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, 2010

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	**The Nasdaq Capital Market**
Preferred Stock Purchase Rights	

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	☐
Non-accelerated filer	☐	Smaller reporting company	x

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 Capital Market under the symbol DSCO on June 30, 2010, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $37 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 on or before March 15, 2011 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 15, 2011, 24,115,151 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

In accordance with General Instruction G(3) to the Annual Report on Form 10-K, the information required to be disclosed in Part III of this Annual Report on Form 10-K is incorporated by reference from either (i) our definitive proxy statement, if filed with the Commission not later than 120 days after the end of our 2010 fiscal year, or (ii) if such definitive proxy statement is not filed with the Commission within such 120-day period, an amendment to this Annual Report on Form l0-K that will be filed with the Commission not later than the end of such 120-day period.

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 (RDS) 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 for the prevention of RDS, Surfaxin LS™ (our initial 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 will not be satisfied with the results of our efforts to (i) finally validate our optimized fetal rabbit biological activity test (BAT), (ii) demonstrate that the BAT has the ability to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product, and (iii) demonstrate the comparability of drug product used in the Surfaxin Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use through prospectively-designed, side-by-side preclinical studies (i.e., concordance studies) using the optimized BAT and the well-established preterm lamb model of RDS;

- 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 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;
- risks relating to our efforts to manufacture within our planned time frame the additional batches of Surfaxin for use in our comprehensive preclinical program and to complete the investigation into the manufacture of the two batches manufactured in January 2011 that did not meet specification;
- risks, if we succeed in gaining approval of Surfaxin and our other drug products, relating to our lack of marketing and distribution capabilities, which we will have to develop internally or secure through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products and drug product candidates;
- risks, if we succeed in gaining approval of Surfaxin and our other drug products, that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians, patients and others in the medical community;
- 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 BAT, 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 other factors 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, although we have regained compliance with the Minimum Bid Price Requirement of The Nasdaq Capital Market® by implementing a reverse split, we will be unable to maintain compliance with the listing requirements of Nasdaq, including without limitation those relating to market capitalization and stockholders equity, which could increase the probability that our stock will be delisted from Nasdaq, which could cause our stock price to decline;

- risks related to our need for significant additional capital to continue our planned research and development activities and continue operating as a going concern, which if derived from additional financings, could result in equity dilution;

- 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 risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;

- the risks that we will be unable to attract and retain key employees in a competitive market for skilled personnel, which could affect our ability to develop and market our products; 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.

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For the Fiscal Year Ended December 31, 2010

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 Capital Market, where our symbol is DSCO.

We are a biotechnology company developing surfactant therapies to treat respiratory disorders and diseases for which there 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 normal respiratory function and survival. 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 inactivation, we believe that our proprietary drug product and aerosolization device technology platforms make 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 neonatal populations. We have filed a New Drug Application (NDA) for our first product based on our novel KL_4 surfactant technology, Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in 2009. The safety and efficacy of Surfaxin for the prevention of RDS in premature infants previously has been demonstrated in a large, multinational Phase 3 clinical program and we believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit Biological Activity Test (BAT). Based on our interactions with the FDA regarding optimizing and revalidating the BAT, we integrated a number of protocolized method refinements into the BAT in 2010 that were intended to optimize the performance of the BAT and reduce assay variability. Subsequently, we performed a validation exercise on the new optimized BAT and successfully met all pre-specified acceptance criteria. We have since been conducting a comprehensive preclinical program, employing both the optimized BAT and a well-established preterm lamb model of RDS in a series of prospectively-designed, side-by-side preclinical studies, intended to satisfy the FDA with respect to the BAT and potentially to resolve a key remaining Chemistry, Manufacturing and Controls (CMC) issue that must be addressed to gain U.S. marketing approval for Surfaxin. The FDA has directed us to submit additional data from additional Surfaxin batches, seven of which have already been manufactured. We currently plan to manufacture three additional Surfaxin batches for the comprehensive preclinical program. If successful, we believe that we could file a Complete Response to the 2009 Complete Response Letter in the third quarter of 2011, which, after an anticipated six-month FDA review cycle, could lead to approval of Surfaxin for the prevention of RDS in premature infants in the first quarter of 2012. 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 initial lyophilized KL_4 surfactant, is a dry powder formulation that is resuspended to liquid form 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 product clinical performance. We are developing Surfaxin LS for the prevention and or treatment of RDS in premature infants for both the United States and all other major markets throughout the world. *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 initial proprietary KL_4 surfactant in aerosolized form, which we are developing using our capillary aerosolization technology and novel patient interface, initially to treat premature infants with or at risk for RDS. *See*, "– Proprietary Platform – Surfactant and Aerosol Technologies, – Our Aerosolization Device Technologies – Novel Patient Interfaces and Related Componentry." Premature infants with RDS are treated with surfactants that are administered presently 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 neonatal medicine. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Aerosurf for RDS in Premature Infants." We believe that the RDS market represents a significant opportunity from both a medical and a business perspective and 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 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. 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. In that regard, in 2010 an investigator-initiated Phase 2a clinical trial concluded assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of our aerosolized KL_4 surfactant in patients with Cystic Fibrosis (CF). *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – 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 conducted and are planning additional 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 "Surfactant Replacement Therapy for Respiratory Medicine – 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 continue to assess an array of potential strategic alliances and financing opportunities to potentially accomplish our development and commercialization objectives. 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 focus on our RDS programs, primarily Surfaxin, and conserve our resources, predominantly by curtailing and pacing investments in our other 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 market opportunity.

- Surfaxin is the first synthetic, peptide-containing surfactant that, if approved, will provide healthcare practitioners with an alternative therapy to the currently-approved, animal-derived surfactants that are standard of care today. The safety and efficacy of Surfaxin for the prevention of RDS has previously been demonstrated in a comprehensive Phase 3 clinical program. In April 2009, we received a Complete Response Letter (2009 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 were no questions regarding clinical trial data and no indication that the FDA has any concerns related to our other quality control and release tests or the manufacturing process for Surfaxin. We have had several interactions with the FDA intended to gain direction regarding our plans for final validation of the BAT, which we believe is a key remaining CMC issue that we must address to potentially gain FDA marketing approval of Surfaxin. Taking into account the FDA's responses, we have optimized the BAT and expect to conclude a comprehensive preclinical program and file a Complete Response to the 2009 Complete Response Letter in the third quarter of 2011. During the anticipated six-month FDA review cycle, we anticipate that the FDA will conduct certain pre-approval reviews, including an inspection of our Surfaxin manufacturing operations and related quality assurance/quality control facilities, and potentially the facilities of our third-party raw materials suppliers. We believe that Surfaxin for the prevention of RDS in premature infants could gain marketing approval in the United States as early as the first quarter of 2012. *See* "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin for the Prevention of RDS in Premature Infants."

- We also are developing Surfaxin LS, our initial lyophilized (dry powder) formulation that is resuspended to liquid form prior to use, with the objective of improving ease of use for healthcare practitioners, eliminating the need for cold-chain storage, and potentially further improving clinical performance. We are developing Surfaxin LS for both the United States and all other major markets throughout the world. We are in the process of conducting a technology transfer of the Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations. We also plan to seek regulatory and scientific guidance with respect to a planned Surfaxin LS late-stage global registration clinical program from the FDA and the European Medicines Agency (EMA) in 2011. We believe that collectively, over time, Surfaxin and Surfaxin LS, if approved, have the potential to displace the use of animal-derived surfactants in all major markets throughout the world.

- Aerosurf, our lead aerosolized KL_4 surfactant program, holds the promise to significantly expand the use of surfactant therapy in premature infants by potentially providing neonatologists with a means of administering KL_4 surfactant to infants 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. In December 2010, the National Institutes of Health (NIH) awarded us Phase I of a Fast Track Small Business Innovation Research Grant to support up to $580,000 of Aerosurf development activities. Following conclusion of the Phase I grant activities, we anticipate that the NIH may potentially award us a Phase II grant which could provide up to an additional $1.8 million to support further development.

  We are currently advancing our preclinical development activities for Aerosurf and, with the assistance of third-party medical device engineers, optimizing the design of the capillary aerosolization device for anticipated clinical development and potential commercial use. Our plans for 2011 include finalizing the Aerosurf clinical / potential commercial device design, finalizing the patient interface clinical / potential commercial device design and seeking regulatory guidance from the FDA and EMA for the planned Aerosurf development program. In the future, we plan to initiate a Phase 2a clinical trial for Aerosurf in premature infants with or at risk for RDS.

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 with or at risk for RDS to be treated with surfactant therapy.

- Although we continue to conserve resources and pace our investment in exploratory development programs, we are conducting limited exploratory development of our KL_4 surfactant to investigate its use for addressing Cystic Fibrosis (CF) and Acute Lung Injury (ALI). In addition, resources permitting, we plan in the future on continuing to assess the feasibility of whether our KL_4 surfactant, either alone or in combination with our capillary aerosolization technology, may represent a novel approach for drug combination therapies by efficiently delivering small- and large-molecule therapeutics to the lung.

