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, 2009

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value Preferred Stock Purchase Rights	**The Nasdaq Global Market**

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

None

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO 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 30, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $126 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 1, 2009 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 5, 2010, 153,892,960 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 2010 definitive proxy statement, which is expected to be filed by us with the Commission within 120 days after the close of our 2009 fiscal year.

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

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "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 in premature infants; 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 technology platform, including planning for and timing of any clinical trials and potential development milestones; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our drug products, if approved; and plans regarding potential strategic alliances and other collaborative 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 actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

- risks related generally to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product candidates, including our lead products that we are developing to address Respiratory Distress Syndrome (RDS) in premature infants: Surfaxin® (lucinactant) for the prevention of RDS, Surfaxin LS™ (our lyophilized KL_4 surfactant) and Aerosurf® (our initial aerosolized KL_4 surfactant);

- the risk that we and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;

- 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 strategic development partners or pursuant to collaboration arrangements;

- the risk that the FDA will not be satisfied with the results of our efforts to optimize and revalidate our fetal rabbit biological activity test (BAT) and to demonstrate that the BAT has the ability to distinguish change in Surfaxin drug product over time, which is needed to advance our KL_4 surfactant pipeline;

- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks relating to our research and development activities, which involve time-consuming and expensive preclinical studies and other efforts, and potentially multiple clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail, and which must be conducted using sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities;
- risks relating to our ability to develop and manufacture drug products and drug-device combination products based on our capillary aerosolization technology for clinical studies and, if approved, for commercialization of our 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 may encounter problems or delays in manufacturing or assembling drug products, drug product substances, capillary 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 we may be unable to identify potential strategic partners or collaborators with whom we can develop and, if approved, commercialize our products in a timely manner, if at all;
- the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;
- the risk that, if approved, market conditions, the competitive landscape or otherwise may make it difficult to launch and profitably sell our products;
- the risk that we may not be able to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development or commercialization of our drug products and combination drug-device products);
- risks that the unfavorable credit environment will adversely affect our ability to fund our activities, that our share price will not reach or remain at the price level necessary for us to access capital under our Committed Equity Financing Facilities (CEFFs), that the CEFFs may expire before we are able to access the full dollar amount potentially available thereunder, and that additional equity financings could result in substantial equity dilution;
- the risk that we will be unable to regain compliance with the Minimum Bid Price Requirement of The Nasdaq Global Market prior to the expiration of the grace period currently in effect, which could increase the probability that our stock will be delisted from Nasdaq and cause our stock price 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 and that other companies may develop competing therapies and/or technologies;

- the risk that we may become involved in securities, product liability and other litigation;
- risks related to reimbursement and health care reform that may adversely affect us;
- the risk that the FDA may not approve Surfaxin® or may subject the marketing of Surfaxin® to onerous requirements that significantly impair marketing activities;
- the risk that we may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin ® ; and
- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this report.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this report or the documents incorporated by reference herein speak only of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly 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.

Table of Contents to Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2009

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. We were incorporated as a Delaware corporation in 1992. 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 therapies to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel KL_4 proprietary 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 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 developing our lead products, Surfaxin®(lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. In April 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to our New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL_4 surfactant technology. The letter focused primarily on certain aspects of our fetal rabbit biological activity test (BAT, a quality control and stability release test for Surfaxin and our other KL_4 pipeline products), specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time. We met with the FDA in June 2009 and by teleconference in September 2009 to discuss specific proposals to resolve this sole remaining Chemistry, Manufacturing & Control (CMC) issue, which must be addressed to obtain approval of Surfaxin. Based on these and other interactions with the FDA, we are currently implementing a protocol intended to optimize and revalidate the BAT and thereafter plan to initiate a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT. If successful, we believe that we could be in a position to file a Complete Response to the April 2009 Complete Response Letter in the first quarter of 2011, which could lead to approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in 2011. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for use in neonatal medicine. For a detailed discussion on the progress of our Surfaxin NDA, *see* "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin for the Prevention of RDS in Premature Infants." *See also*, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our KL_4 Surfactant Technology."

Surfaxin LS, our lyophilized KL_4 surfactant, is a dry powder formulation that is resuspended as a liquid prior to use and is intended to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin LS™ – Lyophilized Surfaxin for RDS in Premature Infants." 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. If approved, we believe that Aerosurf will make it possible to administer surfactant into the lung without subjecting patients to invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of surfactant therapy in pediatric medicine. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Aerosurf for RDS in Premature Infants."

In addition to our lead products, we plan over time to develop our KL_4 surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies. Our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development. We have an ongoing Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF) and our KL_4 surfactant is the subject of an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL_4 surfactant in patients with Cystic Fibrosis (CF). *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Acute Respiratory Failure (ARF) – Surfaxin for ARF," and " – Cystic Fibrosis." We are conducting research and preclinical development with our KL_4 surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL_4 surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Serious Respiratory Indications Associated with Inflammation of the Lungs – Acute Lung Injury (ALI)," and " – KL_4 Surfactant in Combination with Other Therapeutics to Treat a Wide Range of Disease."

An important priority is to secure strategic and financial resources to potentially maximize the inherent value of our KL_4 surfactant technology. We would prefer to accomplish our objectives through strategic alliances. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL_4 surfactant technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our pipeline programs.

BUSINESS STRATEGY

Our goal is to develop a robust pipeline of products based on our proprietary KL_4 surfactant technology to potentially significantly improve the medical outcomes of patients, from premature infants to adults, suffering debilitating respiratory diseases and conditions. Key elements of our strategy for achieving this goal include:

- We plan to continue to focus our research and development 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. We further believe that our neonatal pipeline programs, Surfaxin, Surfaxin LS and Aerosurf, have the potential to greatly improve the management of RDS and, collectively, represent the opportunity, over time, to expand the current RDS estimated worldwide annual market of $200 million to a $1 billion opportunity.

    - Surfaxin is the first synthetic, peptide-containing surfactant that, if approved, will represent an alternative therapy to the currently-approved, animal-derived surfactants. The safety and efficacy of Surfaxin for RDS has previously been demonstrated in a comprehensive Phase 3 clinical program. In April 2009, we received a Complete Response Letter from the FDA with respect to our Surfaxin NDA that focused primarily on issues related to our BAT. Consistent with previous communications from the FDA, there continues to be no questions regarding clinical trial data and no indication that the FDA has any concerns related to other quality assurance tests or the manufacturing process for Surfaxin. To resolve the sole remaining CMC issue, we are currently pursuing a comprehensive preclinical program that, if successful, could lead to marketing approval of Surfaxin for the prevention of RDS in premature infants in the United States in 2011.

    - We also are developing a lyophilized (dry powder) formulation, Surfaxin LS, which, among other things, is being developed to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. We are currently developing our regulatory strategy for a Phase 3 global registration clinical program intended to gain 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, our aerosolized KL_4 surfactant, holds the promise to significantly expand the use of surfactant therapy in premature infants and pediatric patients by potentially providing neonatologists and pediatricians with a means of administering KL_4 surfactant to infants and children without the risks currently associated with administration of currently-approved surfactants, which require invasive endotracheal intubation and mechanical ventilation. We believe that Aerosurf, if approved, will allow for a potentially significant increase in the number of infants who will benefit from surfactant therapy, given that many such infants currently are not treated because the benefits of surfactant therapy are believed to be outweighed by the risks of invasive administration. We are currently advancing our preclinical development activities and preparing to further engage the FDA and foreign regulators with respect to our clinical program. Thereafter, we plan to initiate a Phase 2 clinical program for Aerosurf.

We believe that the pipeline of Surfaxin, Surfaxin LS and particularly Aerosurf could significantly advance the treatment of RDS and make it possible for many more infants at risk for RDS to be treated with surfactant therapy. Our KL_4 surfactant technology also has the potential to address other serious and debilitating neonatal and pediatric indications, many of which represent significant unmet medical needs, potentially redefining pediatric respiratory medicine.

- ARF in young children occurs after they have been exposed to serious respiratory infections, such as influenza (including the type A serotype referred to as H1N1) or respiratory syncytial virus (RSV), and leads to an impairment in lung function and the need for endotracheal intubation and mechanical ventilation (the current standard of care). Children with ARF usually suffer surfactant inactivation as part of the disease process. We are conducting a Phase 2 clinical trial to determine whether the administration of Surfaxin improves lung function and results in a shorter duration of mechanical ventilation and stay in the neonatal intensive care unit (NICU) or pediatric intensive care unit (PICU) for children up to two years of age suffering with ARF. Enrollment is near completion and top-line results are expected to become available in the second quarter of 2010.

· We also plan to continue to invest in a number of exploratory development programs. We are initially targeting Cystic Fibrosis (CF), Acute Lung Injury (ALI), and the feasibility of drug combination therapies utilizing our KL_4 surfactant.

- Our aerosolized KL_4 surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in Cystic Fibrosis (CF) patients. The trial has been designed to assess the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL_4 surfactant in CF patients. The trial is being conducted at The University of North Carolina with the support of the Cystic Fibrosis Foundation and results are anticipated in the second quarter of 2010.

- We are presently conducting preclinical experiments in collaboration with a prominent academic investigator assessing the potential application of our aerosolized KL_4 surfactant in the prevention and treatment of ALI, a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer.

- We have also initiated a drug combination preclinical program to assess whether our KL_4 surfactant, either alone or in combination with our capillary aerosolization technology, may represent a novel approach for efficient delivery of small and large molecule therapeutics to the lung.

We plan to initially develop these programs through a proof-of-concept phase and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or utilize other financial alternatives to fund their further development and/or worldwide commercialization, if approved. There can be no assurance that we will succeed in demonstrating proof-of-concept or entering into any such alliance or collaboration arrangement or identifying any such financial alternative, but if we are successful, we believe that these programs could address significant unmet medical needs and potentially redefine therapeutic approaches to a variety of respiratory diseases.

- An important priority for us is to strengthen our long-term strategic and financial position to advance our KL_4 surfactant pipeline programs and maximize shareholder value. Our near-term plans include:

    - We will continue to seek strategic alliances and other collaborative arrangements for the development and/or commercialization of our KL_4 surfactant product candidates that would provide financial support (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), development capabilities, and ultimately commercial expertise to advance our KL_4 technology. We also are reviewing various financial alternatives that would provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded.

    - We have $10.5 million outstanding under our loan with Quintiles (formerly PharmaBio Development, Inc. and NovaQuest™). The outstanding principal and all accrued interest, is due and payable on April 30, 2010. We are pursuing a potential strategic restructuring of this loan and we are also considering alternative means of financing its payment should that become necessary. However, there can be no assurance that any such restructuring will occur or financing alternatives will be obtained.

    - Following receipt of the April 2009 Complete Response Letter, to conserve our cash, we reduced our workforce from 115 to 91 employees and implemented further cost-containment measures throughout 2009. As of December 31, 2009, we had 77 full-time employees. We plan to continue to closely manage our expenditures in 2010. Until we secure an alliance or other financing alternative, we plan to focus our financial resources on our neonatal RDS programs, primarily the potential approval of Surfaxin, while limiting investments in our other pipeline programs.

- We have, and will continue, to invest in maintaining and enforcing 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 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 have, and will continue to evaluate, and invest in, our quality systems and manufacturing capabilities, including at our manufacturing operations in Totowa, New Jersey, and our analytical and medical device development 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. With respect to 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 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 described below. 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. We provide estimates and projections to give the reader an understanding of our strategic priorities, but we caution that the reader should not rely on our estimates and projections. These estimates and projections are forward-looking statements, which we intend be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. For a discussion of forward-looking statements, *see* "Forward-Looking Statements" on page ii of this Annual Report on Form 10-K.

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 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 peptide 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 licensed 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 December 2009, research was published in the Proceedings of the National Academy of Sciences indicating that a naturally occurring phospholipid in pulmonary surfactant, palmitoyl-oleoyl-phosphatidylglycerol (POPG), suppresses respiratory syncytial virus (RSV) infection and associated inflammation in both in vitro and in vivo models (Numata et al, Proc Nat Acad of Sci, Dec 09). The research demonstrates that POPG inhibits the spreading of RSV infection in mice exposed to RSV. We believe that our KL_4 surfactant, which contains relatively high concentrations of POPG, is the only surfactant in which POPG is a recognized active pharmaceutical ingredient. This study further supports our belief that our KL_4 surfactant may play a unique role in addressing several debilitating respiratory disorders.

- In May 2009, data from a preclinical study was presented at the Pediatric Academic Societies Annual Meeting (PAS), that compared Surfaxin, at a dose of 5.8 mL/kg (the dose used in the Surfaxin Phase 3 clinical trials for RDS), with Curosurf® (poractant alfa), a currently available surfactant derived from pig lung and the most prescribed surfactant in Europe, at a dose of 2.5 mL/kg (the dose prescribed in its label), in the well-established preterm lamb model. The purpose of the study was to test the hypothesis that a larger dose volume of surfactant could potentially result in more homogeneous distribution of surfactant throughout the lungs and may ultimately result in improved pulmonary and clinical outcomes. The data showed that both surfactants significantly increased pulmonary compliance and tidal volume in this preterm lamb model of RDS without adversely affecting heart rate, blood pressure, or cerebral blood flow, irrespective of the dose volume employed. However, significantly more homogeneous lung distribution of Surfaxin ($p < 0.001$) was observed compared with Curosurf, as measured by pulmonary distribution of a mix of gold-labeled microspheres and surfactant.

- Also in May 2009, data from a preclinical study was presented at PAS that demonstrated a favorable physiologic benefit and subsequent survival impact on treating ALI in an animal model for this severe respiratory condition. The objective of the study was to examine the effectiveness of KL_4 surfactant in treating newborn piglets with severe ALI. The results demonstrated that piglets treated with KL_4 surfactant experienced a statistically significant improvement in oxygenation ($p < 0.001$), as well as better structural integrity of the lung tissue ($p < 0.05$) and improved survival ($p < 0.05$).

- A study that assessed the impact of exogenous surfactants, including Surfaxin, on hyperoxic-induced lung injury in an in-vitro cell-culture model was published in Pediatric Research, a prominent peer-reviewed journal, in July 2008 and concluded that our KL4 surfactant reduced inflammation and cell injury in this model, resulting in improved cell survival and function compared with both a saline control and Survanta® (beractant), a currently available surfactant derived from cow lung and the most prescribed surfactant in the United States.

- In May 2008 at the 2008 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, Curosurf, or no surfactant replacement therapy. The chosen animal model, the preterm lamb, 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 presented at the 2008 PAS in May 2008 investigated the antimicrobial properties of Surfaxin. In that study, gram-positive and gram-negative bacteria-containing 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 the 2008 PAS in May 2008, a study was presented that assessed the potential for KL_4 to induce an immune response known as anaphylaxis in a well-established animal model. 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 in this animal model, even when the immune system was potentiated and sensitized.

- In May 2007, a study was presented at the 2007 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.

We believe that 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. The clinical relevance of such attributes has not been adequately established and, accordingly, 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.

- In April 2009, we presented a pharmacoeconomic analysis of data from our pivotal SELECT and STAR Phase 3 clinical trials for Surfaxin at the 2009 International Congress on Clinical Pharmacy (ICCP) in Orlando, Florida. The analysis shows that in-hospital costs are higher for infants who require reintubation after surfactant administration and successful extubation, when compared with infants who do not require reintubation. The presentation also included previously-reported data demonstrating that infants treated with Surfaxin in the SELECT and STAR trials required less reintubation compared with infants treated with currently available animal-derived surfactants.

