4 Surfactant to potentially address Cystic Fibrosis (CF), Acute Lung Injury (ALI), and other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

Note 2 - Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our CEFFs, capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through a combination of these sources, as well as sales revenue from our product candidates, beginning with Surfaxin for RDS, if approved.

Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. We are currently focused on developing our lead KL_4 Surfactant products, Surfaxin, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting pediatric populations. The FDA has established April 17, 2009 as its target action date to complete its review of our Surfaxin NDA. (*See* "Business – Surfactant Replacement Therapy (SRT) for Respiratory Medicine.") As of December 31, 2008, we had $24.8 million in cash and marketable securities and three CEFFs, under which we may potentially raise (subject to certain conditions, including stock price and volume limitations) up to an aggregate of $114.2 million, although the 2006 CEFF, which currently has available up to approximately $34.3 million, will expire in May 2009. (*See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities"). However, there can be no assurance that our research and development projects will be successful, that products developed (including Surfaxin) will obtain necessary regulatory approval, that any approved product will be commercially viable, that any of the three CEFFs will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Note 3 – Summary of Significant Accounting Policies

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.

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.

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 United States treasury notes and high-quality commercial paper. Marketable securities are carried at fair market value, based on quoted market prices for these or similar instruments. 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 that provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs.

Fair Value of Financial Instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities and restricted cash. The fair values of the Company's cash equivalents and marketable securities are based on quoted market prices. The carrying amount of cash equivalents and marketable securities is equal to their respective fair values at December 31, 2008 and December 31, 2007.

Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which the Company believes approximates fair value.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

Long-lived assets

Our long-lived assets, primarily consisting of equipment, are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's undiscounted cash flows are less than its carrying value, an impairment is recorded and the asset is written down to its estimated value. No impairment was recorded during the years ended December 31, 2008, 2007 and 2006, as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Revenue recognition – research and development – strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. Funds received from these agreements are recorded as deferred revenue and are recognized over the performance period as specified in the agreements when all performance obligations are satisfied. Grant revenue is recorded upon receipt of funds.

Research and development

Research and development costs consist primarily of expenses associated with our personnel, facilities, manufacturing operations, formulation development, research, clinical, regulatory and other preclinical and clinical activities. Research and development costs are charged to operations as incurred.

Stock-based compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), "*Share-Based Payment,*" using the modified-prospective-transition method. *See* Note 11 – Stock Options and Stock-Based Employee Compensation, for a detailed description of our recognition of stock-based compensation expense.

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.

Comprehensive Loss

Comprehensive loss consists of net loss plus the changes in unrealized gains and losses on available-for-sale securities. Comprehensive loss for the years ended December 31, 2008, 2007 and 2006 are as follows:

(in thousands)	December 31,		
	2008	2007	2006
Net loss	$ (39,106)	$ (40,005)	$ (46,333)
Change in unrealized (losses)/gains on marketable securities	(41)	42	2
Comprehensive loss	$ (39,147)	$ (39,963)	$ 46,331)

Net loss per common share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding for the periods. For the years ended December 31, 2008, 2007 and 2006, 25.1 million, 20.3 million and 17.3 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants and vesting of restricted stock awards. Due to our net loss, these potentially issuable shares were not included in the calculation of diluted net loss per share as the effect would be anti-dilutive, therefore basic and dilutive net loss per share are the same.

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 surfactant replacement therapies 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.

Recent Accounting Pronouncements

In December 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-1, “Accounting for Collaborative Arrangements”(EITF Issue No. 07-1). EITF 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. We adopted EITF Issue No. 07-1 on January 1, 2009; it did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), *"Business Combinations"* (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 noncontrolling 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 to business combinations for which the acquisition date is on or after January 1, 2009. The adoption of SFAS 141(R) had no immediate impact, however it will have an impact on the accounting for any potential future business combinations.

Note 4 – Fair Value Measurements

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards No. 157 (*Fair Value Measurements)*(SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements.

Under SFAS 157, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of SFAS 157 did not have a material effect on our results of operations and financial condition.

Fair Value on a Recurring Basis

Assets measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations as of December 31, 2008.

	Fair Value	Fair value measurement using		
(in thousands)	December 31, 2008	Level 1	Level 2	Level 3
Money markets (1)	$ 19,994	$ 19,994	$ –	$ –
U.S. treasury notes	4,096	4,096	–	–
Certificate of deposit	600	600	–	–
Total	$ 24,690	$ 24,690	$ –	$ –

(1) Dreyfus Treasury & Agency Cash Management Fund.