    - Our aerosolized KL_4 surfactant was evaluated in an investigator-initiated Phase 2a clinical trial in CF patients conducted at The University of North Carolina with the support of the Cystic Fibrosis Foundation. The trial concluded in 2010 and demonstrated that aerosolized KL_4 surfactant delivery to CF patients was feasible, generally safe and well tolerated and further demonstrated evidence of pharmacologic response via improvement in mucociliary clearance versus patient baseline. Additionally, in 2010 the FDA granted us orphan drug designation for the treatment of CF with KL_4 surfactant.

    - We believe that our aerosolized KL_4 surfactant, administered as an early-intervention therapy, may be potentially effective as a preventive measure for patients at risk for ALI, a syndrome entailing pulmonary function compromise, significant inflammation and increased lung permeability, all associated with pulmonary surfactant dysfunction. 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. In 2010, we concluded a Phase 2 clinical trial of Surfaxin administered intratracheally as a liquid bolus in children with acute respiratory failure (ARF), a critical pediatric respiratory condition that is often caused by severe respiratory infections and has a similar presentation to ALI. The objective of the study was to evaluate the safety and tolerability of intratracheal administration of Surfaxin and to assess whether Surfaxin treatment could decrease the duration of mechanical ventilation in children with ARF. Data from the trial indicate that, based on patient stratification by severity of lung injury, Surfaxin treatment meaningfully reduced time on mechanical ventilation in the least severe patient segment. We believe this supports the rationale for an early-intervention strategy, prior to disease progression to a severe state requiring intubation, for our aerosolized KL_4 surfactant to serve as a potentially effective preventive measure for patients at risk for ALI.

  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.

    - Since receipt of the 2009 Complete Response Letter, we have implemented cost-containment measures to conserve cash, including reducing our workforce and limiting investments in our pipeline programs. We plan to continue closely managing our expenditures in 2011 and focus our financial resources on our RDS programs, primarily activities in support of the potential approval of Surfaxin.

    - During 2010, we completed two public offerings of our common stock and warrants resulting in aggregate net proceeds of $24.2 million, after taking into account transaction related fees and expenses. Also in 2010, we restructured and paid off our $10.6 million loan with PharmaBio Development Inc. (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. (Quintiles). Contemporaneously with the restructuring, we completed a sale of our common stock and warrants to PharmaBio resulting in net proceeds of $2.1 million. We also raised approximately $2.0 million in additional capital in 2010 by drawing on our CEFF ($1.4 million), completing a second offering of common stock and warrants to PharmaBio ($500,000), and receiving $245,000 in grant proceeds awarded us under the Patient Protection and Affordable Care Act of 2010. In February 2011, we completed a public offering of our common stock and warrants resulting in net proceeds of approximately $21.6 million, after taking into account transaction related fees and expenses.

- We continue to assess 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) and development and commercial capabilities to advance our KL_4 technology. We also are assessing 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 assessing 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, 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 Surfaxin 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 preclinical, 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 are in the process of conducting a technology transfer of the lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in such formulations. 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, December 2010; 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, New England Journal of Medicine (NEJM), 2008, Eichenwald, Stark; The Cystic Fibrosis Foundation website; Discovery Labs Primary Market Research, 2010; 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 to 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 iii of this Annual Report on Form 10-K, and “Item 1A – Risk Factors.”

PROPRIETARY PLATFORM – SURFACTANT AND AEROSOL TECHNOLOGIES

Pulmonary surfactants are protein and phospholipid 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. KL_4 is our synthetic peptide that is designed to closely mimic the essential attributes of surfactant protein B (SP-B).

Many respiratory disorders are associated with surfactant deficiency or surfactant degradation. However, the use of surfactant therapy presently has limited application and is FDA-approved only for managing RDS in premature infants. Currently available surfactants are derived from pig and cow lungs using a chemical extraction process. Although clinically effective, these surfactants have several 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 may 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 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 that is most important for the proper functioning of the respiratory system. Our synthetic surfactant may be manufactured to precise specifications and formulated as a liquid instillate, lyophilized formulation (dry powder), or aerosolized liquid. In October 1996, 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).

Our KL_4 surfactant is a synthetic surfactant that can be manufactured consistently and with minimal lot-to-lot 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 non-immunogenic 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. Several preclinical studies assessing the potential advantages of our KL_4 surfactant technology have been presented at major medical congresses and are summarized below:

- In December 2010, data were presented at the 2010 Annual Hot Topics in Neonatology Congress in Washington, DC demonstrating that Aerosurf, in a dose-dependent fashion, meaningfully improved lung function and lung structural integrity and reduced lung tissue inflammatory marker levels in a preclinical study using the well-established preterm lamb model of RDS. Aerosurf is our initial form of aerosolized KL_4 surfactant created via our proprietary capillary aerosolization technology that we are currently developing for premature infants with or at risk for RDS. In this preclinical study, preterm lambs were randomized to receive continuous positive airway pressure (CPAP) alone or CPAP plus either 10, 20, 30, or 90 minutes of Aerosurf exposure. The results demonstrated that treatment with Aerosurf resulted in a dose-dependent improvement in lung function and a decrease in lung interleukin-8, an established marker of respiratory inflammation, with marked differences following 20 minutes of aerosol exposure and no further improvement following 30 and 90 minutes of exposure. Additionally, improvement in oxygenation was observed to a greater degree in the 10, 20, and 30 minute dosing groups compared with CPAP alone or the 90 minute dosing group and Aerosurf preserved lung structural integrity in all exposure groups.

- In May 2010, data were presented at the 2010 American Thoracic Society International Conference from a preclinical study using KL_4 surfactant in an established porcine model of lung transplantation. The objective of this study was to assess the potential protective role of KL_4 surfactant in reducing ischemia-reperfusion injury by administering KL_4 surfactant to donor lungs prior to harvest and transplantation in an experimental pig lung transplant model. In transplanted donor lungs that were treated with KL_4 surfactant prior to lung harvest and transplantation, a significant improvement in oxygenation ($p < 0.05$) was observed, as well as preservation of lung surfactant composition ($p < 0.05$) and a significant reduction in oxidative damage ($p < 0.05$) compared with animals receiving untreated transplanted lungs. The study demonstrated a potentially important protective role in a newly transplanted lung, reducing ischemia-reperfusion injury often seen after lung transplantation, and suggesting that KL_4 surfactant may play an important protective role in minimizing lung damage triggered by ischemia-reperfusion injury following lung transplantation.

- In May 2010, data from two preclinical studies were presented at the Pediatric Academic Societies (PAS) Annual Meeting that demonstrate that our initial lyophilized KL_4 surfactant, Surfaxin LS, improves lung function and oxygenation while attenuating lung inflammation in the preterm lamb model of RDS. In one study, lyophilized KL_4 surfactant was compared to commercially available animal-derived surfactants to assess improvements in pulmonary function (lung compliance, functional residual capacity and ventilator support requirements), integrity of lung tissue structure, and the potential impact on inflammatory mediators in preterm lambs with RDS. This study demonstrated that treatment with lyophilized KL_4 surfactant, compared with untreated controls, resulted in significant improvements in pulmonary function ($p < 0.05$), significantly better microscopic lung tissue structure ($p < 0.05$), and a significant reduction in two potent inflammatory mediators: interleukin (IL) – 8 and myeloperoxidase ($p < 0.05$). Significant improvements in pulmonary function were observed in lambs treated with the animal-derived surfactants, Survanta® (beractant, a surfactant derived from cow lung and the most prescribed surfactant in the United States) and Curosurf® (poractant alfa, a surfactant derived from pig lung and the most prescribed surfactant in Europe), compared with controls ($p < 0.05$); however, oxygenation was significantly improved in lambs treated with lyophilized KL_4 surfactant compared with those treated with comparator animal-derived surfactants ($p < 0.05$).

- In another study presented at PAS, the effects of lyophilized KL_4 surfactant on pulmonary function and peri-dosing associated effects of surfactant administration in preterm lambs with RDS were compared to those of Curosurf. Both surfactants significantly improved pulmonary function ($p < 0.05$). However, lambs treated with lyophilized KL_4 surfactant required significantly lower mechanical ventilator pressures to maintain pulmonary function compared with Curosurf-treated lambs ($p < 0.05$). Additionally, lambs treated with Curosurf experienced significant reductions in heart rate and rapidly increased brain oxygenation during the peri-dosing period ($p < 0.05$), in contrast to lambs treated with lyophilized KL_4 surfactant. The study investigators concluded that lyophilized KL_4 surfactant may enable ventilation at lower mean airway pressures which may reduce the incidence of chronic lung disease.

- 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 PAS 2009 Annual Meeting, 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 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.

- 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 an integral part, such as ALI, ARF 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 KL_4 surfactant has demonstrated attributes that we believe are uniquely beneficial in the treatment of premature infants at risk for RDS and warrant further scientific assessment to address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies.