- Our Phase 3 clinical study, SELECT, has demonstrated that Surfaxin is safe and efficacious when used for the prevention of RDS in premature infants. Data taken together from our SELECT and STAR studies demonstrate that Surfaxin improved survival (continuing through at least one year of life) and other outcomes versus the animal-derived 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 into the lung.

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 (dry powder) formulation that is then resuspended 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;
- Potentially eliminating the need for warming; and
- Potentially improve drug product stability with extended shelf life.

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. We restructured our alliance in March 2008 and entered into exclusive license agreements with PMUSA, with respect to the United States, and Philip Morris Products S.A., with respect to all territories outside of the United States. 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*, "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights **–** Philip Morris USA Inc. and Philip Morris Products S.A."

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 lung aerosol delivery. Aerosol is created by pumping KL_4 surfactant drug formulation through a heated capillary wherein the excipients are converted to a 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 surface 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 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 KL_4 surfactant, we have generated an aerosol that:

- retains the surface-tension lowering properties of a functioning surfactant;
- retains the surfactant composition of our liquid KL_4 surfactant;
- has a drug particle size believed to be suitable for deposition into the lung; 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; and
- produces in-vivo evidence of uniform lung distribution and superior efficacy vs. nasal continuous positive airway pressure (nCPAP) alone.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

The only commercial, pulmonary 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 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 37 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 problems 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 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 may not be 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 clinical 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, expand the surfactant-eligible patient population, 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. If approved, Surfaxin will represent the first synthetic, peptide-containing surfactant approved for use in pediatric medicine.

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 a 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 throughout the developed world. The STAR trial demonstrated the overall safety and non-inferiority of Surfaxin compared with 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 data from 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, accordingly, warrants further study.

In April 2009, after previously receiving three Approvable Letters, we received a Complete Response Letter for this NDA. As was the case with the previous letters, which had focused primarily on the Chemistry, Manufacturing and Controls (CMC) section of our NDA, this Complete Response Letter did not question the quality of our clinical trial data or call for additional clinical trials demonstrating safety or efficacy. Rather, this Complete Response Letter was focused certain aspects of the BAT, specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

During our Phase 3 clinical trials, we employed an array of quality control and release tests, but we did not employ a BAT to evaluate biological activity in Surfaxin clinical drug product. We later validated and implemented the BAT as a recurring quality control test to confirm biological activity for Surfaxin release and stability. Based on guidance from the FDA in meetings in 2006 and 2008, to demonstrate comparability between Surfaxin clinical drug product and the to-be-manufactured drug product, we conducted studies with the to-be-manufactured Surfaxin drug product that replicated studies that had been previously conducted using the Surfaxin clinical drug product in the well-established preterm lamb model. These studies demonstrated to the FDA's satisfaction comparability between the Surfaxin clinical drug product and the to-be-manufactured drug product. However, as using the preterm lamb model as a quality control and release test in the future manufacture of Surfaxin is neither cost-effective nor practical, it became necessary to correlate the data demonstrated in the preterm lamb model to the data generated using the BAT. Accordingly, we included data intended to satisfy the FDA on this point in the Complete Response that we submitted in response to an earlier Approvable Letter in October 2008.

Following receipt of the April 2009 Complete Response Letter, at an end-of-review meeting on June 2, 2009, we presented some additional data from the preterm lamb model experiments and the BAT, together with a comprehensive statistical evaluation of that data based on a comparison of regression lines, prepared in accordance with standard statistical methods. We believed that the data adequately demonstrated comparability between the preterm lamb model and the BAT. However, the FDA did not accept our analysis and indicated that, to gain approval of Surfaxin using preclinical data, the studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between the BAT and the preterm lamb model over time. Given the variability observed in the BAT at that time and the expected variability in animal models generally, we and the FDA believed it unlikely that we could establish the degree of consistency that the FDA required using the animal models.

Also at the June 2, 2009 meeting, the FDA suggested that, as an alternative to demonstrating comparability using preclinical data, we could consider conducting a limited clinical trial while simultaneously employing an optimized BAT for release and ongoing stability testing of the to-be-manufactured Surfaxin drug product. On September 2009, we held a teleconference with the FDA and discussed in detail our plans to optimize the precision of the BAT method and its subsequent validation. We also discussed the design of a proposed limited clinical trial and whether conducting such a trial while simultaneously employing the newly-optimized and revalidated BAT could potentially resolve the remaining FDA requirement for Surfaxin approval. We proposed a trial design intended primarily to assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with RDS. The FDA indicated that a PD approach is consistent with their expectation for a limited clinical trial and, subject to further review and ethical consideration, provided direction regarding trial design specifics.

After collaborating with leading academic neonatologists, in November 2009 we submitted to the FDA a proposed protocol for a Surfaxin limited clinical trial that incorporated a PD clinical trial design. However, in February 2010, we received a letter from the FDA advising us that, since an acceptable animal model (preterm lamb) of RDS already exists, a PD clinical trial approach would not be appropriate. As a result, instead of pursuing a limited clinical trial, we are now focused on completing the optimization and revalidation of the BAT and developing a comprehensive preclinical program intended to meet the FDA's requirements.

Prior to initiating a program to optimize the BAT, we submitted our optimization protocol to the FDA for comment. Optimization is now well underway and, while not complete, is presently meeting all pre-specified acceptance criteria. Upon successful conclusion of BAT optimization and revalidation, we plan to conduct a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the preterm lamb model. The results from these studies are intended to demonstrate to the FDA's satisfaction that the BAT is able to adequately discriminate biologically active Surfaxin drug product from inactive Surfaxin drug product and establish the Surfaxin drug product's final acceptance criteria with respect to biological activity (as assessed by the BAT) for release and ongoing stability. We believe that implementing the method improvements to optimize the BAT makes it more likely that the results of the planned preclinical program will demonstrate the level of comparability between data generated using the BAT and the preterm lamb model that the FDA requires.

We believe that compared to the conduct of a PD clinical trial, this approach could reduce the time and expense required to gain potential Surfaxin approval. If our comprehensive preclinical program successfully establishes comparability to the standard set by the FDA, we believe that a Complete Response could be submitted to the FDA in the first quarter of 2011.

Surfaxin LS™ – Lyophilized Surfaxin for RDS in Premature Infants

Surfaxin LS is our lyophilized (dry powder) formulation of Surfaxin, which is resuspended as a liquid just prior to administration. We believe that Surfaxin LS has the potential to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. In addition, we believe that Surfaxin LS may demonstrate characteristics that could provide other clinical benefits.

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 to discuss our proposed development program that would consist of a single Phase 3 clinical trial. Similarly, to gain regulatory approval for Surfaxin LS in Europe, we plan to request a scientific advice meeting with the EMEA. If we can gain the agreement of the two regulatory agencies, we anticipate conducting a single clinical trial to gain regulatory approval for Surfaxin LS in the United States and Europe. We anticipate initiating a clinical program after we have secured appropriate strategic alliances and necessary capital.

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 potentially providing neonatologists with a means of administering KL_4 surfactant to infants without the risks (including serious lung injury and other complications) associated with administration of currently-approved surfactants, which require 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.

In addition, 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, of this total, we estimate that approximately 130,000 are diagnosed with RDS and approximately 86,000 are treated with surfactant replacement therapy. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS)." 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*, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our Capillary Aerosolization Technology." 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. We have continued to conduct certain developmental and preclinical activities to support our regulatory package. We have met with and received guidance from the FDA with respect to the design of our planned Phase 2 clinical program. We are currently advancing our preclinical development activities and preparing to further engage the FDA and foreign regulators with respect to our clinical program. Thereafter, we plan to initiate a Phase 2 clinical program for Aerosurf.

In addition, until such time as it became necessary to conserve our cash resources by limiting our investment in pipeline programs, we undertook development activities focused on the next-generation capillary aerosolization system for use in potential Phase 2/3 clinical trials for Aerosurf and, if approved, future commercial activities. We worked closely 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 suspending that activity, our engineering team has continued to make progress with the design of the next-generation capillary aerosolization system. We plan to reengage with the engineering and design firm following the potential approval of Surfaxin. We will determine the timing and amount of our investment based on an assessment of our financial resources and competing priorities at that time.

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,* "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights **–** Philip Morris USA Inc. and Philip Morris Products S.A."

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 28th 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 prevention or 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.

Resources permitting, we plan in the future 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 seek a strategic alliance and/or other collaborative arrangement prior to further developing our KL_4 surfactant to address this disease.

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, including influenzas such as the type A influenza serotype referred to as H1N1 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.

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 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 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. Enrollment is near completion and top-line results are expected to become available in the second quarter of 2010.

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 (via improvement in mucociliary clearance) of our aerosolized KL_4 surfactant. We anticipate the results from this trial in mid-2010.

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, thereafter determine whether to seek strategic alliances or collaboration arrangements or utilize other financial alternatives to fund their further development and/or worldwide commercialization, if approved. There can be no assurance that we will be successful or that we will be able to enter into any such strategic alliance, collaboration arrangement or financial alternatives. 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 ALI annually and there are no currently approved therapies other than supportive respiratory care.

We believe that our aerosolized KL_4 surfactant may potentially be effective as a preventive measure to treat patients at risk for ALI. We are engaged in research and preclinical studies in collaboration with a prominent academic investigator to assess the use of our KL_4 surfactant to potentially address ALI in an animal model. 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 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 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.

KL_4 Surfactant in Combination with Other Therapeutics to Treat a Wide Range of Disease

A key characteristic of our KL_4 surfactant is its ability to spread throughout the lung and coat the entire surface area of the respiratory tree. We therefore believe that our KL_4 surfactant, either as a liquid or in combination with our capillary aerosolization technology, may be a superior mechanism to deliver small- and large-molecule therapeutics to the lung. We are currently conducting formulation development and preclinical studies to assess the potential of combining our KL_4 surfactant with other active therapies, including potentially antibiotics, protease inhibitors and oligonucleotides. We believe that delivering these therapeutics in combination with our KL_4 surfactant may potentially greatly enhance their effectiveness. If we successfully demonstrate proof-of-concept through these efforts, we would expect to develop and, if approved, commercialize these combination products in collaboration with one or more alliance partners, although there can be no assurance that we will succeed in entering into any such arrangement.

Research and Development

Our research and development activities are initially focused primarily on developing our proprietary KL_4 surfactant technology and capillary aerosolization technology into a series of pipeline programs that would support a significant pediatric critical care 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 are actively assessing various strategic and financial alternatives to secure necessary capital and advance our KL_4 respiratory pipeline programs to maximize shareholder value, although we would prefer to accomplish our objectives through strategic alliances that would provide financial support (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), development capabilities, and ultimately commercial expertise to maximize the potential of our KL_4 surfactant technology. We are also reviewing various financial alternatives that would provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL_4 surfactant technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our pipeline programs.

If we are able to secure the necessary capital, 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 determine whether to seek strategic alliances or collaboration arrangements or utilize other financial alternatives to fund their further development and/or worldwide commercialization, if approved. 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 also rely on contract research organizations (CROs) to support operations of our planned multi-center trials in certain countries;
- 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 expertise in FDA regulatory matters. We also consult extensively with independent FDA and international regulatory experts, including former senior scientific staff of the FDA;
- engineering expertise that supports 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 capabilities to manufacture our KL_4 surfactant for use in pre-clinical and clinical studies. We also rely on third-party manufacturers to manufacture our capillary aerosolization systems and related components; and
- research, analytical and medical device development laboratories and manufacturing facilities and related capabilities, including our 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, 2009, 2008 and 2007, our research and development expenses were $19.1 million, $26.6 million and $26.2 million, respectively.

Manufacturing and Distribution

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 comprised of four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications.

Our product candidates are manufactured by combining raw materials, such as KL_4, which is provided by Bachem California, Inc., and PolyPeptide Laboratories Inc., and other active ingredients, including certain lipids that are provided by suppliers such as Genzyme Pharmaceuticals, a division of the Genzyme Corporation, and Avanti Polar Lipids, Inc. Other than KL_4, for which we have two suppliers, we currently obtain our active ingredients from single sources, although we plan to initiate a program to qualify secondary suppliers when our financial resources permit. Our risk of losing a source of supply is mitigated by the fact that we generally maintain a minimum of six-months supply of all critical active ingredients. 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. Our inactive raw materials and critical components are generally readily available from multiple sources. 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 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*, "Item 2 – 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 we experienced stability failures in certain batches of Surfaxin that had been manufactured by our contract manufacturer. We initiated a comprehensive formal investigation and implemented a corrective action and preventative action (CAPA) plan. We manufactured three new Surfaxin process validation batches in February 2007 and in March 2008 submitted to the FDA 12-month stability data on these new batches. We have since submitted 16-month stability data on these process validation lots. We believe stability data for these and subsequent lots support at least a 12-month shelf life for Surfaxin.

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. For a discussion of certain manufacturing risks and uncertainties, *see* "Item 1A – 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 the drug substances used to make our products, 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 all of our analytical, quality and development activities. The activities conducted in our 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 expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to exploit our internal 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 Totowa facility to support production of our drug product candidates. In February 2010, we completed construction of a new medical device development laboratory, which is equipped to support the assembly of capillary aerosolization system disposable dose packets in a controlled environment in two class 10,000 hoods following clean room procedures. This new laboratory greatly enhances our ability to leverage our internal development engineering resources and manage ongoing preclinical development activities for Aerosurf, while at the same time controlling the related expense and conserving our financial resources.

We plan to have manufacturing capabilities, primarily at our Totowa manufacturing operations, to produce commercial supplies of Surfaxin, if approved, and to meet our anticipated pre-clinical, clinical, formulation development and, if approved, potential future commercial requirements of our other KL_4 surfactant product candidates. During the period of formulation development for our lyophilized KL_4 surfactant, including Surfaxin LS, to conserve our financial resources, we plan to enter into arrangements with one or more contract manufacturing organizations. *See*, Item 2 – Properties.

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*, "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Philip Morris USA Inc. and Philip Morris Products S.A."

To manufacture capillary aerosolization devices and related components for our Phase 2 Aerosurf clinical trials, we expect to utilize third-party contract manufacturers and suppliers. We expect to use third-party integrators to assemble the aerosolization systems for us. We also have the capability to assemble the disposable dose delivery packets at our new medical device development laboratory at our headquarters location in Warrington, Pennsylvania. 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 us or our third-party integrator 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 arranged with Kloehn, Inc. to act as manufacturer of certain components and integrator of the prototype aerosol-generating base unit and disposable dose delivery packets. *See*, "Item 1A – 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 the drug substances used to make our products, 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. In anticipation of potential Surfaxin approval in May 2008, to provide for distribution services, we arranged for ASD Specialty Healthcare, Inc. to act as our sole wholesaler in the United States. This arrangement continues to be available to us.

Our collaboration with Esteve provides that Esteve has responsibility for distribution of our KL_4 surfactant products in Andorra, Greece, Italy, Portugal and Spain. *See*, "–Business Operations – Strategic Alliances and Collaboration Arrangements." In other parts of the world, we plan to evaluate third-party distribution capabilities prior to commercializing in those regions.

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

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 KL_4 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/or commercialization of certain of our KL_4 surfactant products, including Surfaxin and Aerosurf in the Former Esteve Territories.

Potential Alliances and Collaboration Arrangements

We continue to seek strategic alliances and other collaborative arrangements for the development and/or commercialization of our KL_4 surfactant product candidates that would provide financial support (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), development capabilities, and ultimately commercial expertise to advance our KL_4 technology. We also are reviewing various financial alternatives that would provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. *See*, "– Business Strategy," and "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 enforcing 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 exclusivities, including potential orphan drug and new drug product 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. 5,952,303, 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).