Note 5 – Marketable Securities

The following is a summary of available-for-sale marketable securities as of December 31, 2008 and 2007:

(in thousands)	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
December 31, 2008				
U.S. treasury notes	$ 2,047	$ 1	$ –	$ 2,048
Total	$ 2,047	$ 1	$ –	$ 2,048
December 31, 2007				
Commercial paper	$ 16,010	$ 42	$ –	$ 16,052
Certificates of deposit	26	–	–	26
Total	$ 16,036	$ 42	$ –	$ 16,078

The available-for-sale marketable securities consist of United States treasury notes, certificates of deposits, and high-quality commercial paper 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 that provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs.

Note 6 – Restricted Cash

Restricted Cash consists of a 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 location in Warrington, Pennsylvania (*See* Note 14 – "Commitments" for further discussion on our leases). 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.

Note 7 – Property and Equipment

Property and equipment as of December 31, 2008 and 2007 was comprised of the following:

(in thousands)	December 31, 2008	2007
Equipment	$ 7,143	$ 6,976
Furniture	791	802
Leasehold improvements	2,813	2,889
Subtotal	10,747	10,667
Accumulated depreciation	(4,782)	(3,598)
Property and equipment, net	$ 5,965	$ 7,069

Equipment primarily consists of: (i) manufacturing equipment to produce our KL_4 Surfactant products, including Surfaxin and Aerosurf, for use in our clinical trials and potential commercial needs; (ii) laboratory equipment for manufacturing, analytical, research and development activities; and (iii) computers and office equipment to support our overall business activities.

Leasehold improvements primarily consists of construction of a new analytical and development laboratory in our Warrington, Pennsylvania headquarters, which was completed in 2007 and where we consolidated the analytical, quality and development activities previously located in Doylestown, Pennsylvania and Mountain View, California. The activities conducted in our new laboratory include release and stability testing of raw materials as well as clinical and, if approved, commercial drug product supply. We also perform development work with respect to our aerosolized KL_4 Surfactant and novel formulations of our KL_4 Surfactant Technology. The laboratory has expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics. The laboratory will be amortized through the end of our lease term for our Warrington, Pa headquarters in 2013. In addition, in 2007, we built a microbiology laboratory at our manufacturing facility in Totowa, NJ to support production of our drug product candidates. The microbiology laboratory will be amortized through the end of our lease term for our Totowa, NJ facility in 2014.

Depreciation expense for the years ended December 31, 2008, 2007, and 2006 was $1.6 million, $1.5 million (including $0.4 million of depreciation expense associated with an adjustment to the useful lives of fixed assets), and $0.9 million, 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 and recorded an additional charge to depreciation expense in 2007 of $0.4 million.

Note 8 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2008 and 2007 were comprised of the following:

(in thousands)	December 31, 2008	2007
Accounts payable	$ 2,111	$ 758
Accrued compensation[(1)]	2,390	2,347
Accrued manufacturing	1,174	1,186
Accrued research and development	374	846
All other accrued expenses	1,375	2,707
Total accounts payable and accrued expenses	$ 7,424	$ 7,844

(1) Accrued compensation consists of potential employee incentive arrangements (per plans adopted and approved by the Board of Directors), contractual future severance arrangements for union employees at our manufacturing operations, and employees' unused earned vacation, As part of an effort to conserve cash resources, the Compensation Committee of the Board of Directors did not award year-end cash bonuses to employees at the end of the year ended December 31, 2008, but plans to reconsider this decision, if cash resources permit, following the potential approval of Surfaxin by the FDA.

Note 9 - Debt

Loan Payable – PharmaBio Development, Inc.

PharmaBio Development, Inc. (PharmaBio), a Strategic Investment Group of Quintiles Transnational Corp., extended to us a secured, revolving credit facility of $8.5 to $10 million in 2001. Under an October 2006 restructuring, the outstanding principal balance of $8.5 million is due and payable on April 30, 2010 and, since October 1, 2006, interest has accrued at the prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, is 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, 2008, the outstanding balance under the loan was $10.1 million ($8.5 million of pre-restructured principal and $1.6 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

For the years ended December 31, 2008, 2007 and 2006, we incurred interest expense associated with the PharmaBio loan of $0.5 million, $0.7 million and $0.8 million, respectively. The decrease in interest expense in 2008 was due to a decline in the prime rate during 2008 from 7.25% to 3.25%. In addition, for the years ended December 31, 2008, 2007 and 2006, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to PharmaBio in October 2006 of $0.5 million, $0.5 million and $0.1 million, respectively.