RDS in Premature Infants

- In May 2010, results from our previously-conducted Phase 2a feasibility study of Aerosurf for the prevention of RDS in premature infants were published in the *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. In this feasibility study, Aerosurf was administered to seventeen infants within 30 minutes of birth using a commercially-available aerosolization device via nCPAP over a three-hour duration. Aerosurf was generally safe and well tolerated with twelve (71%) of the infants requiring a single dose of Aerosurf only. In addition, all infants survived through the assessment period (day 28 of life), fifteen (88%) infants survived with no evidence of Bronchopulmonary Dysplasia (BPD) at day 28 of life, and five (29%) infants required intubation and mechanical ventilation (commonly known as nCPAP failure). The study investigators concluded that Aerosurf can be safely administered via nCPAP to preterm infants at risk for RDS and may provide an alternative to surfactant administration via an endotracheal tube.

- 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 pivotal 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 (a supportive Phase 3 trial) 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, including follow-on neonatal patient assessment through the first year of life, have been presented at several international medical meetings and trial results were published in *Pediatrics*, the Official Journal of the American Academy of Pediatrics and a premier medical journal for pediatric healthcare practitioners.

Cystic Fibrosis

- In October 2010, results from an investigator-initiated Phase 2a clinical trial of aerosolized KL_4 surfactant in patients with CF was presented at the North American Cystic Fibrosis Conference. The trial demonstrated that aerosolized KL_4 surfactant delivery to CF patients was feasible, generally safe and well tolerated and was not associated with serious adverse events. Both aerosolized KL_4 surfactant and the active comparator, aerosolized saline control, produced a marked, significant ($p < 0.01$) increase from patient baseline in mucociliary clearance measured one hour after the last dose in both whole lung and peripheral lung compartments. We believe these results support further scientific assessment of a potential complementary therapeutic role for aerosolized KL_4 surfactant specifically targeting airway mucus adhesions.

Acute Respiratory Failure / Acute Lung Injury

- In 2010, we concluded and reported results from a Phase 2 clinical trial evaluating the safety and tolerability of intratracheal administration of Surfaxin (as a liquid bolus) and assessing whether Surfaxin treatment could decrease the duration of mechanical ventilation in children with ARF. Data from the trial demonstrate that, based on patient stratification by severity of lung injury, Surfaxin treatment significantly reduced time on mechanical ventilation in the least severe patient segment ($p < 0.01$). Additionally, Surfaxin intervention reduced the need for a second dose ($p < 0.05$), suggesting a decrease in disease severity following surfactant treatment. ARF is a critical pediatric respiratory condition with a similar presentation to ALI that is often caused by severe respiratory infections. We believe the results from the ARF trial suggest the rationale for an early-intervention strategy, prior to disease progression to a severe state requiring intubation, for our aerosolized KL_4 surfactant as a potentially effective preventive measure for patients at risk for ALI.

Bronchopulmonary Dysplasia (BPD)

- In 2009, 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, were published in Pediatrics. In the clinical trial, infants were randomized to receive, in addition to standard of care, either a Surfaxin standard or low dose or sham air as a control. Observations from this pilot estimation study included that infants treated with the Surfaxin standard dose, as compared to those in the control group experienced a lower incidence of death or BPD (58% vs. 66%), a higher survival rate through 36 weeks post-menstrual age (89% vs. 84%), and fewer days on mechanical ventilation. 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. We believe that the results of our estimation trial suggest that our KL_4 surfactant may potentially represent a novel therapeutic option for infants at risk for BPD.

KL_4 Surfactant Drug Product Formulation Flexibility

The initial formulation of our KL_4 surfactant technology, Surfaxin, is a liquid instillate that is 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 (such as Surfaxin LS) 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:

- lowered 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;
- improved ease of administration and time of drug product preparation;
- potentially eliminating continuous cold chain storage and refrigeration;
- potentially eliminating the need for warming prior to product use; and
- potentially improving drug product stability and extending shelf life.

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.

Our Aerosolization Device Technologies

Capillary Aerosolization Technology

We have worldwide exclusive rights to our capillary aerosolization technology through exclusive license agreements with Philip Morris USA Inc. (PMUSA), in the United States and with a former affiliate of PMUSA, Philip Morris Products S.A., in all territories outside of the United States. Each of these license agreements provides us with exclusive rights 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. With the assistance of third-party medical device engineers, we are currently optimizing the design of the capillary aerosolization device for anticipated clinical development and potential commercial use.

In studies conducted with our initial prototype and newer-generation capillary aerosolization systems and 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;
- 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 physiologic outcomes versus nasal continuous positive airway pressure (nCPAP) alone in an animal model of RDS.

Novel Patient Interfaces and Related Componentry

In connection with the development of our aerosolized KL_4 surfactant technology, we have and plan to continue to develop a number of novel patient interfaces and related components intended to increase the efficiency of aerosol delivery to the patient and simultaneously reduce drug wastage. To date, we have developed such interfaces and related components with a focus on the neonatal patient population, initially to be used in our Aerosurf program to treat premature infants with or at risk for RDS. We believe that our proprietary technology, novel interfaces and related circuitry, should allow for more efficient delivery of aerosols to the patient, reduce drug compound dilution and wastage, and result in more precise aerosol dosing. We are presently assessing these technologies and devices to determine whether they have application beyond neonatal patient populations and could potentially benefit pediatric and adult patients by increasing the effectiveness of aerosolized delivery of a broad range of drug products.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

The only pulmonary surfactants commercially 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 include:

Respiratory Distress Syndrome in Premature Infants (RDS)

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in neonatal intensive care units (NICUs). One of the most common respiratory problems is RDS. RDS is a condition in which premature infants are born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen. Premature infants born prior to 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, thereby increasing their risk of developing further serious respiratory complications. Neonatologists generally try to avoid mechanically ventilating infants due to perceived risks associated with intubation, such as the risk of trauma and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits of invasive surfactant administration clearly outweigh the associated risks. For all but the very low birth weight infants with severe RDS, a common ventilatory support treatment alternative to intubation and mechanical ventilation is nasal CPAP (nCPAP). Unfortunately, a significant number of infants do not adequately respond to nCPAP and require subsequent surfactant administration via intubation and mechanical ventilation, an outcome referred to as nCPAP failure. 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. Several recent published studies point toward a high rate of nCPAP failure in the neonatal population.

We estimate that approximately 360,000 low birth weight premature infants are born annually in the United States and at risk for RDS (approximately 600,000 children inclusive of the United States, major European medical markets and Japan). Of the United States total, we estimate that approximately 130,000 are diagnosed with RDS and approximately 86,000 are treated with surfactant replacement therapy, either for the prevention or treatment of RDS. We also estimate that approximately 240,000 infants receive early nCPAP (as an initial RDS management strategy in lieu of initial intubation and mechanical ventilation). Recent peer-reviewed, published studies report rates of nCPAP failure ranging between 60-80% of children receiving early nCPAP, depending on gestational age evaluated (Finer *et al*, NEJM 2010; Morely *et al*, NEJM 2008).

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 at risk of 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 neonatal 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 recent 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.

After previously receiving three Approvable Letters, we received the 2009 Complete Response Letter for this NDA. As was the case with the previous letters, the 2009 Complete Response Letter focused primarily on the Chemistry, Manufacturing and Controls (CMC) section of our NDA and did not question the quality of our clinical trial data or call for additional clinical trials demonstrating safety or efficacy. Rather, the 2009 Complete Response Letter was focused on certain aspects of the BAT (an important quality control release and stability test for Surfaxin). We believe that a key remaining step to potentially gain FDA marketing approval for Surfaxin is to satisfy the FDA as to the final validation of the BAT and whether the BAT can adequately reflect the biological activity of Surfaxin throughout its shelf life and discriminate biologically active from inactive Surfaxin drug product.

Based on several interactions with the FDA concerning the BAT, we integrated a number of protocolized method refinements in 2010 intended to optimize the performance of the BAT and reduce assay variability, successfully meeting all pre-specified acceptance criteria. We have been conducting a comprehensive preclinical program that calls for multiple Surfaxin batches to be used to demonstrate concordance between the BAT and the well-established preterm lamb model of RDS by performing a series of prospectively-designed, side-by-side preclinical studies (i.e., concordance studies). Data from the preterm lamb model and BAT concordance studies will be submitted in our planned upcoming Complete Response to the FDA and are intended to support final BAT validation and to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use. The comprehensive preclinical program is also intended to provide data that will result in the FDA's agreement on final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of Surfaxin drug product.

We have continued to interact with the FDA with respect to final BAT validation and recently received a communication from the FDA that focuses on certain technical criteria relating to final validation and directs us to increase the sample size of specified data sets by testing additional Surfaxin batches. To be responsive to the FDA's direction, we plan on submitting data in the upcoming Complete Response from several Surfaxin batches that have been previously manufactured, as well as data from more-recently manufactured Surfaxin batches. In December 2010, we began manufacturing additional Surfaxin batches for use in the comprehensive preclinical program. As a result, we now have seven Surfaxin batches that can be used for this purpose. We routinely employ an array of quality control and release tests to assess all of the batches we produce. In January 2011, quality control testing performed by us indicated that two other newly-manufactured Surfaxin batches did not meet one of the pre-specified release specifications and, therefore, cannot be used in the comprehensive preclinical program. Quality control testing to date indicates that all other Surfaxin batches that we have manufactured since December 2010 successfully meet all specifications, including the specification that the two unacceptable batches did not meet, and continue to pass our ongoing release and stability testing.