U.S. Patent No. 5,164,369; U.S. Patent No. 5,260,273; U.S. Patent No. 5,789,381 and U.S. Patent No. 6, 613,734 have expired on November 17, 2009. The patent term of U.S. Patent No. 5,407,914 has been extended until November 17, 2010 with further extensions potentially available until November 17, 2014. European counterparts of these patents will expire in June 2012. U.S. Patent No. 5,952,303 will expire on March 29, 2017. U.S. Patent No. 5,748,891 will expire on October 22, 2016. U.S. Patent No. 6,013,764 will expire on June 25, 2017. U.S. Patent No. 6,120,795 will expire on March 4, 2017. U.S. Patent No. 6,492,490 will expire on June 25, 2017.

We also have licensed certain pending patent 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 Canada, Europe and Japan.

Our KL_4- Related 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 synthetic peptide containing pulmonary surfactants. Our patent activities have focused particularly on improved formulations and delivery of aerosolized pulmonary surfactant.

In November 2005, we filed U.S. and International patent applications (US 11/274,701 which is now U.S. Patent No. 7,582,312 issued on September 1, 2009 and PCT US/2005/041281, now expired), 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 11/326,885 which is now U.S. Patent No 7,541,331 issued on June 2, 2009 and PCT/US06/000308, now expired), 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/2007/020260, now expired) directed to surfactant compositions and methods of promoting mucus clearance and treating pulmonary disorders such as cystic fibrosis.

In March 2009, we filed International patent application (PCT US/2009/037409) directed to improvements of aerosol delivery system and ventilation circuit adaptor.

Philip Morris USA Inc. and Philip Morris Products S.A.

In March 2008, we restructured our December 2005 strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility from Chrysalis 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 restated our prior agreement as of March 28, 2008 and entered into an Amended and Restated License Agreement with PMUSA with respect to the United States (U.S. License Agreement), and, as PMUSA had 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 on 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, the 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.

As part of 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. 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.

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 (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases. 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. The aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2023, or, in some cases, possibly later. Our license will expire as to each licensed product in a each country on the latest of: (a) the 10^{th} anniversary of the date of the first commercial sale in such country; (b) the date on which the sale of such licensed product ceases to be covered by a valid patent claim in such country, or (c) the date a generic form of the product is introduced in such country. 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, "Item 1A – Risk Factors – If we cannot protect our intellectual property, other companies could use our technology in competitive products. 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"; " – 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 for the treatment of RDS in premature infants. However, as our proposed indication for Surfaxin is for the prevention, rather than treatment, of RDS, it is not certain whether the FDA will apply this regulatory exclusivity to our proposed initial indication for Surfaxin. Accordingly, we are in the process of applying to the FDA to amend this exclusivity designation to include the prevention indication. Alternatively, as we believe that in the context of neonatal RDS, prevention and treatment are nearly identical, 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 enable us to receive regulatory assistance in the further development process, and to access reduced regulatory fees throughout its marketing life. 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 in newborn infants, 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*, "Item 1A – Risk Factors – Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete."

Currently, the FDA has approved surfactants as replacement therapy only for the prevention and treatment of RDS in premature infants. The most commonly used of these approved surfactants are Curosurf® (poractant alfa), which is derived from a chemical extraction porcine (pig) lung, and Survanta® (beractant), 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 Cornerstone Therapeutics Inc. Survanta is marketed by the Abbott Nutritionals, Inc. ONY, 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 and medical device development 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*, "Item 1A – 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*, "Item 1A–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 post-marketing 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 and a Complete Response Letter, 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 and the Complete Response Letter that we received did not require additional clinical trials demonstrating safety and efficacy. Our development programs have, however, been substantially delayed as the FDA has required us to develop additional data to respond to the issues it has raised.

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. In March 2008, the FDA completed a pre-approval inspection of our manufacturing facility in Totowa and issued an Establishment Inspection Report (EIR) indicating an approval recommendation for our Surfaxin NDA. The FDA may determine to re-inspect our Totowa facility or our laboratory facilities located at Warrington, Pennsylvania, at any time. *See*, "Item 1A – 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 the drug substances used to make our products, 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, although the approval of the FDA carries considerable weight, international regulators are not bound by the findings of the FDA and 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 available 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, "Item 1A – 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", "–We may not successfully develop and market our products, and even if we do, we may not become profitable," 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," and " – Even assuming that we gain regulatory approval to market our drugs, if the FDA and foreign regulators later withdraw their approval or otherwise restrict marketing, our business would be materially harmed."

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*, "Item 1A – 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 – Patents and Proprietary Rights."

EMPLOYEES

As of March 1, 2010, we have approximately 77 full-time employees, all employed in the United States. In connection with our manufacturing operations in Totowa, New Jersey, we have 15 employees subject to a collective bargaining arrangement which expires on December 3, 2010.

As of December 31, 2009, we had employment agreements with 12 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. In February 2010, we provided notice of non-renewal with respect to all but the agreements that we maintain with the following officers: Chief Financial Officer, General Counsel, and the senior officers in charge of Manufacturing, Corporate Development, and Human Resources. The employment of the officers whose agreements will not be renewed were not terminated and they will remain as at-will employees and, in lieu of the benefits provided under their employment agreements, will be entitled to certain severance benefits. The loss of services from these executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. *See*, "Item 1A – Risk Factors – We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's website at "http://www.sec.gov." We make available 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.

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 become 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 we can commercialize them. In addition, after making significant investments, the development, 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, 2009, we have an accumulated deficit of approximately $357.6 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, 2009, 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, 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 strategic alliances and other financing alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail 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.

In addition, we may face significant challenges if conditions in the global financial markets do not significantly 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 our CEFFs (which are subject to certain limitations), we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. 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 delay new product development and clinical trial plans.

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 test, make and 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. This approval process includes (i) preclinical studies and clinical trials of each drug product candidate and active pharmaceutical ingredient to establish its safety and effectiveness, and (ii) confirmation by the FDA and foreign regulators that 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 for a drug product on a timely basis or at all.

In particular, we filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. On April 17, 2009, we received a Complete Response Letter for this NDA. We met with the FDA in June 2009 and September 2009 to discuss proposals for resolving the sole remaining issue regarding our BAT. We are currently developing a comprehensive preclinical program that will consist of a series of prospectively-designed, side-by-side preclinical studies employing an optimized and revalidated BAT and the well-established preterm lamb model of RDS. *See*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin for the Prevention of RDS in Premature Infants." The FDA indicated that to gain approval of Surfaxin, data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Even if our current efforts to optimize and revalidate the BAT are successful, we may not succeed with our side-by-side studies or, even if we do succeed with our side-by-side studies, the FDA may not accept the results or may interpret the data in a different manner such that, 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 with respect to Surfaxin could potentially delay or prevent the approval of our other products and would have a material adverse effect on our business.

Even assuming that we gain regulatory approval to market our drugs, if the FDA and foreign regulators later withdraw their approval or otherwise restrict marketing, our business would be materially harmed.

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. Without regulatory approval, we will not be able to market our products. 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 withdrawal of our regulatory approval or significant restriction on our ability to market our products after approval would have a material adverse effect on our business.

The April 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin have caused us to make fundamental changes in our business strategy, which now focuses on securing strategic alliances, and take additional steps to conserve our financial resources, which may subject us to unanticipated risks and uncertainties.

Following receipt of the April 2009 Complete Response Letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce.

Because of the delay in our gaining approval of Surfaxin, we also made fundamental changes in our business strategy. To secure capital and develop and, if approved, commercialize our KL_4 surfactant pipeline programs and products, we are now seeking to enter into strategic alliances, development agreements or other collaboration arrangements in all markets, including the United States, and are reviewing various other financial alternatives that would provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs and meet our capital requirements, including potentially satisfying our loan with Quintiles, and continue our operations. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded.

Assuming that we are able to identify strategic partners and secure such strategic alliances, our ability to execute our current operating plan will be dependent on numerous factors, including, the performance of third-party strategic partners and collaborators with whom we may contract. Under these arrangements, our partners may control key decisions relating to the development, and assuming approval, commercialization, of our products. The rights of our partners would limit our flexibility in considering development strategies and in the alternatives for the commercialization of our products. In addition, if we breach or terminate our strategic alliance agreements or if our strategic partners otherwise fail to conduct their activities in a timely manner, or if there is a dispute about our respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capabilities to commercialize our products in the United States. If we fail to successfully develop these relationships, or if we or our partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of our products.

For example, 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. In that event, we may need to seek other partners and collaboration arrangement, or we may have to develop our own internal capabilities to market the covered products in the Esteve territory without a collaboration arrangement.

As we continue to manage our cash resources and work towards securing potential strategic alliances, we have also reassessed 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. Also, as we reassess our regulatory position and financial resources, 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.

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 April 2009 Complete Response 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 development and 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, such as a decrease in the oxygen level of the blood upon administration, or currently unknown to us. 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 and our aerosolized KL_4 surfactant is the subject of an investigator-initiated Phase 2a trial assessing the safety, tolerability and short-term effectiveness of aerosolized KL_4 surfactant in patients with CF. We are also planning to initiate clinical studies in support of other products in our KL_4 surfactant technology pipeline. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or the drug substances used to make our products, 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 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;
- casualty damage to a facility; and
- shortages of qualified personnel.

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

Manufacturing or quality control problems have in the past occurred and may again occur at our Totowa, New Jersey facility, or may occur at the facilities of a contract manufacturer of 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 similar 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.

We manufacture our own drug products at our facility in Totowa, New Jersey. 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 preclinical experiments and 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 identify or maintain relationships with our manufacturers, assemblers and integrator of our capillary aerosolization systems or subcomponents, the timeline of our plans for the development and, if approved, commercialization of Aerosurf could suffer.

In connection with the development of the drug-device combination aerosol formulation of our KL_4 surfactant technology, including Aerosurf, we currently plan to rely on third-party contract manufacturers to manufacture and assemble the subcomponents of our capillary aerosolization technology and to assemble and integrate the component parts to support our preclinical experiments, planned clinical studies and potential commercialization of Aerosurf. Certain of these 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.

We 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 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 excipients 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 excipients, 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 related 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 component parts, many of which are comprised of a large number of subcomponent parts that we expect will be produced by potentially a large number of manufacturers. We and our suppliers may not be able to (i) produce our drug substances, or manufacture materials and excipients 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 excipients or one or more of our drug product device subcomponents, components and subassemblies. If we do not maintain manufacturing and service relationships that are important to us and are not able to identify a replacement supplier or vendor or develop our own manufacturing capabilities, our ability to obtain regulatory approval for our products could be impaired or delayed and our costs could substantially increase,. 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.

Under our restructured license agreement with PMUSA/PMPSA, we now have rights to develop the capillary aerosolization technology, which will require us to build internal development capabilities or enter into future collaborations or other arrangements to gain the engineering expertise required to support our development activities.

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.

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. If we are unable to identify design engineers and medical device experts to support our development efforts, including 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.
- To advance the development of our capillary aerosolization technology, we will require additional capital and may seek a potential strategic partner or third-party collaborator to provide financial support and the necessary medical device development expertise. 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.

The realization of any of the foregoing risks would have a material adverse effect on our business.

To market, sell and distribute our products, we plan to enter into distribution arrangements and marketing alliances, which could require us to give up rights to our drug product candidates.

We have limited experience in marketing or selling pharmaceutical products and have a limited marketing and sales team. To market, sell and distribute our products, we may rely on third-party distributors to distribute, or enter into marketing alliances to sell, our products, both internationally and 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.

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 related to providing incentives and inducements. Violation of these laws can result in substantial penalties.

We intend to market and sell Surfaxin, if approved, through one or more strategic partners or other collaborators. 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.

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 and the commercial requirements to meet changing customer demand are 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.

We will require significant additional capital to continue our planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution.

Until such time as we are able to commercialize any of our lead products, if approved, and generate revenues, we will need substantial additional funding to conduct our ongoing research and product development activities and continue to operate as a going concern. Our operating plans require that we make prudent investments in preclinical studies and our drug product and device development programs, and focus our resources on being in a position to initiate key clinical programs only after we have secured strategic and financial alternatives needed to provide the necessary capital. We would prefer to accomplish our objectives through strategic alliances. If we are unable to raise substantial additional funds through strategic alliances or other alternatives, including potentially, future debt and equity financings, we may be forced to further limit many, if not all, of our programs, which could have a material adverse impact on our business plan. In the meantime, as we attempt to conserve our financial resources, we may experience additional delays in certain of our development programs.

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 Quintiles, which is due and payable, together with approximately $2.0 million accrued interest, on April 30, 2010. We are pursuing a potential strategic restructuring of this loan with Quintiles and we are also considering alternative means of financing its payment should that become necessary. The Quintiles loan is secured by substantially all of our assets, including our proprietary technologies, 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. A breach of any of these restrictions could result in a default under the Quintiles loan documents. If a default were to occur, Quintiles 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 Quintiles, whether at maturity or in connection with acceleration of the loan following a default, Quintiles 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. and a loan from the Commonwealth of Pennsylvania, Department of Community and Economic Development, Machinery and Equipment Loan Fund (MELF). As of December 31, 2009, an aggregate of $1.0 million was outstanding under the facility and the loan. If we were unable to pay our creditors when due amounts owed, they would have the right to proceed against the collateral securing the debt. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities – GE Business Financial Services Inc."

If we require additional funds to support our capital programs, there can be no assurance that we will be able to secure a lender that 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 become unavailable to us if we do not comply with their conditions.

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 being fully 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 public filings.

Our common stock is listed for quotation on The Nasdaq Global Market. During the twelve month period ended December 31, 2009, the price of our common stock ranged from $0.33 to $2.40. 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, 2009, the average daily trading volume in our common stock was approximately 3,586,958 shares and the average number of transactions per day was approximately 4,621. The instability observed in our daily volume and number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices.

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. 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.

If we are unable to regain compliance with the Minimum Bid Price Requirement of The Nasdaq Global Market prior to June 1, 2010, our stock price may decline and our common stock may be subject to delisting from Nasdaq. If our stock were no longer listed on Nasdaq, the liquidity of our securities would be impaired.

On December 2, 2009, we received a letter from The Nasdaq Stock Market indicating that for 30 consecutive business days our common stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5450(a)(1). Under the Nasdaq Listing Rules, if during the 180 calendar days following the date of the notification, or prior to June 1, 2010, the closing bid price of our stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and the common stock will continue to be eligible for listing on The Nasdaq Global Market.

If we do not achieve compliance with the minimum bid price requirement by June 1, 2010, Nasdaq will provide us with written notification that the common stock is subject to delisting. We may, at that time, appeal Nasdaq's determination to a Nasdaq Hearing Panel. Such an appeal, if granted, would stay delisting until a ruling by the panel. Alternatively, if we are at that time in compliance with all initial listing standards for the Nasdaq Capital Market other than the minimum bid price requirement, we could apply to transfer the listing of our common stock to the Nasdaq Capital Market and thereby receive an additional grace period of 180 days to regain compliance with the minimum bid price requirement.

If our stock price does not exceed the minimum bid price of $1.00 within the time frames set forth above, our common stock will be subject to delisting. If our common stock were no longer listed on The Nasdaq Global Market or the Nasdaq Capital 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.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our CEFFs, 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. The issuance of shares of our common stock under the CEFFs has, and the issuance of shares 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 (from 6% to 15%, depending upon the market price) to the daily volume weighted average price of our common stock on each trading day, which will further dilute the interests of other stockholders. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)." Furthermore, 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.