Equipment Loans

Our equipment loan liabilities as of December 31, 2008 and 2007 are as follows:

(in thousands)

	2008	2007
GE Business Financial Services, Inc.		
Short-term	$ 2,385	$ 2,625
Long-term	664	2,991
Total	3,049	5,616
Pennsylvania Machinery and Equipment Loan		
Short-term	57	–
Long-term	428	–
Total	485	–
Total Short-term	2,442	2,625
Total Long-term	1,092	2,991
Total	$ 3,534	$ 5,616

For the years ended December 31, 2008, 2007 and 2006, we incurred interest expense associated with our equipment loans of $0.6 million, $0.6 million and $0.5 million, respectively.

Equipment Financing Facility with GE Business Financial Services Inc.

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide us a $12.5 million facility (Facility) to fund our capital programs. Upon execution of the Credit Agreement, we simultaneously drew down approximately $4.0 million to prepay all of our then-outstanding indebtedness under a previous facility. Over the term of the Facility, we received $7.2 million, $4.0 million of which was associated with the prepayment of a previous facility and $2.3 million of which was associated with construction and equipment for a new analytical and development laboratory built in our Warrington, Pennsylvania corporate headquarters in 2007. The right to draw under this Facility expired on November 30, 2008.

Advances to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our previous facility is amortized over a period of 27 months. 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 are 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%.

Our obligations under the Facility are secured by a security interest in (i) the financed property and equipment, and (ii) all of our intellectual property (Supplemental Collateral), subject to limited exceptions set forth in the Loan Agreement. The Supplemental Collateral will be released on the earlier to occur of (a) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (b) 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, GE and PharmaBio entered into an Intercreditor Agreement under which GE 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).

Pennsylvania Machinery and Equipment Loan Fund (MELF)

Effective September 8, 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department) and executed a Promissory Note, pursuant to which the Department made a loan to us from the Machinery and Equipment Loan Fund in the amount of $500,000 (MELF Loan) to fund the purchase and installation of new machinery and equipment and the upgrade of existing machinery and equipment at our new analytical and development laboratory in Warrington, Pennsylvania. Principal and interest on the MELF Loan is payable in equal monthly installments over a period of seven years. Interest on the principal amount will accrue at a fixed rate per annum equal to 5.0%. We may prepay the MELF Loan at any time without penalty.

In addition to customary terms and conditions, the MELF Agreement provides that we must meet certain criteria regarding retention and creation of new jobs within a three-year period. In the event that we fail to comply with this requirement, the interest rate on the Promissory Note, except in limited circumstances, will be adjusted to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Note 10 – 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.

Committed Equity Financing Facilities (CEFFs)

We have entered into Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in which Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allow us, at our discretion, to raise capital at the time and in amounts deemed suitable to us, to support our business plans. We have access to each CEFF for a period of 2 to 3 years from inception. We are not obligated to utilize any of the funds available under the CEFFs. Should we choose to utilize any of the CEFFs, our ability to access the funds available under the CEFFs is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2008, the Company had CEFFs for future financings as follows:

(in millions, except per share data and trading days)	Expiration	Minimum Price to Initiate Draw Down[1]	Minimum VWAP for Daily Pricing[2]	# of Trading Days In Each Draw Down[2]	Amount per Contract		Potential Availability at December 31, 2008	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
2006 CEFF	May 12, 2009	$ 2.00	85% of prior day closing price	8	11.7	$ 50.0	4.5	$ 34.3
May 2008 CEFF	June 18, 2011	$ 1.15	90% of prior day closing price	8	19.3	$ 60.0	15.6	$ 54.9
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60	90% of prior day closing price	6	15.0	$ 25.0	15.0	$ 25.0

(1) To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day of the draw down must be at least equal to the minimum price set forth above.

(2) If on any trading day, the daily volume-weighted average of our common stock (VWAP) is less than the minimum VWAP set forth above, no shares are purchased on that trading day and the aggregate amount of the draw down is reduced for each such day 1/8th (1/6th for the Dec. 2008 CEFF) of the amount that we originally designated. Unless we and Kingsbridge agree 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.