Presently, we are continuing to manufacture additional Surfaxin batches to support the Complete Response and, at the same time, in accordance with our quality assurance procedures and pharmaceutical manufacturing practices, we are conducting an investigation into the manufacture of the Surfaxin batches that did not meet specification to determine the probable cause. We currently plan to manufacture three additional Surfaxin batches for the comprehensive preclinical program. If successful, we believe that we could file a Complete Response in the third quarter 2011, which, after an anticipated six-month FDA review cycle, could lead to potential U.S. marketing approval for Surfaxin in the first quarter of 2012.

In April 2008, the FDA completed a pre-approval inspection (PAI) of our manufacturing facility and issued an Establishment Inspection Report reflecting a successful inspection. Following our planned submission of the Complete Response and prior to gaining potential FDA marketing authorization for Surfaxin, we believe that the FDA will likely conduct another PAI of our manufacturing facility and re-assess the quality assurance/quality control facilities for Surfaxin including those of our third-party raw material suppliers and testing laboratories. We also anticipate that the Complete Response, in addition to including the results of the comprehensive preclinical program, will include routine regulatory submissions, such as an updated clinical trial safety report for Surfaxin. In addition, although we have previously discussed the principal content of the Surfaxin package insert with the FDA, we believe that the FDA may want to update the format and content of the package insert in connection with a potential Surfaxin approval to comply with mandated format changes as well as to reflect updated information regarding Surfaxin.

Background to the Comprehensive Preclinical Program

During our Phase 3 clinical trials, we did not employ a BAT to evaluate biological activity in Surfaxin clinical drug product. We later implemented the BAT as a recurring quality control test to confirm biological activity for Surfaxin release and stability. Based on guidance from the FDA, 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 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 (associated with the pre-optimized BAT) and the expected variability in animal models generally, we and the FDA believed it would be a significant challenge to establish the degree of consistency that the FDA required through preclinical experimentation 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 employ an optimized BAT while simultaneously conducting a limited clinical trial. On September 2009, we held a teleconference with the FDA and discussed in detail our plans to optimize the precision of the BAT and its subsequent validation. We also discussed and subsequently proposed the design of a limited clinical trial intended primarily to assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with RDS. Although the FDA initially indicated that such a PD clinical trial design, simultaneously employing an optimized and revalidated BAT, could potentially resolve the remaining FDA requirement for Surfaxin approval, in February 2010 the FDA advised 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 focused on integrating a number of protocolized method refinements into the BAT intended to optimize its performance and reduce assay variability. We completed these optimization activities in 2010 and then conducted testing that demonstrated that all pre-specified acceptance criteria were met and that BAT optimization had resulted in a greater than 40% reduction in BAT variability relative to the BAT methodology that was employed prior to 2010. We have since been employing the optimized BAT in the comprehensive preclinical program (involving a series of side-by-side preclinical studies employing the BAT and the preterm lamb model of RDS) intended to satisfy the FDA as to the final validation of the BAT and gain potential FDA marketing approval for Surfaxin. Throughout these efforts, we have been interacting with the FDA and have previously submitted, at the FDA's suggestion, proposals both outlining specific BAT method refinements and detailed aspects of final BAT validation. We have incorporated the FDA's direction into our plans to complete the comprehensive preclinical program, including increasing the sample size of specified data sets by testing additional Surfaxin batches for which we are presently concluding the manufacture. In addition, the FDA's responses include detailed direction with respect to generating limited additional confirmatory data through further concordance testing. We plan to generate these additional data for inclusion in the Complete Response, which data must be consistent with the concordance data generated to date.

Surfaxin LS™ – Lyophilized Surfaxin for RDS in Premature Infants

Surfaxin LS is our initial lyophilized (dry powder) formulation of Surfaxin that is resuspended to liquid form just prior to administration and that we are developing for the prevention and or treatment of RDS in premature infants. We believe that our lyophilized KL_4 surfactant 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.

We are in the process of conducting a technology transfer of the Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations. We also plan to seek regulatory and scientific guidance with respect to the planned Surfaxin LS Phase 3 global registration clinical program with the FDA and the EMA in 2011. Our objective is to develop Surfaxin LS for both the United States and all other major markets throughout the world and if we can gain the agreement of the FDA and the EMA, 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 initial 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, which can be administered via nCPAP, holds the promise to significantly expand the use of our KL_4 surfactant in neonatal 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.

Prior 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 December 2010, data were presented at the 2010 Annual Hot Topics in Neonatology Congress in Washington, DC demonstrating that Aerosurf (using our capillary aerosolization technology), in a dose-dependent fashion, meaningfully improved lung function and lung structural integrity and reduced lung tissue inflammatory marker levels in a preclinical study using the well-established preterm lamb model of RDS. In addition, preclinical developmental studies using the lamb model of RDS were presented at the 2007 Annual Hot Topics in Neonatology meeting held in Washington, DC, demonstrating that Aerosurf (also using our capillary aerosolization technology) improved lung function and reduced inflammatory markers associated with lung injury and chronic lung disease.

We are currently developing Aerosurf using our capillary aerosolization technology. See, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Device Technology – Capillary Aerosolization Technology." With the assistance of third-party medical device engineers, we are optimizing the design of the capillary aerosolization device for anticipated clinical development and potential commercial use. Our plans for 2011 include finalizing the Aerosurf clinical / potential commercial device design, finalizing the patient interface clinical / potential /commercial device design and seeking regulatory guidance from the FDA and EMA for the planned Aerosurf development program. In the future, we plan to initiate a Phase 2a clinical trial for Aerosurf in premature infants with or at risk for RDS. However, as these activities require significant investments in research, engineering, device development and manufacturing capabilities, and regulatory expertise, 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 met with and received guidance from the FDA with respect to the design of our planned Phase 2 clinical program. We have continued to conduct certain developmental and preclinical activities to support our regulatory package and are currently advancing our preclinical development activities and preparing to further engage the FDA and EMA with respect to our clinical program.

We believe that Aerosurf is a highly promising program. In December 2010, the National Institutes of Health (NIH) awarded us Phase I of a Fast Track Small Business Innovation Research Grant to support up to $580,000 of Aerosurf development activities. Following conclusion of the Phase I grant activities, we anticipate that the NIH may potentially award us a Phase II grant, which could provide up to an additional $1.8 million to support further development. 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."

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.

Our aerosolized KL_4 surfactant was recently evaluated in an investigator-initiated Phase 2a clinical trial in Cystic Fibrosis (CF) patients conducted at The University of North Carolina with the support of the Cystic Fibrosis Foundation. The trial concluded in 2010 and was designed as a double-blind, randomized study to evaluate whether 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. The trial demonstrated that aerosolized KL_4 surfactant delivery to CF patients was feasible, generally safe and well tolerated and was not associated with serious adverse events. Both aerosolized KL_4 surfactant and the active comparator, aerosolized saline control, produced a marked, significant ($p < 0.01$) increase from patient baseline in mucociliary clearance measured one hour after the last dose in both whole lung and peripheral lung compartments. We believe these results support further scientific assessment of a potential complementary therapeutic role for aerosolized KL_4 surfactant specifically targeting airway mucus adhesion. Additionally, in 2010 the FDA granted us orphan drug designation for the treatment of CF with KL_4 surfactant.

We believe that our novel synthetic, peptide-containing surfactant has unique attributes, potentially including 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 and, possibly in the future, 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 conclude any such strategic alliance, collaboration arrangement or financial alternative. 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.

In 2010, we concluded and reported results from a Phase 2 clinical trial evaluating the safety and tolerability of intratracheal administration of Surfaxin (as a liquid bolus) and assessing whether Surfaxin treatment could decrease the duration of mechanical ventilation in children with ARF. Data from the trial demonstrate that, based on patient stratification by severity of lung injury, Surfaxin treatment significantly reduced time on mechanical ventilation in the least severe patient segment. ARF is a critical pediatric respiratory condition with a similar presentation to ALI that is often caused by severe respiratory infections. We believe the results from the ARF trial suggest the rationale for an early-intervention strategy, prior to disease progression to a severe state requiring intubation, for our aerosolized KL_4 surfactant as a potentially effective preventive measure for patients at risk for ALI.

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)") may be an effective treatment for COPD, potentially improving outcomes for these very ill patients.