We also filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-151654) on June 13, 2008 (which was declared effective shortly thereafter) 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. We have issued securities pursuant to this shelf registration statement on two prior occasions, including in February 2010, and may do so again in the future in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

As of March 5, 2010, we had 153,892,960 shares of common stock issued and outstanding. In addition, as of December 31, 2009, approximately (i) 14.8 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 17.8 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 137,435 shares of our common stock were 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, 2009, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately seventeen percent (17%) 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. 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 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 successfully obtain patents, defend our patents and otherwise prevent others from infringing our proprietary rights, including our trade secrets.

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.

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, both individually and 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, began to expire in November 2009, and will expire on various dates ending in 2017 or, in some cases, possibly later. Of the patents that have expired, we have filed to extend our most important patent one year, with further extensions possible into 2014. 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*, "– 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 members of our executive management team 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 August 2009, Dr. Capetola resigned his position with us as President and Chief Executive Officer and a member of our Board of Directors. Our Board elected W. Thomas Amick, our Chairman of the Board, to act as Chief Executive Officer for an interim period. Mr. Amick, who is otherwise employed by another biotech company as its Chief Executive Officer, is able to devote only a portion of his time to his duties as our interim Chief Executive Officer. Until such time as we employ a full-time Chief Executive Officer, our dependency on the remaining members of our management team to exhibit strong leadership skills and effectively manage our operations is increased. While we expect that, once we have secured sufficient strategic and financial resources to support the continuing development of our KL_4 surfactant technology and support our operations, we will seek to attract candidates to lead our management team, there can be no assurances that we will be successful in that endeavor.

As of December 31, 2009, we had employment agreements with 12 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. In February 2010, we provided notice of non-renewal with respect to all but the agreements that we maintain with the following officers: Chief Financial Officer, General Counsel, and the senior officers in charge of Manufacturing, Corporate Development, and Human Resources. The employment of the officers whose agreements will not be renewed were not terminated and they will remain as at-will employees and, in lieu of the benefits provided under their employment agreements, will be entitled to certain severance benefits. The loss of services from these executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals.

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 lawsuits brought by their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors have greater resources and more experience than we, 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 that 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 annual 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 examine 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 Amended and 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 KL_4 surfactant 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 an analytical and development laboratory within our Warrington, Pennsylvania headquarters location. 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.

In February 2010, we completed construction of a new medical device development laboratory within our Warrington, Pennsylvania headquarters location that will support the further development of our capillary aerosolization systems. The facility includes capabilities to assemble disposable dose packets in a controlled environment in two class 10,000 hoods following clean room procedures. We also use this laboratory for component parts and finished assembly inspection and storage. Having this new laboratory greatly enhances our ability to leverage our internal development engineering resources and manage ongoing preclinical development activities for Aerosurf, while at the same time controlling the related expense and conserving our financial resources.

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. The lease for our Totowa facility expires in December 2014. In addition to customary terms and conditions, the lease is subject to the landlord's right, upon two years' prior notice, to terminate the lease early. This early 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, depending upon the timing of the notice, if we satisfy certain financial conditions, the landlord would be obligated to make early termination payments to us. 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 2012, 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.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions to which we are a party or of which our property is the subject 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 or financial condition.

ITEM 4. RESERVED.

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 1, 2010, the number of stockholders of record of shares of our common stock was approximately 142 and the number of beneficial owners of shares of our common stock was approximately 25,924. As of March 5, 2010, there were 153,892,950 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 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
First Quarter 2009	$ 0.91	$ 1.48
Second Quarter 2009	$ 0.71	$ 2.40
Third Quarter 2009	$ 0.33	$ 1.69
Fourth Quarter 2009	$ 0.61	$ 1.38

We have not paid dividends on our common stock and do not expect to declare and pay dividends on our common stock in the foreseeable future.

Sales of Unregistered Securities

During the 12 months ended December 31, 2009, 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, 2009. During 2009, we completed nine draw downs under our CEFFs with Kingsbridge and issued an aggregate of 10,732,615 shares of our common stock in connection with these draw downs. The shares of common stock issued under our CEFFs were issued pursuant to the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(2) of such act for transactions not involving a public offering. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)."

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, 2009, 2008 and 2007 and with respect to the Consolidated Balance Sheets as of December 31, 2009 and 2008 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, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 and 2005 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 and the information disclosed in "Item 7 - - Management's Discussion and Analysis of Financial Condition and Results of Operations," included elsewhere in this Annual Report.

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

	For the year ended December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Revenues from collaborative agreements	$ -	$ 4,600	$ -	$ -	$ 134
Operating Expenses:					
Research and development	19,077	26,566	26,200	23,716	24,137
General and administrative	10,120	16,428	13,747	18,386	18,505
Restructuring charges	–	–	–	4,805	–
In-process research and development	–	–	–	–	16,787
Total expenses[(1)]	29,197	42,994	39,947	46,907	59,429
Operating loss	(29,197)	(38,394)	(39,947)	(46,907)	(59,295)
Other (expense) / income	(1,043)	(712)	(58)	574	391
Net loss	$ (30,240)	$ (39,106)	$ (40,005)	$ (46,333)	$ (58,904)
Net loss per common share - basic and diluted	$ (0.26)	$ (0.40)	$ (0.49)	$ (0.74)	$ (1.09)
Weighted average number of common shares outstanding	115,200	98,116	81,731	62,767	54,094

(1) Included in the net loss for the years ended December 31, 2009, 2008, 2007 and 2006 were non-cash charges for stock-based compensation for employees in accordance with ASC Topic 718 of $2.7 million, $4.6 million, $5.3 million and $5.5 million, respectively.

Consolidated Balance Sheet Data:
(in thousands)

	December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Cash and investments	$ 15,741	$ 24,792	$ 53,007	$ 26,402	$ 50,908
Working capital	176	15,551	43,149	18,999	33,860
Total assets	21,403	32,889	62,744	34,400	56,008
Long-term obligations, less current potion	1,118	12,090	13,494	12,110	3,562
Total stockholder's equity	$ 4,487	$ 10,933	$ 38,781	$ 14,322	$ 34,838

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*, "Item 15 – 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, 2009, 2008 and 2007.

- **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 our novel KL_4 proprietary technology, which 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 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 respiratory problems.

We are developing our lead products, Surfaxin®(lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. Our research and development efforts are currently focused 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. We further believe that Surfaxin, Surfaxin LS and Aerosurf, have the potential to greatly improve the management of RDS and, collectively, represent the opportunity, over time, to significantly expand the current RDS worldwide annual market.

In addition to our lead products, we plan over time to develop our KL_4 surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. Our KL_4 surfactant is in clinical development to potentially address pediatric patients with Acute Respiratory Failure (ARF) and patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL_4 surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL_4 surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

An important priority is to secure strategic and financial resources to potentially maximize the inherent value in our KL_4 surfactant technology. We would prefer to accomplish our objectives through strategic alliances. With respect to our lead products, we are actively engaged in discussions with potential strategic and/or financial partners, although there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded. With respect to our early stage exploratory programs, our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development.

We have focused our current resources on our lead products, primarily to address the requirements to gain the potential approval of Surfaxin in the United States. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL_4 surfactant technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our pipeline programs.

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business" of this Annual Report on Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL_4 pipeline programs.

As of December 31, 2009, we had cash and cash equivalents of $15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of $16.5 million ($15.1 million net). Also, as of December 31, 2009, our $10.5 million loan with Quintiles is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan: however, there can be no assurance that any such restructuring will occur. Currently, under our two Committed Equity Financing Facilities (CEFFs), we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of $69.5 million. However, as of March 1, 2010, neither CEFF was available because the market price of our common stock price was below the minimum price required to utilize the facility. During 2009, we raised aggregate gross proceeds of $22.0 million. In May 2009, we completed a registered direct public offering in resulting in gross proceeds of $11.3 million ($10.5 million net), and, throughout 2009, we raised an aggregate of $10.7 million from 10 draw-downs under our CEFFs. *See*, "– Committed Equity Financing Facilities (CEFFs)", and "– Financings Pursuant to Common Stock Offerings."

Our future capital requirements depend upon many factors, including the success of our efforts to secure one or more strategic alliances or other collaboration arrangements to support our product development activities and, if approved, commercialization plans. We are currently focused on developing our lead KL_4 surfactant products, Surfaxin LS, Aerosurf and Surfaxin, to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that we will be able to secure strategic partners or collaborators to support and advise our activities, that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product 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. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements and continue our operations. Even if we succeed in securing strategic alliances, 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 for the year ended December 31, 2009, in Part IV to this Annual Report on Form 10-K.

Revenue recognition under strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. 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, 2009, 2008 and 2007 was $30.2 million (or $0.26 per share), $39.1 million (or $0.40 per share), and $40.0 million (or $0.49 per share), respectively. Included in the net loss for the years ended December 31, 2009, 2008 and 2007 were stock-based compensation expenses of $2.7 million (or $0.02 per share), $4.6 million (or $0.05 per share), and $5.3 million (or $0.06 per share), respectively.

Revenue

The company did not record any revenues in 2009 and 2007.

In March 2008, we restructured our December 2005 strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility from Chrysalis for the further development of the capillary aerosolization technology. As part of the restructuring, Chrysalis completed a technology transfer to us, provided development support through June 30, 2008, and also paid us $4.5 million to support our future development activities, which we recognized as revenue in 2008. *See*, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Philip Morris USA Inc. and Philip Morris Products S.A."

Research and Development Expenses

Research and development expenses for the years ended December 31, 2009, 2008 and 2007 were $19.1 million, $26.6 million and $26.2 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands) Research and Development Expenses:	Year Ended December 31, 2009	2008	2007
Manufacturing development	$ 9,118	$ 14,165	$ 11,888
Development operations	7,100	9,113	10,196
Direct pre-clinical and clinical programs	2,859	3,288	4,116
Total Research and Development Expenses [(1)]	$ 19,077	$ 26,566	$ 26,200

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

Manufacturing Development

Manufacturing development includes the cost of our 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. Additionally, in 2008 costs included activities to address issues identified in an Approvable Letter that we received from the FDA with respect to Surfaxin in May 2008 (May 2008 Approvable Letter).

The decrease in manufacturing development expenses in 2009 as compared to 2008 is primarily due to our efforts in 2009 to conserve financial resources following receipt of the April 2009 Complete Response Letter.

The increase in manufacturing development expenses in 2008 as compared to 2007 is primarily due to: (i) expenditures in 2008 to support our quality assurance and analytical chemistry capabilities, including implementation and validation of analytical methods and quality testing of drug product for our development programs; (ii) activities related to preparation of the Complete Response to the May 2008 Approvable Letter; and (iii) purchases of active ingredients for the production of Surfaxin.

Manufacturing development expenses included charges of $0.4 million, $0.8 million and $0.7 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, respectively.

Development Operations

Development operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our KL_4 surfactant development programs; (ii) medical affairs activities to provide scientific and medical education support in connection with our KL_4 surfactant technology pipeline programs; (iii) 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 planned Phase 2 clinical trials and; (iv) pharmaceutical development activities, including development of a lyophilized (dry powder) formulation of our KL_4 surfactant. These costs include personnel, expert consultants, outside services to support regulatory, data management and device development activities, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The decrease in development operations expenses in 2009 as compared to 2008 is primarily due to our efforts in 2009 to conserve financial resources and limit investment in our KL_4 respiratory pipeline programs following receipt of the April 2009 Complete Response Letter. The decrease in development operations expenses in 2008 as compared to 2007 is primarily due to cost reductions resulting from the relocation of our analytical testing and pharmaceutical development activities previously performed at our laboratories located in Doylestown, Pennsylvania, and Mountain View, California, and consolidation of those activities into our new laboratory space in Warrington, Pennsylvania, in the fourth quarter of 2007. The decrease in 2008 from 2007 was partially offset by expenditures in 2008 associated with our medical affairs capabilities, including medical science liaisons and symposiums at key pediatric medical meetings in anticipation of the potential approval and commercial launch of Surfaxin in May 2008. Expenses associated with medical affairs activities were $0.6 million, $2.0 million and $0.8 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Development operations expenses included charges of $0.3 million, $0.7 million and $0.9 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, 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; (iii) activities related to addressing the items identified in the April 2009 Complete Response Letter; and (iv) activities related to preparation of the Complete Responses (submitted in November 2007 and October 2008, respectively) to an Approvable Letter received from the FDA with respect to Surfaxin in April 2006 (April 2006 Approvable Letter) and the May 2008 Approvable Letter.

Direct pre-clinical and clinical programs expenses in 2009 included: (i) costs associated with activities to address issues identified in the April 2009 Complete Response 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 Surfaxin LS and Aerosurf for RDS in premature infants.

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 following receipt of the May 2008 Approvable Letter.

The decrease in direct pre-clinical and clinical program expenses in 2009 compared to 2008 and 2007 is primarily due to our efforts to conserve financial resources and limit our investment in research and development programs in anticipation of potentially securing a strategic or financial alternative to fund our research and development activities.

Research and Development Expenses by Category

We also track our research and development expenses in major categories as shown in the following table:

	2009	2008	2007
Salaries & Benefits	$ 8,693	$ 11,651	$ 9,808
Contracted Services	4,832	6,378	8,522
Rents & Utilities	1,310	1,628	2,105
Depreciation	1,235	1,511	1,135
Raw Materials & Supplies	1,466	2,241	1,091
Stock-Based Compensation	694	1,503	1,681
All Other	847	1,654	1,858
Total	$ 19,077	$ 26,566	$ 26,200

Year-to-year changes in salaries, benefits and stock-based compensation generally reflect changes in the size and mix of our employee base over time. In the second half of 2007, we increased our workforce in anticipation of the potential commercial launch of Surfaxin in 2008 and, with the prospect of generating revenues, a potential acceleration of our investment in our pipeline programs. We maintained our employee base at approximately the same level throughout 2008. Following receipt of the April 2009 Complete Response Letter for Surfaxin, we reduced our workforce and restructured certain functions in research and development, primarily medical affairs. *See*, "– Results of Operations – General and Administrative Expenses."

Contracted services include the cost of pre-clinical studies, clinical trial activities, certain components our manufacturing operations, quality control and analytical testing of our drug product, biological activity testing, consulting services, aerosol device design and engineering services, etc. Contracted services decreased over the three-year period primarily due to limiting our investment in our KL_4 pipeline programs to conserve financial resources following receipt of the May 2008 Approvable Letter.

Rents and utilities are associated with our leased manufacturing, laboratory and related facilities, including our manufacturing operations in Totowa, New Jersey. The decrease in rents and utilities over the three-year period is due to termination of leases for office and analytical laboratory space in Doylestown, Pennsylvania, and Mountain View, California, in mid-2008. The activities performed at these locations were consolidated in the fourth quarter of 2007 into our new analytical and development laboratory at corporate headquarters at, in Warrington, Pennsylvania.

Depreciation is associated with manufacturing and laboratory equipment, as well as leasehold improvements at our manufacturing operations in Totowa and our laboratories and related space at our headquarters in Warrington, Pennsylvania. The increase in depreciation from 2007 to 2008 is associated with investments made to complete the new analytical and development laboratory in Warrington, Pennsylvania, at the end of 2007. Approximately $300,000 of depreciation in 2008 (and 2009) represents a full year of depreciation with respect to the new laboratory. The decline from 2008 to 2009 is due to our limiting purchases of equipment during 2008 and 2009 to conserve financial resources. In addition, certain older assets became fully depreciated in this period, resulting in a decrease in depreciation expense.