Each draw down is limited in amount as follows:

- 2006 CEFF – 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;
- May 2008 CEFF – the lesser of 3.0 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or $10 million; and
- December 2008 CEFF – the lesser of 1.5 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or $3 million.

The purchase price of shares sold to Kingsbridge under the CEFFs is at a discount to the VWAP (as defined in the applicable agreement) for each of the trading days following our initiation of a “draw down” under the CEFF, as follows:

Daily VWAP	% of VWAP	(Applicable Discount)
2006 CEFF		
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)%
May 2008 CEFF		
Greater than $7.25 per share	94%	(6)%
Less than or equal to $7.25 but greater than $3.85 per share	92%	(8)%
Less than or equal to $3.85 but greater than $1.75 per share	90%	(10)%
Less than or equal to $1.75 but greater than or equal to $1.15 per share	88%	(12)%

Daily VWAP	% of VWAP	(Applicable Discount)
December 2008 CEFF		
Greater than $7.25 per share	94%	(6)%
Less than or equal to $7.25 but greater than $3.85 per share	92%	(8)%
Less than or equal to $3.85 but greater than $1.75 per share	90%	(10)%
Less than or equal to $1.75 but greater than or equal to $1.10 per share	88%	(12)%
Less than or equal to $1.10 but greater than or equal to $.60	85%	(15)%

In addition, Kingsbridge may terminate the CEFFs under certain circumstances, including if a material adverse event relating to our business continues for 10 trading days after notice of the material adverse event.

CEFF Financings

The financings that we have completed under the 2006 CEFF are:

In May 2006, we completed a financing under the 2006 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 2006 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 2006 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 2006 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 2006 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.

In September 2008, we completed a financing under the 2006 CEFF, resulting in proceeds of $1.3 million from the issuance of 676,360 shares of our common stock at an average price per share, after the applicable discount, of $1.85.

Also, 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, 2008, the Class C Investor Warrant had not been exercised.

The financings that we have completed under the May 2008 CEFF are:

On July 11, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.6 million from the issuance of 1,104,850 shares of our common stock at an average price per share, after the applicable discount, of $1.41.

On July 31, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.5 million from the issuance of 991,537 shares of our common stock at an average price per share, after the applicable discount, of $1.51.

On October 17, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.3 million from the issuance of 913,827 shares of our common stock at an average price per share, after the applicable discount, of $1.44.

On November 20, 2008, we completed a financing under the May 2008 CEFF, resulting in proceeds of $0.3 million from the issuance of 221,202 shares of our common stock at an average price per share, after the applicable discount, of $1.13.

On January 2, 2009, we completed a financing that was initiated in 2008 under the May 2008 CEFF, resulting in proceeds of $0.5 million from the issuance of 478,783 shares of our common stock at an average price per share, after the applicable discount, of $1.04.

Subsequently, in 2009, we initiated and completed additional financings under the May 2008 CEFF, as follows:

On January 16, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of $0.4 million from the issuance of 419,065 shares of our common stock at an average price per share, after the applicable discount, of $1.04.

On February 18, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of $1.0 million from the issuance of 857,356 shares of our common stock at an average price per share, after the applicable discount, of $1.17.

Also, on May 22, 2008, in connection with the May 2008 CEFF, we issued a warrant to Kingsbridge to purchase up to 825,000 shares of our common stock at an exercise price of $2.506 per share, which expires in November 2013 and is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.1 million. As of December 31, 2008, the Investor Warrant had not been exercised.

No financings have been completed under the Dec 2008 CEFF. On December 22, 2008, in connection with the December 2008 CEFF, we issued a warrant to Kingsbridge to purchase up to 675,000 shares of our common stock at an exercise price of $1.5132 per share, which is fully exercisable for a five-year period beginning May 12, 2009. The warrant is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $1.0 million.

In connection with a CEFF that we entered in 2004, which has since been terminated, 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 expires in January 2010 and is exercisable, 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 (up to the maximum deduction allowed, excluding "catch up" amounts) in newly issued shares of common stock. For the years ended December 31, 2008, 2007 and 2006, the match resulted in the issuance of 231,287, 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 summarizes shares of our common stock reserved for future issuance upon the exercise of warrants.