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 aerosolized using our capillary aerosolization technology, may be a superior mechanism to deliver small- and large-molecule therapeutics to the lung. We have conducted and are planning additional exploratory preclinical studies to assess the feasibility of using our KL_4 surfactant in combination with small- and large-molecule therapeutics, including potentially antibiotics, protease inhibitors and oligonucleotides, to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease. 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, 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 demonstrating proof of concept or in entering into any such arrangement.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are initially focused primarily on potentially gaining regulatory approval for Surfaxin for the prevention of RDS in premature infants and on developing our proprietary KL_4 surfactant technology and capillary and related 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 plan to closely manage our expenditures in 2011 and focus our financial resources on our RDS programs, primarily activities in support of the potential approval of Surfaxin. We are actively assessing various strategic and financial alternatives to secure necessary capital and advance our KL_4 respiratory pipeline programs, 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) and development and commercial capabilities 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. We have implemented cost-containment measures to conserve cash, including reducing our workforce and limiting investments in our pipeline programs. 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:

- physicians with expertise in pediatric and pulmonary medicine and extensive contacts in the neonatal 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 monitoring of clinical trials that we may conduct. We also plan to 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 are assessing and 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 plan to rely on contract manufacturing organizations (CMOs) to produce certain formulations of our KL_4 drug product; 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, 2010, and 2009, our research and development expenses were $17.1 million, and $19.1 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 other active ingredients, including certain lipids that are provided by suppliers such as Corden Pharma (from a facility that was owned previously by Genzyme Pharmaceuticals) and Avanti Polar Lipids, Inc. We currently obtain our active ingredients from single-source providers, although we plan to qualify secondary suppliers when our financial resources permit. Our risk of losing a source of supply is somewhat 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 under our sole operational control and are presently configured to produce liquid formulations of our KL_4 surfactant drug product such as Surfaxin, which is manufactured as a liquid instillate to be administered intratracheally via an endotracheal tube to neonates. These operations also play 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. 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 possibly other KL_4 surfactant liquid drug product candidates. We are also establishing contract manufacturing capabilities for the production of Surfaxin LS, our initial lyophilized (dry powder) formulations of our KL_4 surfactant drug product, which is resuspended to liquid form just prior to administration. Presently, we are in the process of conducting a technology transfer of the Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations.

In 2006, we experienced stability failures in certain batches of Surfaxin that were manufactured for us by our then-contract manufacturer. After conducting a formal investigation and implementing a corrective action and preventative action (CAPA) plan, we successfully manufactured three new Surfaxin process validation batches in February 2007. The stability data on these process validation lots has been submitted to the FDA and we believe that these data and data from numerous subsequent lots support at least a 12-month shelf life for Surfaxin.

In April 2008, the FDA completed a pre-approval inspection (PAI) of our manufacturing facility and issued an Establishment Inspection Report indicating an approval recommendation for our Surfaxin NDA. In December 2010, we began manufacturing additional Surfaxin batches for use in the comprehensive preclinical program. As a result, we now have seven Surfaxin batches that can be used for this purpose. We routinely employ an array of quality control and release tests to assess all of the batches we produce. In January 2011, quality control testing performed by us indicated that two other newly-manufactured Surfaxin batches did not meet one of the pre-specified release specifications and, therefore, cannot be used in the comprehensive preclinical program. Quality control testing to date indicates that all other Surfaxin batches that we have manufactured since December 2010 successfully meet all specifications, including the specification that the two unacceptable batches did not meet, and continue to pass our ongoing release and stability testing.

We currently plan to manufacture three additional Surfaxin batches for the comprehensive preclinical program, which, if successful, would position us to file a Complete Response to the 2009 Complete Response Letter in the third quarter of 2011. At the same time, in accordance with our quality assurance procedures and pharmaceutical manufacturing practices, we are conducting a comprehensive investigation into the manufacture of the Surfaxin batches that did not meet specification with the objective of determining a probable cause and, if appropriate, implementing a corrective action and preventative action plan. In connection with our efforts to gain FDA marketing approval for Surfaxin, we anticipate that the FDA will likely conduct another PAI of our Totowa, NJ, manufacturing facility and assess the quality assurance/quality control facilities for Surfaxin including those of our third-party raw material suppliers and testing laboratories. *See*, "Item 1A – Risk Factors – Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business."

Our manufacturing strategy includes investing in our analytical and quality systems. We have consolidated all of our in-house analytical, quality and development activities at our analytical and development laboratory in our headquarters in Warrington, Pennsylvania. Activities conducted there 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. In addition, we have 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 we believe 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.

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."

We are currently developing Aerosurf using our capillary aerosolization technology. We have worked with selected component manufacturers and an integrator to manufacture and integrate our initial prototype capillary aerosolization system. We are currently focused on developing an optimized capillary aerosolization device to meet regulatory and ease-of-use design requirements for Aerosurf and prepare for potential Phase 2 and further clinical trials. We expect to rely on third-party contract manufacturers to manufacture and assemble the subcomponents of our capillary aerosolization technology, including novel patient interfaces and related components, 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. *See*, "Item 1A – Risk Factors – Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business."

Distribution

We are currently manufacturing Surfaxin as a liquid instillate that requires cold-chain storage and distribution. In anticipation of potential approval of Surfaxin in the first quarter of 2012, 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 specified surfactant products in Andorra, Greece, Italy, Portugal and Spain. *See*, "– Business Operations – Strategic Alliances and Collaboration Arrangements – Laboratorios del Dr. Esteve, S.A." 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 and Latin 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. The alliance will terminate as to each covered product, on a country-by-country basis, upon the latest to occur of: the expiration of last patent claim related to a covered product in such country; the first commercial sale in such country of the first-to-appear generic formulation of the covered product, and the tenth anniversary of the first sale of the covered product in such country. In addition to customary termination provisions for breach of the agreement by a party, the alliance agreement may be terminated by Esteve on 60 days' prior written notice, up to the date of receipt of the first marketing regulatory approval, or, on up to six months' written notice, if the first marketing regulatory approval has issued. We may terminate the alliance agreement in the event that Esteve acquires a competitive product (as defined in the agreement).

Potential Alliances and Collaboration Arrangements

We continue to assess several approaches for the development and/or commercialization of our KL_4 surfactant product candidates, focusing on ways to potentially commercialize Surfaxin in the United States. 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) and development and commercial capabilities 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. Under the license agreement, we are obligated to pay the licensors fees of up to $2.5 million in the aggregate upon our achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for certain designated products. In addition, we have paid $450,000 to date for milestones that have been achieved. In addition, we are required to make royalty payments at different rates, depending upon type of revenue and country, in amounts of up to a high single-digit percent of net sales (as defined in the agreement) of licensed products sold by us or sublicensees, or, if greater, a percentage of royalty income from sublicensees in the low double digits. The license agreement will expire, on a country-by-country basis, upon expiration of the last patent containing a valid claim covering a licensed product in such country. In addition to customary termination provisions for breach of the agreement by a party, we may terminate the agreement, as to countries other than the U.S. and Western Europe territories (as defined in the agreement), on a country-by-country basis, on six months' prior written notice; and as to the entire agreement, on 60 days' prior written notice.

Patents covering our proprietary precision-engineered surfactant technology that have been issued or are pending worldwide include composition of matter, formulation, manufacturing and uses and include the following 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 a pulmonary lavage method of treating RDS with these surfactants. 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, 2011 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. U.S. Patent No. 6,013,619 will expire on April 28, 2017

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).

We also have licensed or optioned for license certain patents and pending patent applications from Scripps 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. For example, selected compositions of pulmonary surfactants and protease inhibitors and methods of administering these compositions are claimed in the U.S. Patent No. 7,863,241 titled "Compositions for treatment and prevention of pulmonary conditions" which issued on January 4, 2011 and will expire on February 17, 2025.

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, now expired), 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.

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.

Each of the above-listed PCT applications has entered national phase in Europe and Japan, among other countries.

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

In March 2008, we restructured our December 2005 strategic alliance with 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. In addition to customary termination provisions for breach of the agreements, we may terminate the License Agreements, in whole or in part, upon advance written notice to the licensor. In addition, either party to each License Agreement may terminate upon a material breach by the other party (subject to a specified cure period).

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 (as defined below) 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 the amount of any minimum royalties paid. 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.

Capillary Aerosolization Technology Patents and Patent Rights

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. The aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2023, or, in some cases, possibly later. Our license under each License Agreement, unless terminated earlier, will expire as to each licensed product, on a country-by-country basis, upon the latest to occur of: the date on which the sale of such licensed product ceases to be covered by a patent claim of an issued and unexpired patent in such country; the date a generic form of the product is introduced in such country; and the tenth anniversary of the first commercial sale of such licensed product.

Other Aerosolization Device Patents and Patent Rights

In March 2009, we filed International patent application (PCT US/2009/037409) directed to improvements of an aerosol delivery system and ventilation circuit adaptor. The International patent application is an interim phase in the prosecution of patents and is now expired. Beginning on September 16, 2010, this application entered national phase in US, Europe and Japan, among other countries and is currently pending. The claims of this application are directed to a novel patient interface and related aerosol circuitry that are intended to increase the efficiency of aerosol delivery to the patient by allowing more efficient delivery of aerosols to the patient, reduce drug compound dilution and wastage and result in more precise aerosol dosing. *See*, "Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Device Technology – Novel Patient Interfaces and Related Componentry."

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, we believe the FDA will likely not apply this regulatory exclusivity to our proposed initial indication for Surfaxin. However, as we believe that in the context of neonatal RDS, there may be sufficient scientific justification to support that 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 and treatment of BPD in premature infants, (ii) our KL_4 surfactant for the treatment of ARDS in adults, and (iii) our KL_4 surfactant for the treatment of CF.

The European Commission grants "Orphan Medicinal Product" designation for pharmaceutical products for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people which provides for exclusive marketing rights for indications in Europe for 10 years (subject to revision after six years) following marketing approval by the EMA. 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, 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 prevention and treatment of BPD in premature infants, and (ii) our KL_4 surfactant for the treatment of ARDS.