Raw materials and supplies consist of purchases of our active pharmaceutical ingredients for the manufacture of our KL_4 product candidates and supplies to support our manufacturing and laboratory operations, including component parts for the disposable dose delivery packets and patient interface system necessary to administer Aerosurf via our novel capillary aerosolization systems.

All other includes the cost of employee travel, insurances, shipping and taxes.

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, 2009, 2008, and 2007 were $10.1 million, $16.4 million, and $13.7 million, respectively. General and administrative expenses included charges of $2.2 million, $3.1 million and $3.6 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, respectively.

Expenses for pre-launch commercial activities for the years ended December 31, 2009, and 2008 and 2007 were $0.7, $5.0 million, and $2.2 million, respectively. A significant component of 2008 and 2007 general and administrative expenses is associated with pre-launch commercial activities to prepare for the potential approval and commercial launch of Surfaxin in May 2008. These activities began in the second half of 2007 and were accelerated in early 2008 up to receipt of the May 2008 Approvable Letter. Following receipt of the May 2008 Approvable Letter, we scaled back our commercial activities. Throughout the remainder of 2008 and into 2009, we made limited investments in our commercial capabilities in anticipation of the potential approval of Surfaxin in the United States. Following receipt of the April 2009 Complete Response Letter, we have reassessed our business strategy and have curtailed investment in commercial capabilities. We no longer plan to establish our own specialty pulmonary commercial organization to launch our KL_4 surfactant products in the Unites States and are now seeking to enter into strategic alliances to support our research and development programs and, if approved, to commercialize our products in all markets, including the United States. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded.

In addition, following receipt in April 2009 Complete Response Letter, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We incurred a one-time charge of $0.6 million ($0.4 million in general and administrative expenses and $0.2 million in research and development expenses) in 2009 related to the workforce reduction. As of December 31, 2009, we had 77 full-time employees, the majority of which are devoted to research and development.

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 our business operations for the foreseeable future. We may make additional investments in the future to enhance these capabilities as and when required to meet the needs of our business.

To sustain and perfect our potential competitive position, we expect to invest in maintaining our existing patent portfolio, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities, and when appropriate, patent extensions, new patents, new trademarks, and new regulatory exclusivity designations, when available. *See*, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

Other Income / (Expense)

Other income / (expense), net was ($1.0) million, ($0.7) million and ($0.1) million for the years ended December 31, 2009, 2008 and 2007, respectively, as summarized in the chart below:

(Dollars in thousands)	Year Ended December 31,		
	2009	**2008**	**2007**
Interest income	$ 48	$ 842	$ 1,794
Interest expense	(1,096)	(1,614)	(1,906)
Other income / (expense)	5	60	54
Other income / (expense), net	$ (1,043)	$ (712)	$ (58)

Interest income consists of interest earned on our cash and marketable securities. The decrease in interest income in 2009 and 2008 is due to a general decline in market interest rates and in our average cash and marketable securities balance.

Interest expense consists of interest accrued on the outstanding balance of our loan with Quintiles and under our equipment financing facilities. In addition, interest expense includes $0.5 million, $0.5 million and $0.5 million for the years ended December 31, 2009, 2008 and 2007, respectively, associated with the amortization of deferred financing costs for warrants issued to Quintiles in October 2006 as consideration for restructuring our loan in 2006. The decrease in interest expense in 2009 and 2008 is due to a decline in the variable interest rate on our Quintiles loan, which is equal to the U.S. prime rate.

Other income / (expenses) primarily consists of proceeds from the sale of our Commonwealth of Pennsylvania research and development tax credits of $5,000, $0.1 million, and $0.2 million for the years 2009, 2008 and 2007, respectively. The decrease in proceeds from the sale of these tax credits is due to more credits being available for sale in 2007 and 2008 as compared to 2009.

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 the prevention of RDS, if approved.

Following receipt of the April 2009 Complete Response Letter for Surfaxin, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL_4 technology through strategic alliances or other collaboration arrangements. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

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. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors, which is included in our financial statements in this report, contains a notation related to our ability to continue as a going concern. 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 strategic and collaborative arrangements with potential partners and/or future debt and equity financings, 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 development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, 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. Our December 31, 2009 financial statements 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 we be unable to continue in existence.

Our future capital requirements depend upon many factors, including the success of our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL_4 surfactant products to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that we will be able to secure strategic partners to support our activities, that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product 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. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements and continue our operations. 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.

As of December 31, 2009, we had cash and cash equivalents of $15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of $16.5 million ($15.1 million net). Also, as of December 31, 2009, our $10.5 million loan with Quintiles is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan: however, there can be no assurance that any such restructuring will occur. Currently, under our two CEFFs, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of $69.5 million. However, as of March 5, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available because the market price of our common stock was below the minimum price required ($1.15 and $0.60, respectively) to utilize the facility. During 2009, we raised aggregate gross proceeds of $22.0 million. In May 2009, we completed a registered direct public offering in resulting in gross proceeds of $11.3 million ($10.5 million net), and, throughout 2009, we raised an aggregate of $10.7 million from 10 draw-downs under our CEFFs. *See*, "– Committed Equity Financing Facilities (CEFFs)," and "– Financings Pursuant to Common Stock Offerings."

To meet our capital requirements, we continue to consider multiple strategic alternatives, including, but not limited to potential business alliances, commercial and development partnerships, additional financings and other similar opportunities, although there can be no assurance that we will take any further specific actions or enter into any transactions. Until such time as we secure the necessary capital, we plan to continue conserving our financial resources, predominantly by limiting investments in our pipeline programs. *See*, "Item 1A – Risk Factors – We will require significant additional capital to continue our planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution," and "– The terms of our indebtedness may impair our ability to conduct our business," "– Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our CEFFs, 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 $15.7 million, $24.8 million and $53.0 million as of December 31, 2009, 2008 and 2007, respectively. The decrease of $9.1 million in 2009 is primarily due to $30.0 million used in operating activities, capital expenditures and principal payments on equipment loans, partially offset by proceeds of $10.4 million from financings under our CEFFs and $10.5 million from our May 2009 Registered Direct Offering. *See*, "– Committed Equity Financing Facilities (CEFFs)", and "– Financings Pursuant to Common Stock Offerings."

Cash Flows Used in Operating Activities

Cash flows used in operating activities were $27.4 million, $31.8 million and $29.4 million for the years ended December 31, 2009, 2008 and 2007, 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. *See*, "– 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 From / (Used in) Investing Activities

Cash flows from / (used in) investing activities include capital expenditures of $0.1 million, $0.6 million and $3.8 million for the years ended December 31, 2009, 2008 and 2007, 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 conducted at locations in Doylestown, Pennsylvania, and Mountain View, California. The new laboratory expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to exploit our internal 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 terminated in 2008. *See*, "– Contractual Obligations."

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 provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs. As of December 31, 2009, the company did not have any available-for-sale marketable securities.

Cash Flows from Financing Activities

Cash flows from financing activities were $18.3 million, $4.2 million and $59.7 million for the years ended December 31, 2009, 2008 and 2007, respectively, as summarized in the chart below:

(In millions)	Year Ended December 31, 2009	2008	2007
Financings under CEFFs	$ 10.3	$ 6.3	$ 7.0
Financings pursuant to common stock offerings	10.5	–	51.7
Proceeds from equipment financing facilities	–	0.9	2.9
Debt service payments	(2.5)	(3.0)	(1.9)
Cash flows from financing activities, net	$ 18.3	$ 4.2	$ 59.7

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 Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under 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. Each CEFF is available for a period of two or three years from inception. 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, 2009, we had two CEFFs available for future financings as follows: the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). A third CEFF entered in April 2006 expired on May 12, 2009 and is no longer available. 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, 2009	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008 CEFF	June 18, 2011	$ 1.15	90% of the closing market price on the day preceding the first day of draw down	8	19.3	$ 60.0	12.8	$ 51.8
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60		6	15.0	$ 25.0	7.1	$ 17.7

(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 period 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 that we originally designated for the overall draw down is reduced for each such day by 1/8th in the case of the December 2008 CEFF, and 1/6th in the case of the May 2008 CEFF, respectively . 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:

- 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
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.

In connection with the December 2008 CEFF, we issued a warrant to Kingsbridge on December 22, 2008 to purchase up to 675,000 shares of our common stock at an exercise price of $1.5132 per share. The warrant expires in May 2014 and 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. As of December 31, 2009, this warrant had not been exercised.

In connection with the May 2008 CEFF, we issued a warrant to Kingsbridge on May 22, 2008 to purchase up to 825,000 shares of our common stock at an exercise price of $2.506 per share. The warrant 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, 2009, this warrant had not been exercised.

In connection with the 2006 CEFF, we issued a Class C Investor Warrant to Kingsbridge on April 17, 2006 to purchase up to 490,000 shares of our common stock at an exercise price equal to $5.6186 per share. The warrant expires in October 2011 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.8 million. As of December 31, 2009, this Class C Investor Warrant had not been exercised.

In connection with a CEFF that we entered in 2004, we issued a Class B Investor Warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to $12.0744 per share. The warrant expired unexercised in January 2010.

CEFF Financings

The financings that we completed under the December 2008 CEFF are:

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
April 8, 2009	806	$ 1,000	$ 1.24
May 7, 2009	1,273	1,000	0.79
September 23, 2009	1,793	1,583	0.88
October 13, 2009	1,909	1,800	0.94
October 21, 2009	2,101	1,900	0.90

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

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
July 11, 2008	1,105	$ 1,563	$ 1.41
July 31, 2008	992	1,500	1.51
October 17, 2008	914	1,313	1.44
November 20, 2008	221	250	1.13
January 2, 2009	479	500	1.04
January 16, 2009	419	438	1.04
February 18, 2009	857	1,000	1.17
March 31, 2009	1,015	1,094	1.08
October 13, 2009	559	606	1.09

The financings that we completed under the now expired 2006 CEFF are:

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
May 29, 2006	1,079	$ 2,188	$ 2.03
October 11, 2006	1,205	2,300	1.91
November 10, 2006	1,372	3,000	2.19
February 22, 2007	943	2,000	2.12
October 12, 2007	1,909	5,000	2.62
September 9, 2008	676	1,250	1.85

Financings Pursuant to Common Stock Offerings

Historically, we have funded, 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, 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.

In February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of $0.60 per unit, resulting in gross and net proceeds to us of $16.5 million and approximately $15.1 million, respectively. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of $0.85, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis.

In May 2009, we completed a registered direct offering of 14,000,000 shares of our common stock and warrants to purchase 7,000,000 shares of our common stock, sold as units to select institutional investors, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at an offering price of $0.81 per unit, resulting in gross and net proceeds to us of $11.3 million and $10.5 million, respectively. The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of $1.15, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis.

As of December 31, 2009 and March 1, 2010, respectively, up to $138.7 million and $122.2 million of our securities are potentially available for issuance pursuant to the 2008 Universal Shelf.

2005 Universal Shelf

In October 2005, we filed a universal shelf registration statement on Form S-3 (File No. 333-128929) (2005 Universal Shelf) 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.

Debt

Historically, we have funded, 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 Quintiles

Quintiles extended to us a secured, revolving credit facility, which we restructured in October 2006. The outstanding principal balance of the loan, $8.5 million, is due and payable on April 30, 2010, together with all unpaid interest accrued since July 1, 2006. Since October 2006, interest is calculated at the prime rate, compounded annually. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. In addition, our obligations to Quintiles under the loan agreement are secured by a security interest in substantially all of our assets, subject to limited exceptions set forth in the related security agreement.

Also in October 2006, in consideration of Quintiles's agreement to restructure the loan, we entered into a Warrant Agreement with Quintiles, pursuant to which Quintiles has the right to purchase 1.5 million shares of our common stock at an exercise price of $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 Quintiles loan agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise.

As of December 31, 2009, the outstanding balance under the loan was $10.5 million ($8.5 million principal and $2.0 million accrued interest) and was classified as a current liability on the Consolidated Balance Sheets as of such date.

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the Quintiles loan of $0.3 million, $0.5 million and $0.7 million, respectively. The decrease in interest expense in 2009 and 2008 is due to declines in the prime rate during 2008 ranging from 7.25% to 3.25%. During 2009, the prime rate remained at 3.25%. In addition, for the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to Quintiles in October 2006 of $0.5 million, $0.5 million and $0.5 million, respectively.

Equipment Financing Facilities

Historically, we have funded our purchases of capital expenditures through the use of equipment financing facilities, although we currently do not have a facility available. The outstanding principal balance of these facilities as of December 31, 2009 and 2008 was as follows:

(in thousands)	**2009**	**2008**
GE Business Financial Services, Inc.		
Short-term	$ 538	$ 2,385
Long-term	65	664
Total	603	3,049
Pennsylvania Machinery and Equipment Loan		
Short-term	59	57
Long-term	363	428
Total	422	485
Total Short-term	597	2,442
Total Long-term	428	1,092
Total	$ 1,025	$ 3,534

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. The right to draw under this Facility expired on November 30, 2008. Over the term of the Facility, we received $7.2 million, $4.0 million of which was applied to prepayment of a prior facility and $2.3 million of which was associated with construction and equipment for the analytical and development laboratory that we built in our Warrington, Pennsylvania headquarters in 2007.

Proceeds received under the Facility were $0.0 million, $0.4 million and $6.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. Advances under the Facility 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 prior 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 $2.4 million, $3.0 million and $1.2 million for the years ended December 31, 2009, 2008 and 2007, respectively. Interest expense under the Facility was $0.2 million, $0.5 million and $0.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. The remaining outstanding loan balance under the Facility was $0.6 million as of December 31, 2009, which will be paid over the next 21 months, with the final payment in September 2011.

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 Quintiles 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 Quintiles (as discussed above).

Pennsylvania – Department of Community and Economic Development – Machinery and Equipment Loan Fund

We entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department) in September 2008, 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 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 accrues at a fixed rate of five percent (5.0%) per annum. 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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2009, 2008 or 2007, or for the periods then ended.

Contractual Obligations

Payments due under contractual debt obligations at December 31, 2009, including principal and interest, are as follows:

(in thousands)	2010	2011	2012	2013	2014	There-after	Total
Loan payable[(1)]	$ 10,573	$ –	$ –	$ –	$ –	$ –	$ 10,573
Equipment loan obligations[(1)]	722	152	85	85	85	70	1,199
Operating lease obligations	1,127	1,146	1,166	320	150	–	3,909
CEO severance obligations	1,211	–	–	–	–	–	1,211
Total	$ 13,633	$ 1,298	$ 1,251	$ 405	$ 235	$ 70	$ 16,892

[(1)] *See*, "– Liquidity and Capital Resources - Debt." For the purposes of this table, we have assumed that the Quintiles 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, 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 the landlord's right, upon two years' prior notice, to terminate the lease early. This early 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, depending upon the timing of the notice, if we satisfy certain financial conditions, the landlord would be obligated to make early termination payments to us. 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. In connection with our manufacturing operations in Totowa, New Jersey, we have 15 employees subject to a collective bargaining arrangement which expires on December 3, 2010. *See*, "Item 1 – Business – Business Operations – Manufacturing and Distribution," and "Item 2 – Properties."

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 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 laboratory space in Warrington, Pennsylvania.