(in thousands, except price per share data)

	December 31, 2008	December 31, 2007	Exercise Price	Expiration Date
Kingsbridge – December 2008 CEFF(3)	675	–	$ 1.51	6/12/2014
Kingsbridge – May 2008 CEFF(3)	825	–	$ 2.51	11/22/2013
Private Placement – 2006 (1)	2,315	2,315	$ 3.18	11/22/2011

(in thousands, except price per share data)

	December 31, 2008	December 31, 2007	Exercise Price	Expiration Date
PharmaBio - 2006 Loan Restructuring (2)	1,500	1,500	$ 3.58	10/26/2013
Class C Investor Warrants - 2006 CEFF (3)	490	490	$ 5.62	10/17/2011
PharmaBio - 2004 Partnership Restructuring (4)	850	850	$ 7.19	11/3/2014
Class B Investor Warrants - 2004 CEFF (3)	375	375	$ 12.07	1/6/2010
Class A Investor Warrants – 2003	809	809	$ 6.88	9/19/2010
Total	7,839	6,339		

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

(2) Refer to Note 9 – 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 9 – Debt.

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.

Stock options outstanding and available for future issuance as of December 31, 2008 and 2007 are as follows:

(in thousands)	**As of December 31, 2008**	**2007**
2007 Plan		
Outstanding	7,296	3,408
Available for Future Grants	1,204	5,093
Total	8,500	8,501
1998 Plan		
Outstanding	9,916	8,837
Available for Future Grants	–	–
Total	9,916	8,837
Total Outstanding	17,212	12,245
Total Available for Future Grants	1,204	5,093
Total	18,416	17,338

The 1998 Plan was suspended upon approval of the 2007 Plan in June 2007; therefore, no shares were available for future grants under the 1998 Plan. *See* Note 11 – Stock Options and Stock-Based Employee Compensation.

Universal Shelf Registration Statements

2008 Universal Shelf

In June 2008, we filed a universal shelf registration statement on Form S-3 (No. 333-151654) (2008 Universal Shelf) with the SEC for the proposed offering from time to time of up to $150 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at that time. We have not completed any financings under the June 2008 Universal Shelf, such that as of December 31, 2008, the entire $150.0 million remained available.

October 2005 Universal Shelf

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 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.

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.

The October 2005 universal shelf registration statement expired in December 2008 and is no longer available for future financings.

Common shares reserved for potential future issuance under CEFF arrangements

As of December 31, 2008, the Company had three CEFFs available for future financings as follows:

(in thousands)		Potential future issuance as of December 31	
	Expiration	2008	2007
2006 CEFF	May 12, 2009	4,494	5,170
May 2008 CEFF	June 18, 2011	15,618	–
Dec. 2008 CEFF	Feb. 6, 2011	15,000	–

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 205,626 shares reserved for potential future issuance under the 401(k) Plan. In December 2008, the Board of Directors approved an increase of 350,000 shares to the reserve for issuance under the 401(k) Plan. As of December 31, 2008 and 2007, we had 324,339 and 205,626 shares, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 11 – Stock Options and Stock-based Employee Compensation

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

Long-Term Incentive Plans

In June 2007, our shareholders approved the adoption of the 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, thereby enhancing stockholder 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 – 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)

The Committee 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. The Committee will establish the vesting schedule for stock options and the method of payment for the exercise price, which may include cash, shares, or other awards. Although individual grants may vary, option awards generally are exercisable upon vesting, vest based upon three years of continuous service and have a 10-year term. 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 162(m) of the Internal Revenue Code.

Restricted Stock and Restricted Stock Units

The Committee may award restricted stock and restricted stock units and, among other things, establish the applicable restrictions, including any limitation on voting rights or the receipt of dividends, and will establish the manner and timing under which restrictions may lapse. If employment is terminated during the applicable restriction period (other than as a result of death or disability), shares of restricted stock and restricted stock units still subject to restriction will be forfeited, except as determined otherwise by the Committee.

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

The Committee may grant performance awards, which may be denominated in cash, shares, other securities or other awards and payable to, or exercisable by, the participant upon the achievement of performance goals during performance periods, as established by the Committee. The Committee may grant other stock-based awards that are denominated or payable in shares, under the terms and conditions as the Committee will determine. The Committee may decide to include dividends or dividend equivalents as part of a performance or other stock-based award, and may accrue dividends, with or without interest, until the award is paid.