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. Administration of these surfactants requires invasive intubation and mechanical ventilation.. 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.

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 is 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 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 terminating a development program, the approvable letters and the Complete Response Letter that we have 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. See, "Item 1A–Risk Factors – The 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin has caused us to make fundamental changes in our business strategy and to take steps to conserve our financial resources, which may expose us to unanticipated risks and uncertainties. We plan to continue assessing our regulatory position and available resources and may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations, which, if adopted, could prove to be disruptive and detrimental to our development programs.

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 (PAI) of our manufacturing facility in Totowa NJ, and issued an Establishment Inspection Report indicating an approval recommendation for our Surfaxin NDA. In connection with our continuing efforts to gain FDA marketing approval for Surfaxin, we anticipate that the FDA will likely conduct another PAI of our Totowa operations and re-assess ours and other of the quality assurance/quality control facilities for Surfaxin including those of our third-party raw material suppliers and testing laboratories. The FDA may determine to conduct such inspections at any time. *See*, "Item 1A – Risk Factors – Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business."

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 EMA 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 Aerosurf and potentially other of our aerosolized KL_4 surfactant drug product candidates 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, capillary aerosolization technology, and our novel patient interface and related componentry"; "– 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," "– 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 review cycle that can extend a year or more. 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 – Other Regulatory Designations."

EMPLOYEES

As of March 1, 2011, we have 69 employees, 53 of which are full-time, 2 are part-time and 14 are employed in connection with our manufacturing operations in Totowa, New Jersey, subject to a collective bargaining agreement that expires on December 3, 2011. All are employed in the United States. *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." *See also*, "Part III – Item 10 – Directors, Executive Officers and Corporate Governance," and "– Item 11 – Executive Compensation."

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.

If we do not secure FDA approval of Surfaxin for the prevention of RDS in premature infants during the next review cycle, or if other delays associated with the FDA's review process occur, it could have a material adverse effect on our business, financial condition and results of operations, and make it more difficult to secure required additional capital. Moreover, if Surfaxin is approved, we will need additional capital and/or commercialization resources to support the launch of Surfaxin.

Our ability to execute our business plans is dependent in large part upon our ability to complete the comprehensive preclinical program, file the Complete Response to the 2009 Complete Response Letter and satisfy the FDA as to the anticipated review activities that we expect will occur during the six-month review period. There can be no assurance that the FDA will conclude its review within the anticipated time frame. There can be no assurance that we will secure U.S. marketing approval of Surfaxin as a result of this review, if at all. If we are not successful in gaining approval of Surfaxin, it could have a material adverse effect on our business, financial condition and results of operations.

After taking our February 2011 financing into account, we believe that we have sufficient capital to fund our planned research and development activities to the end of the second quarter of 2012. Our plans include activities to potentially advance Surfaxin LS and Aerosurf towards planned Phase 3 and Phase 2 clinical trials, the filing the Complete Response and the potential approval of Surfaxin, which we anticipate could occur in the first quarter of 2012. If we are unable to secure the approval of Surfaxin within this time frame, we will have to seek new capital to continue our operations. Such capital could take the form of strategic partnerships, alliances or financings and other similar transactions. However, if we do not secure FDA marketing approval for Surfaxin, we believe that it may be more difficult to identify strategic partnerships, alliances or financings on terms that are favorable to us, if at all, than it would be if we were to secure FDA approval for Surfaxin. If we are unable to secure additional capital on terms that are acceptable to us, our business would be harmed. *See*, " – The 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin has caused us to make fundamental changes in our business strategy and to take steps to conserve our financial resources, which may expose us to unanticipated risks and uncertainties. We plan to continue assessing our regulatory position and available resources and may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations, which, if adopted, could prove to be disruptive and detrimental to our development programs."

Moreover, as we conserve our resources pending the potential approval of Surfaxin, we have made only limited investments in preparing for the potential commercialization of Surfaxin. Therefore, if we succeed in gaining U.S. marketing approval for Surfaxin, we will need additional capital and or commercialization resources, through strategic partnerships, marketing alliances or other transactions, to fund the commercialization activities associated with the launch of our drug product. If we are unable to secure a strategic partnership, marketing alliance or other similar transaction that would provide for the commercialization of Surfaxin, or if we are unable to secure additional capital to build our own commercial organization, even if we succeed in gaining approval of Surfaxin, we may be unable to launch our product and therefore, could be unable to generate revenues from our approved product to support our business. *See*, "– We currently have limited expertise in marketing or selling pharmaceutical products and limited marketing capabilities, which may restrict our success in commercializing our product candidates. To launch our drug product candidates, if approved, we plan to seek third-party distribution arrangements and marketing alliances, which could require us to give up rights to our drug product candidates. As we continue to assess our business and regulatory position, we may also choose to develop our own sales and marketing capability to launch our products in the United States, which could increase the cost to commercialize our products."

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

We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates. Even if we successfully develop and gain regulatory approval for our products, we still may not generate sufficient or sustainable revenues or we may not become profitable. In addition, even after making significant investments, 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, 2010, we have an accumulated deficit of approximately $376.5 million and we expect to continue to incur significant, increasing operating losses over the next several years. To date, we have generated capital to support our activities primarily from equity financings, research grants, collaboration agreements, and investments. Our ability to operate our business and continue our activities 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, depending on conditions in the global financial markets, we may face significant challengers accessing 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 to commercialize 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. *See*, "Item 1 – Business – Government Regulation."

In particular, we filed with the FDA an NDA for Surfaxin for the prevention of RDS in premature infants. In April 2009, we received a Complete Response Letter for this NDA. We have interacted with the FDA on multiple occasions to discuss and clarify proposals to resolve a key remaining issue that relates to the ability of our optimized BAT to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product. We are currently conducting a comprehensive preclinical program that consists of a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the well-established preterm lamb model of RDS. 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. These studies are intended to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use, and will also be used to gain the FDA's agreement on final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of Surfaxin drug product. *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." Even if we believe that our side-by-side studies are successful, 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, including by requiring us to include warnings and other restrictions in the package inserts for our products, 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 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin has caused us to make fundamental changes in our business strategy and to take steps to conserve our financial resources, which may expose us to unanticipated risks and uncertainties. We plan to continue assessing our regulatory position and available resources and may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations, which, if adopted, could prove to be disruptive and detrimental to our development programs.

Prior to receipt of the 2009 Complete Response Letter, we were planning on establishing our own commercialization organization. To conserve cash resources following receipt of the 2009 Complete Response Letter, we implemented cost-containment measures and reduced our workforce, which primarily affected our commercial organization.

The delay in our gaining approval of Surfaxin also caused us to evaluate our business strategy and implement fundamental changes. To secure capital and to develop and, if approved, commercialize our KL_4 surfactant drug products, we have since focused on identifying potential strategic alliances, development agreements or other collaboration arrangements to develop and commercialize our products in all markets. We have also considered various other financial alternatives that could potentially provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs, meet our capital requirements and continue our operations. Although we continue to consider potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. We plan to continue assessing our regulatory position and available resources with a view to maintaining and strengthening our financial and operational position and, as a result, may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations. 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.

If we succeed in entering into one or more strategic alliances, our ability to execute our current operating plan will depend upon numerous factors, including, the performance of the 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. Such rights of our partners would limit our flexibility in considering development strategies and in commercializing 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, in the alternative and after a potentially unacceptable delay, 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 to secure additional capital while we continue our efforts to potentially gain approval of Surfaxin the United States, we have limited our level of investment in, and have slowed the pace of, our research and development programs to address RDS, including for Surfaxin LS and Aerosurf. Such reductions in investment will cause us to experience delays in the progress of our programs and will lengthen the time to potentially gain approval of our product candidates.

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 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 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 and related materials to meet our pre-clinical and clinical development requirements;
- obtain the capital necessary to fund our research and development efforts, including our business administration, preclinical and clinical organizations, and our quality and manufacturing operations.

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

We have completed our Phase 3 clinical trials for Surfaxin for the prevention of RDS in premature infants and certain Phase 2 trials for other drug product candidates for other indications. If we successfully advance our other KL_4 surfactant development programs through the initial preclinical phase of development, we plan to conduct Phase 2 and/or Phase 3 clinical trials after we have secured adequate capital to support that activity. Such clinical trials generally take two to five years or more to complete and may be delayed by a number of factors. We 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. 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 we, our Scientific Advisory Board (SAB), the trial Safety Monitoring Committee (SMC), 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, our SAB, the SMC or any regulator believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, SAB and/or SMC recommendation, or business reasons.

In addition to our efforts to gain approval of Surfaxin for the prevention of RDS in premature infants, we have completed 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 was 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.

Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of product inventories, which could have a material adverse effect on our business.

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.