Rent expense under all leases for the years ended December 31, 2009, 2008, and 2007 was $1.1 million, $1.2 million and $1.5 million respectively.

Former CEO Commitment

Effective August 13, 2009, Dr. Robert J. Capetola resigned his positions as our President and Chief Executive Officer and as a member of our Board. The Board elected Mr. W. Thomas Amick, Chairman of the Board, to serve as Chief Executive Officer on an interim basis. We entered into a separation agreement and general release (Separation Agreement) with Dr. Capetola providing for (i) an upfront severance payment of $250,000, and (ii) periodic payments in an amount equal to his base salary (calculated at a rate of $490,000 per annum), in accordance with our payroll practices and less required withholdings. The periodic payments will end the earlier of (x) May 3, 2010 or (y) the date, if ever, that a Corporate Transaction (as defined below) occurs. In addition, Dr. Capetola will be entitled to (A) continuation of medical benefits and insurance coverage for a period of 24 or 27 months, depending upon circumstances, and (B) accelerated vesting of all outstanding restricted shares and options, which shall remain exercisable to the end of their stated terms.

The Separation Agreement provides further that, upon the occurrence of a Corporate Transaction prior to May 4, 2010, Dr. Capetola will receive a payment of up to $1,580,000 (the "Additional Severance") or, if any such Corporate Transaction also constitutes a Change of Control (as such term is defined in the Separation Agreement), a payment of up to $1,777,500; provided, however, that, in each case, any such payment will be reduced by the sum of the amounts described in clauses (i) and (ii) of this paragraph that theretofore have been paid. A "Corporate Transaction" is defined in the Separation Agreement as (1) one or more corporate partnering or strategic alliance transactions, Business Combinations or public or private financings that (A) are completed during the Severance Period (as defined in the Separation Agreement) and (B) result in cash proceeds (net of transaction costs) to the Company of at least $20 million received during the Severance Period or within 90 calendar days thereafter, or (2) an acquisition of the Company, by business combination or other similar transaction, that occurs during the Severance Period and the consideration paid to stockholders of the Company, in cash or securities, is at least $20 million. For this purpose, net proceeds will be calculated without taking into account any amounts received by the Company as reimbursement for costs of development and research activities to be performed in connection with any such transaction.

Since August 13, 2009, we have raised approximately $5.89 million in gross proceeds utilizing our CEFFs (*see*, "– Committed Equity Financing Facilities (CEFFs)"). In addition, on February 23, 2010, we completed a public offering that resulted in net proceeds to us of approximately $15.1 million (s*ee*, "– Financings Pursuant to Common Stock Offerings."). As the receipt from financings of more than $20 million qualifies as a Corporate Transaction, our obligation under the Separation Agreement to make payment to Dr. Capetola of the Additional Severance has matured. Therefore, in accordance with the Separation Agreement, on March 5, 2010, we issued a payment to Dr. Capetola in the amount of approximately $1.06 million (less withholding), representing his Additional Severance payment, reduced by the payments previously made to him under the Severance Agreement, which total approximately $0.52 million. Our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due at this time.

Future Milestone Commitment

In addition to the contractual obligations above, we have certain milestone and royalty payment obligations to Johnson & Johnson related to our product licenses. To date, of the $2,500,000 aggregate potential milestone payments, we have paid $450,000 for milestones that have been achieved.

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See, Index to Consolidated Financial Statements on Page F-1 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 Interim 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 Interim 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 Interim 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, 2009. 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, 2009.

Our independent registered public accounting firm has audited management's assessment of our internal control over financial reporting, and issued an unqualified opinion dated March 10, 2010 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 control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc. and Subsidiary

We have audited Discovery Laboratories, Inc. and subsidiary's internal control over financial reporting as of December 31, 2009, 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. 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 our 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, 2009, 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 of Discovery Laboratories, Inc. and subsidiary and our report dated March 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2010

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 2009 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 10, 2010

By: /s/ W. Thomas Amick
W. Thomas Amick, Chairman of the Board
and Principal 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/ W. Thomas Amick	W. Thomas Amick Chairman of the Board and Principal Executive Officer	March 10, 2010
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer (Principal Accounting Officer)	March 10, 2010
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	March 10, 2010
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 10, 2010
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 10, 2010
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 10, 2010

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	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), dated December 9, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 9, 2009.
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	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009
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.
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.

Exhibit No.	Description	Method of Filing
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.
4.11	Form of Stock Purchase Warrant issued in May 2009	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 8, 2009.
4.12	Form of Stock Purchase Warrant issued in February 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 18, 2010.
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.
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.

Exhibit No.	Description	Method of Filing
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
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.

Exhibit No.	Description	Method of Filing
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.
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.

Exhibit No.	Description	Method of Filing
10.30 +	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.
10.31 +	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.
10.32	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.
10.33	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.
10.34	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.
10.35	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.
10.36*	Agreement, dated as of August 13, 2009, by and between Discovery and W. Thomas Amick Regarding Service as CEO on a Part-Time, Interim Basis	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4,2009.
10.37*	Separation of Employment Agreement and General Release, dated as of August 13, 2009, by and between Discovery and Robert J. Capetola	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
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 Stockholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the "Company") as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. and subsidiary at December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, 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, 2009 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.

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, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

March 10, 2010
Philadelphia, PA

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,741	$ 22,744
Available-for-sale marketable securities	–	2,048
Prepaid expenses and other current assets	233	625
Total current assets	15,974	25,417
Property and equipment, net	4,668	5,965
Restricted cash	400	600
Other assets	361	907
Total assets	$ 21,403	$ 32,889
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,294	$ 2,111
Accrued expenses	3,446	5,313
Loan payable, including accrued interest	10,461	–
Equipment loan, current portion	597	2,442
Total current liabilities	15,798	9,866
Loan payable, including accrued interest	–	10,128
Equipment loan, non-current portion	428	1,092
Other liabilities	690	870
Total liabilities	16,916	21,956
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 380,000 and 180,000 shares authorized; 126,689 and 101,588 shares issued, 126,376 and 101,275 shares outstanding at December 31, 2009 and December 31, 2008, respectively	127	102
Additional paid-in capital	365,063	341,293
Accumulated deficit	(357,649)	(327,409)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Accumulated other comprehensive income	–	1
Total stockholders' equity	4,487	10,933
Total liabilities & stockholders' equity	$ 21,403	$ 32,889

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,		
	2009	**2008**	**2007**
Revenue from collaborative arrangement and grants:	$ –	$ 4,600	$ –
Expenses:			
Research & development	19,077	26,566	26,200
General & administrative	10,120	16,428	13,747
Total expenses	29,197	42,994	39,947
Operating loss	(29,197)	(38,394)	(39,947)
Other income / (expense):			
Interest and other income	39	902	2,029
Interest and other expense	(1,082)	(1,614)	(2,087)
Other income / (expense), net	(1,043)	(712)	(58)
Net loss	$ (30,240)	$ (39,106)	$ (40,005)
Net loss per common share - basic and diluted	$ (0.26)	$ (0.40)	$ (0.49)
Weighted average number of common shares outstanding - basic and diluted	115,200	98,116	81,731

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2009, 2008 and 2007
(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 Comprehensive Income/(Loss)	Total
Balance – January 1, 2007	**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**
Comprehensive loss:									
Net loss	–	–	–	–	(30,240)	–	–	–	(30,240)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	(1)	(1)
Total comprehensive loss	–	–	–	–	–	–	–	–	(30,241)
Issuance of common stock, restricted stock awards	21	–	–	–	–	–	–	–	–
Issuance of common stock, 401(k) employer match	347	–	290	–	–	–	–	–	290
Issuance of common stock, May 2009 financing	14,000	14	10,451	–	–	–	–	–	10,465
Issuance of common stock, CEFF financings	10,732	11	10,346	–	–	–	–	–	10,357
Stock-based compensation expense	–	–	2,683	–	–	–	–	–	2,683
Balance – December 31, 2009	**126,689**	**$ 127**	**$ 365,063**	**$ –**	**$ (357,649)**	**(313)**	**$ (3,054)**	**$ –**	**$ 4,487**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2009	**2008**	**2007**
Cash flow from operating activities:			
Net loss	$ (30,240)	$ (39,106)	$ (40,005)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,992	2,215	2,062
Stock–based compensation and 401(k) match	2,973	5,007	5,613
Loss on disposal of property and equipment	–	110	18
Changes in:			
Prepaid expenses and other current assets	392	(56)	(89)
Accounts payable	(817)	1,353	(871)
Accrued expenses	(1,867)	(1,773)	2,762
Other assets	(1)	3	35
Other liabilities and accrued interest on loan payable	153	495	1,080
Net cash used in operating activities	(27,415)	(31,752)	(29,395)
Cash flow from investing activities:			
Purchase of property and equipment	(147)	(632)	(3,765)
Restricted cash	200	-	-
Purchase of marketable securities	–	(25,765)	(38,355)
Proceeds from sale or maturity of marketable securities	2,047	39,754	22,319
Net cash provided by / (used in) investing activities	2,100	13,357	(19,801)
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	20,820	6,292	58,809
Proceeds from equipment loans	–	896	2,862
Principal payments under equipment loan obligations	(2,508)	(2,978)	(1,948)
Net cash provided by financing activities	18,312	4,210	59,723
Net (decrease) / increase in cash and cash equivalents	(7,003)	(14,185)	10,527
Cash and cash equivalents – beginning of year	22,744	36,929	26,402
Cash and cash equivalents – end of year	$ 15,741	$ 22,744	$ 36,929
Supplementary disclosure of cash flows information:			
Interest paid	$ 208	$ 529	$ 676
Non-cash transactions:			
Unrealized gain / (loss) on marketable securities	(1)	(41)	42
Exchange of equipment loan obligation	–	–	3,968

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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 therapies to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel KL_4 proprietary 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 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 developing our lead products, Surfaxin®(lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. In April 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to our New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL_4 surfactant technology. The letter focused primarily on certain aspects of our fetal rabbit biological activity test (BAT, a quality control and stability release test for Surfaxin and our other KL_4 pipeline products), specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time. We met with the FDA at an end-of-review meeting in June 2009 and by teleconference in September 2009 to discuss specific proposals to resolve this sole remaining Chemistry, Manufacturing & Control (CMC) issue, which must be addressed to obtain approval of Surfaxin. Based on these and other interactions with the FDA, we are currently implementing a protocol intended to optimize and revalidate the BAT. This effort is ongoing and, although not necessarily indicative of the final results, the BAT is presently meeting all pre-specified acceptance criteria. Once the BAT is optimized and revalidated, we plan to initiate a comprehensive preclinical program that will consist of a series of a series of side-by-side studies comparing the results of the BAT with those of the well-established preterm lamb model of RDS in order to satisfy the FDA's requirements with respect to the BAT. If these studies are successful, we believe that we could be in a position to file a Complete Response to the April 2009 Complete Response Letter in the first quarter of 2011, which could lead to approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in 2011. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for use in pediatric medicine.

Surfaxin LS, our lyophilized KL_4 surfactant, is a dry powder formulation that is resuspended as a liquid prior to use and is intended to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. 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. If approved, we believe that Aerosurf will make it possible to administer surfactant into the lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of surfactant therapy in pediatric medicine.

In addition to our lead products, we plan over time to develop our KL_4 surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. Our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development. We have an ongoing Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF) and our KL_4 surfactant is the subject of an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL_4 surfactant in patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL_4 surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL_4 surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

We are actively assessing various strategic and financial alternatives to secure the necessary capital to advance our KL_4 respiratory pipeline programs to maximize stockholder value, although we prefer to accomplish our objectives through strategic alliances. We are actively engaged in current discussions with potential strategic and/or financial partners, but there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. Until we secure an alliance or other financing alternative, we will continue to focus our financial resources on the potential approval of Surfaxin, while minimizing investments in our other pipeline programs.

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 the prevention of RDS, if approved.

Following receipt of the April 2009 FDA Complete Response Letter for Surfaxin, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL_4 technology through strategic alliances or other collaboration arrangements. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

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. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors, which is included in our financial statements in this report, contains a notation related to our ability to continue as a going concern. 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 strategic and collaborative arrangements with potential partners and/or future debt and equity financings, 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 development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, 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. Our December 31, 2009 financial statements 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 we be unable to continue in existence.

Our future capital requirements will depend upon many factors, including our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL_4 surfactant products to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of December 31, 2009, we had cash and cash equivalents of $15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of $16.5 million ($15.1 million net). Also, as of December 31, 2009, our $10.5 million loan with Quintiles (formerly PharmaBio Development Inc. and NovaQuest™), a strategic investment group of Quintiles Transnational Corp., is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan; however, there can be no assurance that any such restructuring will occur. Currently, under our two CEFFs, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of $69.5 million. However, as of March 5, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available because the market price of our common stock price was below the minimum price required ($1.15 and $0.60, respectively) to utilize the facility. *See*, Note 10 – Stockholders' Equity, for details about our CEFFs. During 2009, we raised aggregate gross proceeds of $22.0 million. In May 2009, we completed a public offering of or common stock, resulting in gross proceeds of $11.3 million ($10.5 million net), and, throughout 2009, we raised an aggregate of $10.7 million from 10 draw-downs under our CEFFs. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)," and "– Financings Pursuant to Common Stock Offerings."

Note 3 – Summary of Significant Accounting Policies and Recent Accounting Pronouncements

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 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 our Board of Directors (the Board) 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, 2009 and December 31, 2008.

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, 2009, 2008 and 2007, as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Revenue recognition under strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. Upfront, non-refundable license fees received in connection with collaboration agreements are deferred and recognized as revenue over the life of the agreement or period of performance obligations. Revenues derived from the achievement of milestones are recognized when the milestone is achieved, as long as there are no further performance obligations. Deferred revenue results from cash received or amounts receivable in advance of revenue recognition based upon the performance requirements of the contract. 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, other preclinical and clinical activities and medical affairs. 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 Accounting Standards Codification (ASC) Topic 718 *"Stock Compensation,"* 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 Accounting Standards Codification (ASC) Topic 740, *"Accounting for Income Taxes"*. ASC Topic 740 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.

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 ASC 740 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, 2009, 2008 and 2007 are as follows:

(in thousands)	December 31,		
	2009	2008	2007
Net loss	$ (30,240)	$ (39,106)	$ (40,005)
Change in unrealized (losses)/gains on marketable securities	(1)	(41)	42
Comprehensive loss	$ (30,241)	$ (39,147)	$ (39,963)

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, 2009, 2008 and 2007, 30.9 million, 25.1 million and 20.3 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.

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 June 2009, the Financial Accounting Standards Board (FASB) issued *the Accounting Standards Codification*™ (the Codification). The Codification now is the single source of authoritative accounting principles recognized by FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with Generally Accepted Accounting Principles (GAAP), in the United States. The Codification became effective for interim and annual periods ending after September 15, 2009. All other accounting literature not included in the Codification will be nonauthoritative, except for additional authoritative rules and interpretive releases issued by the United States Securities Exchange Commission (SEC). The Codification is not intended to change GAAP; instead, it reorganizes the thousands of US GAAP pronouncements into approximately 90 Accounting Topics. Adoption of the Codification did not have an impact on our consolidated financial statements.