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

Each non-employee directors is entitled to automatic option grants on specified dates as follows: (i) options to purchase 40,000 shares on the date of first election or appointment to the board and (ii) options to purchase 30,000 shares on the date of each subsequent annual stockholders meeting if such director continues to, and has served as a director for at least six months. Non-employee director options vest on the first anniversary of the date of grant (subject to continued service through such date) and will otherwise vest in full upon the termination of service as a result of death or disability. Non-employee director options have a term of ten years (subject to earlier termination twelve months after any termination of service).

Under the 2007 Plan, as of December 31, 2008, options to purchase 7,295,667 shares of common stock were outstanding and 1,204,333 shares were available for potential future grants. Under the 1998 Plan, as of December 31, 2008, options to purchase 9,916,644 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.

A summary of option activity under the 2007 Plan and 1998 Plan as of December 31, 2008 and changes during the period is presented below:

(in thousands, except for weighted-average data)

Stock Options	Price Per Share	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)
Outstanding at December 31, 2005	$0.0026 – $10.60	8,440	$ 6.28	
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	
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	
Granted	1.21 – 2.90	3,950		
Exercised	0.32 – 1.62	(18)	1.21	
Forfeited or expired	0.19 – 10.60	(650)	5.17	
Outstanding at December 31, 2008	$0.81 – $10.43	17,212	$ 3.72	7.1
Exercisable at December 31, 2008	$0.81 – $10.43	10,605	$ 4.63	6.0

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, 2008, 2007 and 2006 was $0.88, $2.05 and $2.33, respectively. The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $13,000, $57,000 and $79,000, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2008 is $3,000.

A summary of the status of our nonvested shares issuable upon exercise of outstanding options and changes during 2008 is presented below:

(shares in thousands)	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2007	4,939	$ 2.18
Granted	4,044	0.88
Vested	(2,199)	2.12
Forfeited	(177)	2.38
Non-vested at December 31, 2008	6,607	$ 1.40

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2008:

(shares in thousands)	Outstanding			Vested and Exercisable		
Price per share	Shares	Weighted Average Price per Share	Weighted Average Remaining Contractual Life	Shares	Weighted Average Price per Share	Weighted Average Remaining Contractual Life
$0.81 – $2.00	4,566	$ 1.68	8.59 years	951	$ 1.68	5.19 years
$2.01 – $4.00	8,114	$ 2.67	7.31 years	5,273	$ 2.65	6.95 years
$4.01 – $6.00	694	$ 4.77	1.97 years	694	$ 4.77	1.97 years
$6.01 – $8.00	1,461	$ 6.88	6.29 years	1,310	$ 6.85	6.30 years
$8.01 – $10.00	2,352	$ 8.93	5.27 years	2,352	$ 8.93	5.27 years
$10.01 – $10.43	25	$ 10.43	5.22 years	25	$ 10.43	5.22 years
	17,212			10,605		

Stock-Based Employee Compensation

As a result of adopting SFAS No. 123(R) on January 1, 2006, we recognized compensation expense for the years ended December 31, 2008, 2007 and 2006 of $4.6 million, $5.2 million and $5.5 million, respectively. For the year ended December 31, 2008, $1.5 million of compensation expense was classified as research and development and $3.1 million of compensation expense was classified as general and administrative. 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.

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,		
	2008	**2007**	**2006**
Expected volatility	77% - 92%	77% - 99%	81% - 101%
Weighted average expected volatility	81%	88%	96%
Expected term	4 and 5 years	4 and 5 years	4 and 5 years
Risk-free interest rate	1.2% - 3.5%	3.5% - 4.6%	4.4% - 5.0%
Expected dividends	–	–	–

The total fair value of the underlying shares of the options vested during 2008, 2007, and 2006 equals $4.7 million, $4.9 million and $5.4 million, respectively. As of December 31, 2008, there was $6.9 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 2.03 years.

Note 12 – Corporate Partnership, Licensing and Research Funding Agreements

Philip Morris USA Inc., d/b/a Chrysalis Technologies

In March 2008, we restructured our December 2005 Strategic Alliance Agreement (Original Alliance Agreement) with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility for the further development of the Capillary Aerosolization Technology, including finalizing design development for the initial prototype aerosolization device platform and disposable dose packets. In connection with the restructuring, we entered into an Amended and Restated License Agreement dated March 28, 2008 (U.S. License Agreement) with PMUSA to amend and restate the Original Alliance Agreement in the United States. As PMUSA assigned to Philip Morris Products S.A. (PMPSA) all rights in and to the Capillary Aerosolization Technology outside of the United States (International Rights), effective the same date, we entered into a License Agreement with PMPSA with respect to the International Rights (International License Agreement) on substantially the same terms and conditions as the U.S. License Agreement. We currently hold exclusive licenses to the Capillary Aerosolization Technology both in and outside of the United States for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, Exclusive Field). In addition, under the U.S. License Agreement, our license to use the Capillary Aerosolization Technology includes other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions.