For example, we manufacture our Surfaxin drug product at our facility in Totowa, New Jersey. In December 2010, we began manufacturing additional Surfaxin batches for use in the comprehensive preclinical program. As a result, we now have seven Surfaxin batches that can be used for this purpose. We routinely employ an array of quality control and release tests to assess all of the batches we produce. In January 2011, quality control testing performed by us indicated that two other newly-manufactured Surfaxin batches did not meet one of the pre-specified release specifications and, therefore, cannot be used in the comprehensive preclinical program. We are continuing to manufacture additional Surfaxin batches to support the Complete Response and, at the same time, in accordance with our quality assurance procedures and pharmaceutical manufacturing practices, we are conducting an investigation into the manufacture of the Surfaxin batches that did not meet specification to determine the probable cause. We currently plan to manufacture three additional Surfaxin batches for the comprehensive preclinical program. If successful, we believe that we could file a Complete Response in the third quarter of 2011, which, after an anticipated six-month FDA review cycle, could lead to potential Surfaxin approval in the first quarter of 2012. There can be no assurance, however, that we will be able to complete the manufacture of the requisite number of batches as planned or that other batches that we manufacture will not fail to meet all release or stability specifications. There can also be no assurance that our ongoing investigation will establish a probable cause for the two batches that did not meet a release specification.

Furthermore, to manufacture the requisite number of Surfaxin batches needed to complete the comprehensive preclinical program, we may have to purchase additional supplies of drug product substances and excipients, which could involve order lead times and acceptance testing activities and result in further delays. If any of the current or additional batches that we plan to manufacture for use in the comprehensive preclinical program do not meet all release and stability specifications, we will have to initiate additional investigations to determine the probable cause of any such failures, which could have a material, adverse effect on our ability to gain regulatory approval of Surfaxin. Failure to complete the manufacture of a sufficient number of batches to potentially satisfy the FDA could result in further delays of the filing of our Complete Response, which would have an material adverse effect on our business.

Manufacturing or quality control problems may again occur at our facility in Totowa, New Jersey, 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 currently do not have a back-up facility. Any interruption of our manufacturing operations at Totowa, NJ, could result in a shortage of drug supply for use in preclinical and clinical activities and, if approved, to satisfy 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.

In connection with our manufacturing activities, 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 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 preclinical programs and 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 we will purchase from a potentially 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 our preclinical programs or 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. To assure compliance with cGMP requirements, we have entered into Quality Agreements with all of our suppliers of active drug substances and related materials. However, we have a requirements contract relating to continued access to active drug substances with only one of three providers of our drug substances. 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.

Failure to develop our capillary aerosolization technology, patient interface technology and related componentry in a timely manner, if at all, would have a material adverse effect on our efforts to develop aerosolized KL_4 surfactant and our business strategy.

Since early 2008, we have been responsible for development of our proprietary capillary aerosolization technology, including finalizing the design of an optimized capillary aerosolization device and disposable dose packets that are suitable for use in our planned Phase 2 and Phase 3 clinical trials. Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not successfully develop an optimized prototype capillary aerosolization system that is suitable for use in a clinical environment, if at all, on a timely basis and such inability may delay or prevent initiation of our planned clinical trials.

- We will require access to sophisticated engineering capabilities. Our plans include our medical device engineering staff working with leading medical device development engineers and medical device design experts that have a successful track record of developing innovative devices for the medical and pharmaceutical industries. If we are unable to identify design engineers and medical device experts to support our development efforts, including for the optimized prototype capillary aerosolization system for use in our planned clinical trials and, potentially, for later development versions of the capillary aerosolization systems, it would impair our ability to commercialize or develop our aerosolized KL_4 surfactant products.

- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and potentially 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.

If we fail to identify or maintain relationships with manufacturers, assemblers and integrator of our capillary aerosolization systems or subcomponents, the timeline of our plans for the development and, if approved, commercialization of our aerosolized KL_4 surfactant, including Aerosurf, could suffer.

In connection with the development of our aerosolized KL4 surfactant, including Aerosurf, which is a drug/device combination product, 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 worked with selected component manufacturers and an integrator to manufacture and integrate our initial prototype capillary aerosolization system. We are currently focused on developing an optimized capillary aerosolization device to meet regulatory and ease-of-use design requirements for Aerosurf and prepare for potential Phase 2 clinical trials. However, as with many device development initiatives, there is a risk that we will not be successful in our development efforts and that the manufacturers and integrator that we identify may not be able to consistently manufacture and integrate, if at all, 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 optimized capillary aerosolization system and, if developed, later 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, regulatory manufacturing requirements. If we do not successfully identify and enter into contractual agreements with manufacturers, assemblers and integrators that have the required expertise to produce our capillary aerosolization systems as and when needed, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL_4 surfactant, including Aerosurf.

We currently have limited expertise in marketing or selling pharmaceutical products and limited marketing capabilities, which may restrict our success in commercializing our product candidates. To launch our drug product candidates, if approved, we plan to seek third-party distribution arrangements and marketing alliances, which could require us to give up rights to our drug product candidates. As we continue to assess our business and regulatory position, we may also choose to develop our own sales and marketing capability to launch our products in the United States, which could increase the cost to commercialize our products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing capabilities. Following receipt of the 2009 Complete Response Letter, we assessed our regulatory and financial position and determined that it would be in our best interest to seek to commercialize our drug product candidates, if approved, through one or more strategic alliances rather than through our own commercial organization. Such alliances could take a number of forms. We may rely on third-party distributors to distribute, or enter into marketing alliances to sell, our products internationally and potentially also 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 and, as a result, we may not be able to commercialize our drug product candidates on a timely basis. If we enter into distribution arrangements and marketing alliances to commercialize our drug product candidates, such arrangements will subject us to a number of risks, including:

- our distributors or collaborators may require that we transfer to them important rights to our products and/or drug product candidates;

- we may not be able to control the amount and timing of resources that our distributors or collaborators devote to the commercialization of our drug product candidates;

- if our distributors or collaborators fail to perform their obligations under our arrangements to our satisfaction, we may not achieve our projected sales and our revenues would suffer. We also may incur additional expense to terminate such arrangements and to identify and enter into arrangements with replacement distributors or collaborators;

- our distributors or collaborators may experience financial difficulties; and

- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to perform its obligations under any arrangement, which would adversely affect our business.

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.

If we do not identify third-party distributors, marketing alliances or other arrangements that have terms that are acceptable to us, or if we determine that our business would be better served by retaining the marketing rights to our products and drug product candidates, we may commercialize our drug product candidates ourselves. This approach would likely cause our commercialization costs to increase, but would potentially avoid the transfer of rights to our products or drug product candidates. Developing an internal marketing and sales capability is potentially a difficult, expensive and time-consuming process and requires a substantial capital investment. Recruiting, training and retaining qualified personnel would be critical to our success. Competition for such personnel is intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully support the launch and continued distribution of our products. We also may be unable to provide competitive incentive to retain our sales force. If we are unable to successfully attract and motivate a commercial team to support the launch and sale of our products, we would have difficulty selling, maintaining and increasing the sales of our products, which would have a material adverse effect on our business.

Even if we develop an internal commercial organization to support the launch of Surfaxin in the United States, we may also need to enter into co-promotion arrangements with third parties where our own personnel are neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our commercial staff and incur additional expense.

We plan to market and sell Surfaxin, if approved, in international markets and potentially in the United States 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.

If we fail to establish or secure marketing and sales capabilities or fail to enter into arrangements with third parties in a timely manner or if such third parties fail to perform, it could adversely affect sales of our products. In addition, even if we establish or secure such capabilities, we and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the restrictions on incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing the sales of our products.

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 support our ongoing research and development activities and continue to operate as a going concern. In addition to focusing our resources on potentially gaining approval of Surfaxin, our current plans require that we make prudent investments in our lead drug product and device development programs, Surfaxin LS and Aerosurf, and focus our resources on being in a position to initiate key clinical programs after we have secured the necessary capital to advance these programs to potential approval. We would prefer to accomplish our objectives through strategic alliances and collaboration arrangements. 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 investments in our development programs, which could have a material adverse effect on our business. In the meantime, as we continue to conserve our financial resources, we will likely experience additional delays in our development programs.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, which will likely result in significant legal and accounting expense and diversion of management resources, and current and potential stockholders may lose confidence in our financial reporting and the market price of our stock will likely decline.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

In our internal control report for our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, management was unable to conclude that we had maintained effective internal control over financial reporting as of September 30, 2010, and identified a material weakness regarding our process and procedures related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments. Upon a reassessment of those financial instruments, in light of GAAP as currently interpreted, we determined that we should have accounted for registered warrants that we issued in May 2009 and February 2010 as derivative liabilities instead of equity. As a result, to reclassify the affected warrants as derivative liabilities, in November 2010, we restated our consolidated financial statements for the periods ended beginning June 30, 2009 through June 30, 2010. The process to restate our financial statements was highly time-consuming, resource-intensive and involved substantial attention from management and significant legal and accounting expense.

To remediate the identified material weakness in our internal controls, we have enhanced our process to identify and correctly apply developments in accounting and to improve our understanding of the nuances of increasingly complex accounting standards. We have improved access to the accounting literature, research materials and documents and increased communication among our legal and finance personnel and third party professionals with whom we consult regarding complex accounting applications.