In May 2009, FASB issued new guidance for accounting for subsequent events. The new guidance, which is now part of Accounting Standards Codification (ASC) Topic 855, *Subsequent Events*, is consistent with existing auditing standards in its definition of subsequent events, but requires disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. There are two types of subsequent events: (1) events that provide additional evidence about conditions that existed at the balance sheet date, and are recognized in the financial statements, and (2) events that provide evidence about conditions that did not exist at the balance sheet date, but arose before the financial statements are issued or are available to be issued, and are not recognized at the balance sheet date. The adoption of the new guidance had no impact on our consolidated financial statements. We evaluated all events or transactions that occurred after December 31, 1009 up through March 10, 2010, the date these financial statements were issued and filed with the SEC. During this period we had three material nonrecognized subsequent events, which are described in Note 18.

In December 2007, FASB issued new guidance for accounting for collaborative arrangements. The new guidance, which is now part of ASC Topic 808, *Collaborative Arrangements*, is effective for fiscal years beginning after December 15, 2008. The scope of the new guidance is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The new guidance 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. The adoption of the new guidance on January 1, 2009 did not have a material impact on our consolidated financial statements.

In December 2007, FASB issued new guidance for accounting for business combinations. The new guidance, which is now part of ASC topic 805, *Business Combinations*, is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. The new guidance 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. ASC Topic 805 also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. We adopted the new guidance on January 1, 2009, which had no immediate impact on our financial statements; however, it may have an impact on the accounting for any potential future business combinations.

Note 4 – Fair Value Measurements

ASC Topic 820, Fair Value Measurements and Disclosures establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements.

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 must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets and liabilities. Level 1 is generally considered the most reliable measurement of fair value under ASC 820.
- 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.

Fair Value on a Recurring Basis

Assets measured at fair value on a recurring basis are categorized in the table below based upon the lowest level of input (Level 1) as of December 31, 2009:

(in thousands)	Fair Value December 31, 2009	Fair value measurement using Level 1	Level 2	Level 3
Money markets (1)	$ 14,690	$ 14,690	$ –	$ –
U.S. treasury notes			–	–
Certificate of deposit	600	600	–	–
	$ 15,290	$ 15,290	$ –	$ –

(1) Dreyfus Treasury & Agency Cash Management Fund.

Note 5 – Marketable Securities

We did not hold any available-for-sale marketable securities as of December 31, 2009. 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

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 our Board 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 held by our bank in the amount of $600,000 to secure a letter of credit in the same notional amount held by our landlord to secure our obligations under our Lease Agreement dated May 26, 2004 for our headquarters location in Warrington, Pennsylvania (*See*, Note 14 – Commitments, for further discussion on our leases). Under the terms of our Lease, beginning in March 2010, the letter of credit (and the related security deposit) will be reduced to $400,000 and will remain in effect at that level 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 and the security deposit will be released.

Note 7 – Property and Equipment

Property and equipment as of December 31, 2009 and 2008 was comprised of the following:

(in thousands)	December 31, 2009	2008
Equipment	$ 7,265	$ 7,143
Furniture	791	791
Leasehold improvements	2,838	2,813
Subtotal	10,894	10,747
Accumulated depreciation and amortization	(6,226)	(4,782)
Property and equipment, net	$ 4,668	$ 5,965

Equipment primarily consists of: (i) manufacturing equipment to produce our KL_4 surfactant products, including Surfaxin and Aerosurf, for use in our preclinical studies, 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 laboratory include release and stability testing of raw materials as well as preclinical, 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 will be amortized through the end of the lease term for our Warrington, Pennsylvania headquarters in 2013. In addition, in 2007, we built a microbiology laboratory at our manufacturing facility in Totowa, New Jersey, to support production of our drug product candidates. The microbiology laboratory will be amortized through the end of the lease term for our Totowa, New Jersey facility in 2014.

Depreciation and amortization expense on property and equipment for the years ended December 31, 2009, 2008, and 2007 was $1.4 million, $1.6 million, and $1.5 million, respectively.

Note 8 – Accrued Expenses

Accrued expenses as of December 31, 2009 and 2008 were comprised of the following:

(in thousands)	December 31, 2009	2008
Accrued compensation[(1)]	$ 1,763	$ 2,390
Accrued manufacturing	568	1,174
Accrued research and development	332	374
All other accrued expenses	783	1,375
Total accounts payable and accrued expenses	$ 3,446	$ 5,313

(1) Accrued compensation consists of potential employee incentive arrangements (pursuant to plans approved by our Board), contractual future severance arrangements for our former President and Chief Executive Officer (*see*, Note 14 – Commitments, for further discussion of this arrangement) and existing union employees at our manufacturing operations, and employees' unused earned vacation.

Note 9 – Debt

Loan Payable – Quintiles

Quintiles (formerly PharmaBio Development, Inc. and NovaQuest™) in 2001 extended to us a secured, revolving credit facility, which we restructured in October 2006. The outstanding principal balance of the loan, $8.5 million, is due and payable on April 30, 2010, together with all unpaid interest accrued since July 1, 2006. Since October 2006, interest is calculated at the prime rate, compounded annually. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. In addition, our obligations to Quintiles under the loan agreement are secured by a security interest in substantially all of our assets, subject to limited exceptions set forth in the related security agreement.

Also in October 2006, in consideration of Quintiles's agreement to restructure the loan, we entered into a Warrant Agreement with Quintiles, pursuant to which Quintiles has the right to purchase 1.5 million shares of our common stock at an exercise price of $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 Quintiles loan agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise.

As of December 31, 2009, the outstanding balance under the loan was $10.5 million ($8.5 million principal and $2.0 million accrued interest) and was classified as a current liability on the Consolidated Balance Sheet as of such date.

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the Quintiles loan of $0.3 million, $0.5 million and $0.7 million, respectively. The decrease in interest expense in 2009 and 2008 is due to declines in the prime rate during 2008 ranging from 7.25% to 3.25%. During 2009, the prime rate remained at 3.25%. In addition, for the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to Quintiles in October 2006 of $0.5 million, $0.5 million and $0.5 million, respectively.

Equipment Loans

Our equipment loan liabilities as of December 31, 2009 and 2008 are as follows:

(in thousands)	**2009**	**2008**
GE Business Financial Services, Inc.		
Short-term	$ 538	$ 2,385
Long-term	65	664
Total	603	3,049
Pennsylvania Machinery and Equipment Loan		
Short-term	59	57
Long-term	363	428
Total	422	485
Total Short-term	597	2,442
Total Long-term	428	1,092
Total	$ 1,025	$ 3,534

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with our equipment loans of $0.2 million, $0.6 million and $0.6 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 a $12.5 million facility (Facility) to fund our capital programs. The right to draw under this Facility expired on November 30, 2008. Over the term of the Facility, we received $7.2 million, $4.0 million of which was applied to prepayment of a prior facility and $2.3 million of which was associated with construction and equipment for the analytical and development laboratory that we built in our Warrington, Pennsylvania headquarters in 2007.

Advances under the Facility 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 prior 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%.

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 Quintiles 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 Quintiles as discussed above.

Pennsylvania Machinery and Equipment Loan Fund (MELF)

We entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), effective September 8, 2008, 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 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 accrues at a fixed rate of five percent (5.0%) per annum. 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 February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of $0.60 per unit, resulting in gross and net proceeds to us of $16.5 million and $15.1 million, respectively. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of $0.85, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis. This offering was made pursuant to the 2008 Universal Shelf (*see*, Universal Shelf Registration Statements of this Note).

In May 2009, we completed a registered direct offering of 14,000,000 shares of our common stock and warrants to purchase 7,000,000 shares of our common stock, sold as units to select institutional investors, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at an offering price of $0.81 per unit, resulting in gross and net proceeds to us of $11.3 million and $10.5 million, respectively.
The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of $1.15, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis. This offering was made pursuant to our 2008 Universal Shelf.

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 the 2005 Universal Shelf (*see*, Universal Shelf Registration Statements of this Note).

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 2005 Universal Shelf.

Committed Equity Financing Facilities (CEFFs)

We have entered into four Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under 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. Each CEFF is available for a period of 2 to 3 years from inception. 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, 2009, we had two CEFFs available for future financings as follows: the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). A third CEFF entered in April 2006 expired on May 12, 2009 and is no longer available. 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)					Amount per Contract		Potential Availability at December 31, 2009	
	Expiration	Minimum Price to Initiate Draw Down[1]	Minimum VWAP for Daily Pricing[2]	# of Trading Days In Each Draw Down[2]	Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008 CEFF	June 18, 2011	$ 1.15	90% of the closing market price on the day preceding the first day of draw down	8	19.3	$ 60.0	12.8	$ 51.8
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60		6	15.0	$ 25.0	7.1	$ 17.7

(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 period 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 that we originally designated for the overall draw down is reduced for each such day by 1/8th in the case of the December 2008 CEFF, and 1/6th in the case of the May 2008 CEFF, respectively . 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:

- 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
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.

In connection with the December 2008 CEFF, we issued a warrant to Kingsbridge on December 22, 2008 to purchase up to 675,000 shares of our common stock at an exercise price of $1.5132 per share. The warrant expires in May 2014 and 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. As of December 31, 2009, this warrant had not been exercised.

In connection with the May 2008 CEFF, we issued a warrant to Kingsbridge on May 22, 2008 to purchase up to 825,000 shares of our common stock at an exercise price of $2.506 per share. The warrant 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, 2009, this warrant had not been exercised.

In connection with the 2006 CEFF, we issued a Class C Investor Warrant to Kingsbridge on April 17, 2006 to purchase up to 490,000 shares of our common stock at an exercise price equal to $5.6186 per share. The warrant expires in October 2011 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately $2.8 million. As of December 31, 2009, this Class C Investor Warrant had not been exercised.

In connection with a CEFF that we entered in 2004, we issued a Class B Investor Warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to $12.0744 per share. The warrant expired unexercised in January 2010.

CEFF Financings

The financings that we completed under the December 2008 CEFF are:

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
April 8, 2009	806	$ 1,000	$ 1.24
May 7, 2009	1,273	1,000	0.79
September 23, 2009	1,793	1,583	0.88
October 13, 2009	1,909	1,800	0.94
October 21, 2009	2,101	1,900	0.90

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

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
July 11, 2008	1,105	$ 1,563	$ 1.41
July 31, 2008	992	1,500	1.51
October 17, 2008	914	1,313	1.44
November 20, 2008	221	250	1.13
January 2, 2009	479	500	1.04
January 16, 2009	419	438	1.04
February 18, 2009	857	1,000	1.17
March 31, 2009	1,015	1,094	1.08
October 13, 2009	559	606	1.09

The financings that we completed under the now expired 2006 CEFF are:

(in thousands, except per share data)

Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
May 29, 2006	1,079	$ 2,188	$ 2.03
October 11, 2006	1,205	2,300	1.91
November 10, 2006	1,372	3,000	2.19
February 22, 2007	943	2,000	2.12
October 12, 2007	1,909	5,000	2.62
September 9, 2008	676	1,250	1.85

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, 2009, 2008 and 2007, the match resulted in the issuance of 346,904, 231,287, and 118,330 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, 2009	December 31, 2008	Exercise Price	Expiration Date
Investor Warrants – May 2009 Financing [1]	7,000	-	$ 1.15	5/13/2014
Kingsbridge – December 2008 CEFF[2]	675	675	$ 1.51	6/12/2014
Kingsbridge – May 2008 CEFF[2]	825	825	$ 2.51	11/22/2013
Private Placement – 2006 [3]	2,315	2,315	$ 3.18	11/22/2011
Quintiles - 2006 Loan Restructuring [4]	1,500	1,500	$ 3.58	10/26/2013
Class C Investor Warrants - 2006 CEFF [2]	490	490	$ 5.62	10/17/2011
Quintiles - 2004 Partnership Restructuring [5]	850	850	$ 7.19	11/3/2014
Class B Investor Warrants - 2004 CEFF [2]	375	375	$ 12.07	1/6/2010
Class A Investor Warrants – 2003	809	809	$ 6.88	9/19/2010
Total	14,839	7,839		

(1) Refer to the Registered Public Offerings and Private Placements section of this Note.
(2) Refer to the Registered Public Offerings and Private Placements section of this Note.
(3) In Nov. 2006, in connection with a sale of 4.6 million shares of our common stock, we issued warrants to purchase common stock at an exercise price equal to $3.18 per share. The warrants expire in Nov. 2011 and, subject to an aggregate share ownership limitation, are exercisable, in whole or in part, for cash, except in limited circumstances, with expected proceeds to us of $7.4 million. As of December 31, 2009, the warrants had not been exercised
(4) Refer to Note 9 – Debt
(5) 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 Quintiles 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, 2009 and 2008 are as follows:

(in thousands)	As of December 31, 2009	2008
2007 Plan		
Outstanding	6,688	7,296
Available for Future Grants	1,812	1,204
Total	8,500	8,500
1998 Plan		
Outstanding	9,298	9,916
Available for Future Grants	–	–
Total	9,298	9,916
Total Outstanding	15,986	17,212
Total Available for Future Grants	1,812	1,204
Total	17,798	18,416

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. As of December 31, 2009 and March 1, 2010, respectively, up to $138.7 million and $122.2 million of our securities are potentially available for issuance pursuant to the 2009 Universal Shelf. *See*, Registered Public Offering and Private Placements in this Note for offerings made pursuant to the 2008 Universal Shelf.

2005 Universal Shelf

In October 2005, we filed a universal shelf registration statement on Form S-3 (File No. 333-128929) (2005 Universal Shelf) with the SEC for the proposed offering, from time to time, of up to $100 million of our debt or equity securities. *See*, Registered Public Offering and Private Placements in this Note for a discussion of offerings pursuant to the 2008 Universal Shelf. The October 2005 Universal Shelf expired in December 2008.

Common shares reserved for potential future issuance under CEFF arrangements

As of December 31, 2009, the Company had two CEFFs available for future financings, as follows:

(in thousands)	Expiration	Potential future issuance as of December 31, 2009	2008
May 2008 CEFF	June 18, 2011	12,768	15,618
December 2008 CEFF	February 6, 2011	7,118	15,000

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

In September 2009 and December 2008, our Board approved an increase of 160,000 and 350,000 shares, respectively, to the reserve for issuance under the 401(k) Plan. As of December 31, 2009 and 2008, we had 137,435 and 324,339 shares, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 11 – Stock Options and Stock-based Employee Compensation

Long-Term Incentive Plans

In June 2007, our stockholders approved the 2007 Plan, which replaced the 1998 Plan, which by its terms would have expired in March 2008. *See,* Note 10 – Common shares reserved for potential future issuance upon exercise of stock options. 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) 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 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 continue to be governed by the terms of that plan and the applicable award agreements.

Award under the two plans may include:

Stock Options and Stock Appreciation Rights (SARs)

The Committee may award nonqualified stock options, incentive stock options, or SARs with a term of not more than 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 grant restricted stock awards (RSAs) 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.

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.

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).

No SARs or Performance Awards have been granted under either plan. No RSAs have been granted under the 2007 Plan. Under the 1998 Plan, in 2007, 56,660 RSAs were granted to certain employees for no cash consideration. These RSAs initially were to vest on the date that Surfaxin for RDS first becomes widely commercially available; however, the Committee amended the vesting provisions in 2009 to provide for vesting on the third anniversary of the grant date. As of December 31, 2009, there were 27,500 unvested restricted stock awards outstanding, which vested on January 3, 2010.

Under the 2007 Plan, as of December 31, 2009, options to purchase 6,687,719 shares of common stock were outstanding and 1,812,281 shares were available for potential future grants. 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, options to purchase 9,297,792 and 9,916,644 shares of common stock were outstanding as of December 31, 2009 and December 31, 2008, respectively. No shares are available for future grants under the 1998 Plan.