In connection with the restructuring, Chrysalis completed a technology transfer, provided development support to us through June 30, 2008, and also paid us $4.5 million to support our future development activities, of which $2.0 million was paid upon execution of the license agreements in March 2008 and $2.5 million was paid upon completion of the technology transfer in June 2008. We are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field in the territories. In connection with exclusive undertakings of PMUSA and PMPSA not to exploit the Capillary Aerosolization Technology for all licensed uses, we are obligated to pay royalties on all product sales, including sales of aerosol devices and related components that are not based on the Capillary Aerosolization Technology; provided, however, that no royalties are payable to the extent that we exercise our right to terminate the license with respect to a specific indication. We also agreed in the future to pay minimum royalties, but are entitled to a reduction of future royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned in prior periods.

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of a broad portfolio of potential Surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Esteve will pay us a transfer price on sales of Surfaxin and other KL_4 Surfactant products. 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 territory. Esteve is obligated 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 territory. As part of a restructuring of this alliance in December 2004, we regained full commercialization rights to our KL_4 Surfactant Technology in portions of the original territory licensed to Esteve, including key European markets, Central America, and South America (Former Esteve Territories) and 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 strategic collaborations for the development and commercialization of certain of our KL_4 Surfactant products, including Surfaxin and Aerosurf in the Former Esteve Territories.

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.

Note 13 – Restructuring Charges

April 2006 Corporate Restructuring

In April 2006, after ongoing analysis of Surfaxin process validation batches that had been manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria, 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, including three senior executives, and represented approximately 33% of our workforce, primarily from our commercial group. All affected employees were eligible for severance payments and continuation of benefits.

We incurred a restructuring charge of $4.8 million in the second quarter 2006 associated with the staff reductions and discontinued commercial programs, which was accounted for in accordance with Statement of Financial Accounting Standards No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* (SFAS No. 146) 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 associated with discontinued commercial programs. As of December 31, 2008, payments totaling $4.5 million had been made related to these items and $0.3 million were unpaid and included in accounts payable and accrued expenses.

Note 14 - Commitments

Future payments due under contractual obligations at December 31, 2008 are as follows:

(in thousands)	2009	2010	2011	2012	2013	There-after	Total
Loan payable[(1)]	$ –	$ 10,573	$ –	$ –	$ –	$ –	$ 10,573
Equipment loan obligations[(1)]	2,946	722	152	85	85	155	4,145
Operating lease obligations	1,143	1,135	1,151	1,168	320	150	5,067
Total	$ 4,089	$ 12,430	$ 1,303	$ 1,253	$ 405	$ 305	$ 19,785

(1) *See* Note 9: "*Debt"*

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

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 an additional three years through February 2013 with additional payments of $3.0 million over the 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 manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires in December 2014, subject to a right of the landlord 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. The total aggregate payments over the term of the lease are $1.4 million. For a discussion of our manufacturing strategy, *see* "Business – Business Operations – Manufacturing and Distribution."

Our lease for 5,600 square feet of office and analytical laboratory space in Doylestown, Pennsylvania was terminated effective July 31, 2008 and all activities at this location have been consolidated into our new laboratory space in Warrington, Pennsylvania. Our lease for 16,800 square feet of office and laboratory space at our facility in Mountain View, California, expired without renewal or extension on June 30, 2008. In December 2007, we consolidated these activities into our new laboratory space in Warrington, Pennsylvania.

Rent expense under all of these leases for the years ended December 31, 2008, 2007, and 2006 was $1.2 million, $1.5 million and $1,4 million respectively.