A summary of option activity under the 2007 Plan and 1998 Plan as of December 31, 2009 and changes during the periods ended December 31, 2007, 2008 and 2009, respectively, 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 Yrs)
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	1.78	
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	
Granted	0.49 – 1.18	297	0.78	
Exercised	—	—	—	
Forfeited or expired	0.81 – 9.17	(1,523)	2.63	
Outstanding at December 31, 2009	$0.49 – $10.43	15,986	$ 3.76	6.1
Exercisable at December 31, 2009	$1.15 – $10.43	13,608	$ 4.09	5.7

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, 2009, 2008 and 2007 was $0.56, $0.88 and $2.05, respectively. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was $0, $13,000 and $57,000, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2009 is $13,000, $0 and $0, respectively.

A summary of the status of our nonvested shares issuable upon exercise of outstanding options and changes during 2009 is presented below:

(shares in thousands)	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2008	6,607	$ 1.40
Granted	297	.56
Vested	(3,636)	1.55
Forfeited	(891)	1.33
Non-vested at December 31, 2009	2,377	$ 1.11

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2009:

(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
$0.49 – $2.00	4,148	$ 1.63	7.86 Years	2,404	$ 1.69	7.23 years
$2.01 – $4.00	7,463	$ 2.66	6.41 Years	6,829	$ 2.65	6.44 years
$4.01 – $6.00	657	$ 4.75	0.88 Years	657	$ 4.75	0.88 years
$6.01 – $8.00	1,350	$ 6.87	5.26 Years	1,350	$ 6.87	5.26 years
$8.01 – $10.00	2,343	$ 8.93	4.24 Years	2,343	$ 8.93	4.24 years
$10.01 – $10.43	25	$ 10.43	4.22 Years	25	$ 10.43	4.22 years
	15,986			13,608		

Stock-Based Compensation

As a result of adopting Accounting Standards Codification (ASC) Topic 718 *"Stock Compensation,"* on January 1, 2006, we recognized compensation expense for the years ended December 31, 2009, 2008 and 2007 of $2.7 million, $4.6 million and $5.3 million, respectively.

Stock-based compensation expenses was classified as follows:

(in thousands)	Years Ended December 31, 2009	2008	2007
Research and development	$ 649	$ 1,501	$ 1,706
General and administrative	2,035	3,127	3,613
Total	$ 2,684	$ 4,628	$ 5,319

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the historical volatility of our common stock 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, 2009	2008	2007
Weighted average expected volatility	99%	81%	88%
Weighted average expected term	4.7 years	4.6 years	4.8 years
Weighted average risk-free interest rate	1.7%	2.1%	4.8%
Expected dividends	–	–	–

The total fair value of the underlying shares of the options vested during 2009, 2008, and 2007 equals $5.6 million, $4.7 million and $4.9 million, respectively. As of December 31, 2009, there was $2.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.37 years.

On August 13, 2009, Dr. Robert J. Capetola, our former President and Chief Executive Officer, resigned his position and with us and as a member of our Board. Under the terms of a Separation of Employment Agreement and General Release dated August 13, 2009 between Dr. Capetola and ourselves, all of Dr. Capetola's outstanding RSAs and options immediately vested and all such RSAs and options shall remain exercisable to the end of their stated terms. During 2009, the company recognized $0.3 million in stock option modification costs related to these items.

Note 12 – Corporate Partnership, Licensing and Research Funding Agreements

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

Philip Morris USA Inc. and Philip Morris Products S.A.

In March 2008, we restructured our December 2005 strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility from Chrysalis 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 restated our prior agreement as of March 28, 2008 and entered into an Amended and Restated License Agreement with PMUSA with respect to the United States (U.S. License Agreement), and, as PMUSA had 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 on 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, the 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.

As part of 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. 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.

Johnson & Johnson and Ortho 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 to the proprietary KL_4 surfactant technology, including Surfaxin, in exchange for certain license fees, milestone payments aggregating up to $2,500,000 and royalties. To date, we have paid $450,000 of such amount for milestones that have been achieved.

Note 13 – Commercial Strategy and Cost Containment Measures

Following receipt of the April 2009 Complete Response Letter for Surfaxin for the prevention of RDS in premature infants, we reviewed all aspects of our business with a view to conserving our cash and implemented a fundamental change in our business strategy. We no longer are planning to establish our own specialty pulmonary organization to commercialize our potential pediatric products in the United States. Rather, to secure capital and advance our KL_4 surfactant pipeline programs, we are now seeking strategic alliances in all markets, including the United States, to support our research and development programs and, if approved, to commercialize our products.

In addition, in April 2009, we implemented cost containment measures and reduced our workforce from 115 to 91 employees, focusing primarily on our commercial and corporate administrative groups. We continue to maintain our core capabilities to support development of our KL_4 surfactant technology, including quality, manufacturing and research and development resources. We incurred a charge of $0.6 million in the second quarter of 2009 associated with staff reductions and the close-out of certain contractual arrangements, which is included within the appropriate line items on the Statements of Operations ($0.4 million in general and administrative expenses and $0.2 million in research and development expenses). As of December 31, 2009, payments totaling $0.6 million had been made related to these items and $29,000 was unpaid, as follows:

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
Q2 2009 Charge	$ 554	$ 74	$ 628
Payments / Adjustments	(450)	—	(450)
Liability as of June 30, 2009	$ 104	$ 74	$ 178
Payments / Adjustments	(97)	(4)	(101)
Liability as of September 30, 2009	$ 7	$ 70	$ 77
Payments / Adjustments	(7)	(41)	(48)
Liability as of December 31, 2009	$ -	$ 29	$ 29

Note 14 – Commitments

Future payments due under contractual obligations at December 31, 2009 are as follows:

(in thousands)	2010	2011	2012	2013	2014	There-after	Total
Loan payable[1]	$ 10,573	$ –	$ –	$ –	$ –	$ –	$ 10,573
Equipment loan obligations[1]	722	152	85	85	85	70	1,199
Operating lease obligations	1,127	1,146	1,166	320	150	–	3,909
CEO Severance obligations	1,211	–	–	–	–	–	1,211
Total	$ 13,633	$ 1,298	$ 1,251	$ 405	$ 235	$ 70	$ 16,892

[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, 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 the landlord's right, upon two years' prior notice, to terminate the lease early. This early 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, depending upon the timing of the notice, if we satisfy certain financial conditions, the landlord would be obligated to make early termination payments to us. 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. In connection with our manufacturing operations in Totowa, New Jersey, we have 15 employees subject to a collective bargaining arrangement which expires on December 3, 2010. For a discussion of our manufacturing strategy, *see*, "Item 1 – Business – Business Operations – Manufacturing and Distribution," in our Annual Report on Form 10-K.

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 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 laboratory space in Warrington, Pennsylvania.

Rent expense under all of these leases for the years ended December 31, 2009, 2008, and 2007 was $1.1 million, $1.2 million and $1.5 million, respectively.

In addition to the contractual obligations above, we have certain milestone and royalty payment obligations to Johnson & Johnson related to our product licenses. To date, of the $2,500,000 aggregate potential amount of such milestone payments, we have paid $450,000 for milestones that have been achieved.

Former CEO Commitment

Effective August 13, 2009, Dr. Robert J. Capetola resigned his positions as our President and Chief Executive Officer and as a member of our Board. We entered into a separation agreement and general release (Separation Agreement) with Dr. Capetola providing for (i) an upfront severance payment of $250,000, and (ii) periodic payments in an amount equal to his base salary (calculated at a rate of $490,000 per annum), in accordance with our payroll practices and less required withholdings. The periodic payments will end the earlier of (x) May 3, 2010 or (y) the date, if ever, that a Corporate Transaction (as defined below) occurs. In addition, Dr. Capetola will be entitled to (A) continuation of medical benefits and insurance coverage for a period of 24 or 27 months, depending upon circumstances, and (B) accelerated vesting of all outstanding restricted shares and options, which shall remain exercisable to the end of their stated terms.

The Separation Agreement provides further that, upon the occurrence of a Corporate Transaction prior to May 4, 2010, Dr. Capetola will receive a payment of up to $1,580,000 (Additional Severance) or, if any such Corporate Transaction also constitutes a Change of Control (as such term is defined in the Separation Agreement), a payment of up to $1,777,500; provided, however, that, in each case, any such payment will be reduced by the sum of the amounts described in clauses (i) and (ii) of this paragraph that theretofore have been paid. A “Corporate Transaction” is defined in the Separation Agreement as (1) one or more corporate partnering or strategic alliance transactions, Business Combinations or public or private financings that (A) are completed during the Severance Period (as defined in the Separation Agreement) and (B) result in cash proceeds (net of transaction costs) to the Company of at least $20 million received during the Severance Period or within 90 calendar days thereafter, or (2) an acquisition of the Company, by business combination or other similar transaction, that occurs during the Severance Period and the consideration paid to stockholders of the Company, in cash or securities, is at least $20 million. For this purpose, net proceeds will be calculated without taking into account any amounts received by the Company as reimbursement for costs of development and research activities to be performed in connection with any such transaction. *See also*, Note 18 – Subsequent Events.

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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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, 2009, 2008 and 2007 is as follows:

(in thousands)	December 31, 2009	2008	2007
Income tax benefit, statutory rates	$ 10,282	$ 13,296	$ 13,601
State taxes on income, net of Federal benefit	423	2,102	2,363
Research and development tax credit	756	1,026	960
Employee Related	(1,471)	(1,306)	(1,118)
Other	(19)	(32)	(24)
Income tax benefit	9,971	15,086	15,782
Valuation allowance	(9,971)	(15,086)	(15,782)
Income tax benefit	$ –	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2009 and 2008, are as follows:

(in thousands)	December 31, 2009	2008
Long-term deferred tax assets:		
Net operating loss carryforwards		
(Federal and state)	$ 126,291	$ 115,401
Research and development tax credits	7,893	7,137
Compensation expense on stock	4,730	4,334
Charitable contribution carryforward	6	6
Other accrued	1,635	2,073
Depreciation	2,341	2,494
Capitalized research and development	2,069	2,411
Total long-term deferred tax assets	144,965	133,857
Long-term deferred tax liabilities	–	–
Net deferred tax assets	144,632	133,857
Less: valuation allowance	(144,965)	(133,857)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2009 and 2008 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, 2009 and 2008, we had available carryforward net operating losses for Federal tax purposes of $315.5 million and $292.6 million, respectively, and a research and development tax credit carryforward of $7.9 million and $7.1 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2028. Approximately $11.9 million of the $315.5 net operating loss carryforwards expire prior to 2013.

At December 31, 2009, we had available carryforward Federal and state net operating losses of $1.8 million and $16,000, 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 net operating loss (NOL) and research and development (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, $1.8 million and $16,000, respectively, relate to stock-based compensation, the tax effect of which will result in a credit to equity as opposed to income tax expense, to the extent these losses are utilized in the future.

On January 1, 2007, we adopted the provisions of Accounting Standards Codification (ASC) Topic 740, *"Accounting for Income Taxes"*. Topic 740 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 Topic 740 apply to all material tax positions in all taxing jurisdictions for all open tax years. The adoption of Topic 740 did not have a material effect on the Company's financial condition or results of operations for the year ended December 31, 2009.

Note 17 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2009 and 2008. The operating results for any quarter are not necessarily indicative of results for any future period.

2009 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	$ –	$ –	$ –	$ –	$ –
Expenses:					
Research and development	5,607	5,052	4,530	3,888	19,077
General and administrative	3,096	2,592	2,417	2,015	10,120
Total expenses	8,703	7,644	6,947	5,903	29,197
Operating loss	(8,703)	(7,644)	(6,947)	(5,903)	(29,197)
Other expense, net	(297)	(264)	(244)	(238)	(1,043)
Net loss	$ (9,000)	$ (7,908)	$ (7,191)	$ (6,141)	$ (30,240)
Net loss per common share - basic and diluted	$ (0.09)	$ (0.07)	$ (0.06)	$ (0.05)	$ (0.26)
Weighted average number of common shares outstanding	102,093	112,712	119,993	125,638	115,200

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 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

Note 18 – Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2009 up through the date we issued these financial statements. During this period we did not have any material recognized subsequent events, however, there were three nonrecognized subsequent events described below:

In February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of $0.60 per unit, resulting in gross and net proceeds to us of $16.5 million and $15.1 million, respectively. *See*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements, for a further discussion of this offering.

With respect to our Former CEO Commitment (*see*, Note 14 – Commitments – Former CEO Commitment), since August 13, 2009, we have raised approximately $5.89 million in gross proceeds utilizing our CEFFs (*see*, Note 10 – Stockholders' Equity – Committed Equity Financing Facilities – CEFF Financings). In addition, on February 23, 2010, we completed a public offering that resulted in net proceeds to us of approximately $15.1 million (*see*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements). As the receipt from financings of more than $20 million qualifies as a Corporate Transaction, our obligation under the Separation Agreement to make payment to Dr. Capetola of the Additional Severance has matured. Therefore, in accordance with the Separation Agreement, on March 5, 2010, we made a payment to Dr. Capetola in the amount of approximately $1.06 million (less withholding), representing his Additional Severance payment, reduced by the payments previously made to him under the Severance Agreement, which total approximately $0.52 million. Our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due at this time.

On February 16, 2010, we announced that we had received written guidance from the FDA advising us that, since an acceptable animal model (preterm lamb) of RDS already exists, a PD clinical trial approach would not be appropriate. We had previously expected, based on prior guidance received from the FDA, that a limited, pharmacodynamic-based (PD) clinical trial in preterm infants would be required to address the sole remaining CMC issue relating to the BAT that must be addressed to obtain approval of Surfaxin for the prevention of RDS in premature infants. As a result, instead of pursuing a limited clinical trial, we are now focused on completing the optimization and revalidation of the BAT and developing a comprehensive preclinical plan intended to meet the FDA's requirements. If these studies are successful, we believe that we could be in a position to file a Complete Response to the April 2009 Complete Response Letter in the first quarter of 2011, which could lead to approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in 2011.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3 No. 333-86105, Form S-3 No. 333-35206, Form S-3 No. 333-72614, Form S-3 No. 333-82596, Form S-3 No. 333-101666, Form S-3 No. 333-107836, Form S-3 No. 333-111360, Form S-3 No. 333-118595, Form S-3 No. 333-121297, Form S-3 No. 333-122887, Form S-3 No. 333-128929, Form S-3 No. 333-133786, Form S-3 No. 333-139173, Form S-3 No. 333-151536, Form S-3 No. 333-151654, and Form S-3 No. 333-156237) of Discovery Laboratories, Inc. and in related Prospectuses

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

(3) Registration Statement (Form S-8 No. 333-33900, Form S-8 No. 333-55900, Form S-8 No. 333-67422. Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-116268, Form S-8 No. 333-127790, and Form S-8 No. 333-138476) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Discovery Laboratories, Inc.

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

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

(6) Registration Statement (Form S-8 No. 333-110412, Form S-8 No. 333-137643, Form S-8 No. 333-156443), and Form S-8 No. 333-164470) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our report dated March 10, 2010, with respect to the consolidated financial statements of Discovery Laboratories, Inc. and subsidiary and of our report dated March 10, 2010, 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, 2009.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2010

Exhibit 31.1

CERTIFICATIONS

I, W. Thomas Amick, 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 10, 2010

/s/ W. Thomas Amick

W. Thomas Amick, Chairman of the Board and
Principal 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 10, 2010

/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, 2009 (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 10, 2010

/s/ s/ W. Thomas Amick

W. Thomas Amick, Chairman of the Board
and Principal 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.