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 15 – Litigation

We are not aware of any pending or threatened legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

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 our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

Note 16 – 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, 2008, 2007 and 2006 are as follows:

(in thousands)	December 31,		
	2008	2007	2006
Income tax benefit, statutory rates	$ 13,296	$ 13,601	$ 15,753
State taxes on income, net of federal benefit	2,102	2,363	2,770
Research and development tax credit	1,026	960	966
Employee Related	(1,306)	(1,118)	–
Other	(32)	(24)	(38)
Income tax benefit	15,086	15,782	19,451
Valuation allowance	(15,086)	(15,782)	(19,451)
Income tax benefit	$ –	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2008 and 2007, are as follows:

(in thousands)	December 31, 2008	2007
Long-term deferred tax assets:		
Net operating loss carryforwards (federal and state)	$ 115,401	$ 102,397
Research and development tax credits	7,137	6,130
Compensation expense on stock	4,334	3,615
Charitable contribution carryforward	6	6
Other accrued	2,073	1,386
Depreciation	2,494	2,653
Capitalized research and development	2,411	2,613
Total long-term deferred tax assets	133,857	118,800
Long-term deferred tax liabilities	–	–
Net deferred tax assets	133,857	118,800
Less: valuation allowance	(133,857)	(118,800)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2008 and 2007 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, 2008 and 2007, we had available carryforward net operating losses for Federal tax purposes of $292.6 million and $258.7 million, respectively, and a research and development tax credit carryforward of $7.1 million and $6.1 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and continue through 2028. Approximately $14.8 million of the $292.6 net operating loss carryforwards expire prior to 2013.

At December 31, 2008, 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, 2008 and 2007, we had available carryforward losses of approximately $271.1 million and $250.2 million, respectively, for state tax purposes. Of the $271.1 state tax carryforward losses, $246.7 million is associated with the state of Pennsylvania, with the remainder associated with New Jersey, California and Florida.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOLs and credits.

A full valuation allowance has been provided against our research and development credits and, if a future assessment requires an adjustment, an adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

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.

On January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The provisions of FIN 48 apply to all material tax positions in all taxing jurisdictions for all open tax years. The adoption of FIN 48 did not have a material effect on the Company's financial condition or results of operations for the year ended December 31, 2008.

Note 17 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2008 and 2007. The operating results for any quarter are not necessarily indicative of results for any future period.

2008 Quarters Ended:					*(in thousands, except per share data)*
	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	$ 2,050	$ 2,500	$ 50	$ –	$ 4,600
Expenses:					
Research and development	7,232	7,439	6,724	5,170	26,566
General and administrative	4,505	5,076	3,726	3,121	16,428
Total expenses	11,737	12,515	10,450	8,291	42,994
Operating loss	(9,687)	(10,015)	(10,400)	(8,291)	(38,394)
Other income / (expense), net	(27)	(200)	(239)	(246)	(712)
Net loss	$ (9,714)	$ (10,215)	$ (10,639)	$ (8,537)	$ (39,106)
Net loss per common share - basic and diluted	$ (0.10)	$ (0.11)	$ (0.11)	$ (0.08)	$ (0.40)
Weighted average number of common shares outstanding	96,649	96,691	98,619	100,474	98,116

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
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 common shares outstanding	69,989	83,825	84,642	88,469	81,731

Note 18 – Subsequent Events

Financings pursuant to the CEFF

On January 16, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately $0.4 million from the issuance of 419,065 shares of our common stock at an average price per share, after the applicable discount, of $1.04.

On February 18, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately $1.0 million from the issuance of 857,356 shares of our common stock at an average price per share, after the applicable discount, of $1.17.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Annual Report (Form 10-K) of Discovery Laboratories, Inc. of our report dated March 11, 2009, with respect to the consolidated financial statements of Discovery Laboratories, Inc.

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, Form S-3 No. 333-38282, Form S-3 No. 333-151536, Form S-3 No. 333-151654, and Form S-3 No. 333-156237) of Discovery Laboratories, Inc.;

(2) Registration Statement (Form S-8 No. 333-110412, Form S-8 No. 333-137643 and Form S-8 No. 333-156443) pertaining to the Discovery Laboratories, Inc. 401(k) Plan;

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

(4) Registration Statement (Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-116268, Form S-8 No. 333-127790, 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.;

(5) 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; and

(6) 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 11, 2009, with respect to the consolidated financial statements of Discovery Laboratories, Inc. and subsidiary and of our report dated March 11, 2009, 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, 2008.

Philadelphia, Pennsylvania
March 11, 2009

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 11, 2009

/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 11, 2009

/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, 2008 (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 11, 2009

/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.