Any failure to maintain internal controls could adversely affect our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and Nasdaq, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We can give no assurance that additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, although we believe that we have remediated the material weakness that we identified in November 2010, in the future our controls and procedures may no longer be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. Responding to inquiries from the SEC or Nasdaq in the future will, regardless of the outcome, likely consume a significant amount of our management resources and cause us to incur significant legal and accounting expense. Further, many companies that have restated their historical financial statements have experienced a decline in stock price and related stockholder lawsuits.

Our Committed Equity Financing Facilities may become unavailable to us if we do not comply with their conditions.

Except for our CEFFs (which are subject to certain limitations), we currently do not have arrangements to obtain additional financing. 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 to fund our activities and the CEFFs may expire. For example, as of December 31, 2010, we had three CEFFs that were potentially available to us. However, in February 2011, the December 2008 CEFF expired without having been fully utilized. In addition, as we agreed in connection with our February 2011 offering that we would not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in May 2011, we will have a limited time to initiate draw downs under the May 2008 CEFF before it expires on June 18, 2011. 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 on our ability to finance our activities.

In addition, our ability to draw down under any new CEFF in the future may be impaired. In February 2011, we issued five-year warrants that contain anti-dilution provisions that potentially adjust the exercise price of these warrants upon the issuance of securities at prices lower than the warrant exercise price. The warrant anti-dilution provisions are not triggered by draw downs under our existing CEFFs but would be triggered by draw downs under any new CEFF. In that event, the potential dilutive effect of a draw down under a future CEFF could be increased if the discounted purchase price of such draw down is less than the exercise price of the warrants, which could result in a decline in the market price of our stock.

If our current CEFFs should become unavailable, due to expiration or for any reason, if we are unable to successfully raise sufficient additional capital through a new CEFF, 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 that event, the market price of our common stock may decline further.

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 Capital Market. During the twelve month period ended December 31, 2010, the price of our common stock, adjusted for the 1-for-15 reverse stock split that was made effective on December 28, 2010, ranged between $2.52 and $12.58. 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, 2010, the average daily trading volume in our common stock, adjusted for the 1-for-15 reverse stock split, was approximately 175,455 shares, and the average number of transactions per day, adjusted for the 1-for-15 reverse stock split, was approximately 2,465. 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 may be filed against us in the future are ultimately determined to be meritless or unsuccessful, they would involve substantial costs and a diversion of management attention and resources, which could negatively impact our business.

If we fail to adhere to the strict listing requirements of The Nasdaq Capital Market®, we may be subject to delisting. As a result, our stock price may decline and, following a hearing, our common stock may be delisted. If our stock were no longer listed on the Nasdaq Capital Market, the liquidity of our securities likely would be impaired.

Our common stock currently trades on the Nasdaq Capital Market under the symbol DSCO. If we fail to adhere to the market's strict listing criteria, our stock may be delisted. This could potentially 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 the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. We believe that current and prospective investors would view an investment in our common stock more favorably if it continues to be listed on the Nasdaq Capital Market.

In December 2009, we received a letter from The Nasdaq Global Market® (Global Market) indicating that we had failed to comply with Nasdaq Listing Rule 5450(a)(1) (Minimum Bid Price Rule), which requires that we maintain a minimum closing bid price of $1.00 per share. Under the Nasdaq Listing Rules, to avoid delisting, the closing bid price of our stock had to rise above $1.00 for a minimum of 10 consecutive business days during the 180 calendar days following the date of the notification, or prior to June 1, 2010. Anticipating that we would not regain compliance with the Minimum Bid Price Rule on or before June 1, 2010, in May 2010, we applied to transfer our common stock to the Nasdaq Capital Market, which was effective on June 4, 2010. Based on our ability to comply with all listing requirements of the Nasdaq Capital Market other than the Minimum Bid Price Rule, Nasdaq also granted us an additional 180 days, or until November 29, 2010, to regain compliance with the Minimum Bid Price Rule.

On November 30, 2010, we received written notification from Nasdaq that our common stock was subject to delisting because we had not regained compliance with the Minimum Bid Price Rule within the 180-day period previously granted. We requested a hearing with a Nasdaq Hearing Panel, which stayed the delisting of our stock pending the Panel's review. On December 28, 2010, we implemented a 1-for-15 reverse stock split, after which the closing market price of our stock was above $1.00. On January 11, 2011, following our hearing, the Nasdaq Hearing Panel determined that we had regained compliance with the Minimum Bid Price Rule because our common stock had maintained a minimum closing bid price of $1.00 per share over a period of 10 consecutive business. Currently, our common stock continues to comply with all Nasdaq Listing Requirements for the Nasdaq Capital Market.

Although we have regained compliance with the Minimum Bid Price Rule, there can be no assurance that we will be able to maintain continued compliance with the Minimum Bid Price Rule or the other listing requirements of Nasdaq. There can be no assurance that the closing bid price of our common stock will continue to trade above $1.00. Moreover, if trading activity in our common stock were to reduce the total market capitalization of our company, we may find it difficult to fund our activities, which would result in reductions in our stockholders' equity. In addition to the Minimum Bid Price Rule, certain other Nasdaq continued listing requirements require that we maintain a market capitalization of at least $35 million or stockholders' equity of at least $2.5 million. If we are unable to meet these requirements we would receive another delisting notice from the Nasdaq Capital Market for failure to comply with one or more of the continued listing requirements.

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 4.38% to 17.5%, 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 several prior occasions, 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 15, 2011, we had 24,115,151 shares of common stock issued and outstanding. In addition, as of December 31, 2010, approximately (i) 4.3 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 0.9 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 58,018 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. In addition, in February 2011, we issued five-year warrants that contain an anti-dilution provision that, subject to certain exclusions, potentially adjusts the exercise price of these warrants upon the issuance of securities at prices lower than the warrant exercise price. For the purpose of valuing securities that we may issue in the future in unit offerings, this anti-dilution provision values the warrant portion of a unit offering based on a Black Scholes pricing model. When such Black Scholes value is subtracted from the actual per-unit price of the offering, per-share value of the shares issued in such unit offering is decreased for the purposes of the anti-dilution provision. If we issue shares or units or warrants in a financing that triggers the anti-dilution provision of our February 2011 five-year warrants, the exercise price of the February 2011 five-year warrants will be lowered thereby, increasing the likelihood that such warrants would be exercised. As a result of such warrant adjustments, we may be required to issue more shares of common stock, or shares at lower prices, 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 March 15, 2011, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately thirteen percent (13%) 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, our novel capillary aerosolization technology, and our novel patient interface and related componentry.

Our technology platform is based on the scientific rationale of using our KL_4 surfactant technology, our capillary aerosolization technology and our novel patient interface and related componentry 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 individuals 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.

W. Thomas Amick, our Chairman of the Board and Chief Executive Officer joined our company on a full-time basis as Chief Executive Officer in October 2010. As of October 18, 2010, we entered into an executive employment agreement with Mr. Amick, which expires in October 2011 and contains an automatic one-year renewal at the end of each term, unless otherwise terminated by either party.

As of December 31, 2010, we had employment agreements with four executive officers in addition to Mr. Amick, including: President and Chief Financial Officer and Treasurer; Executive Vice President, General Counsel and Secretary; Chief Operating Officer; and Senior Vice President, Human Resources. These agreements provide for automatic one-year renewal at the end of each term, unless otherwise terminated by either party, and will expire in May 2012. In addition, in May 2010, we entered into retention agreements with five other officers under which each officer is provided certain severance benefits, based on title. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

We expect that, once we have secured sufficient strategic and financial resources to support our operations, including the continuing development of our KL_4 surfactant technology, we will seek to attract candidates to join our management and development teams, although there can be no assurances that we will be successful in that endeavor. Moreover, although our five senior executive officers have agreements that include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, such noncompete provisions can be difficult and costly to monitor and enforce, such that we may not be successful in retaining these individuals and, if any should resign, in enforcing our noncompetition agreements with them.

We may be unable to attract and retain necessary executive talent. Our industry generally seeks to attract and retain executive talent with compensation packages that include a significant equity component. At this time, however, we have only limited equity incentives available. Moreover, the equity incentives, including options and restricted stock, that we have issued are, for the most part, significantly devalued or out of the money and less likely to be exercisable in the future. We plan on seeking stockholder approval for additional authorizations to support the use of equity incentives in the future. However, there can be no assurance that our stockholders will approve such incentives and, even if our stockholders approve new equity incentives, that we will be able to attract and retain key executive talent in the interim period.

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. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key 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.

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 foreign regulatory 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 our products. As none of our products are approved, we currently have limited or no experience in these areas. 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.

Our business activities expose us to liability claims and the use of our products in clinical trials exposes us to product liability claims. If any such claims are brought against us, we may experience reduced demand for our products or damages that exceed our insurance coverage and we may incur substantial costs.

Our business activities, including testing, manufacturing and, if approved, marketing our drug products and medical devices exposes us to liability risks. Using our drug product candidates or medical devices in clinical trials also may expose us to product liability claims. If any of our products are approved for commercial sale, the risk of product liability claims will be increased. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. In addition, we are subject to product liability claims involving our capillary aerosolization and other medical devices and alleged mechanical failures, design defects, or other safety issues that result in an unsafe condition leading to injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts and medical device disclosures may also arise.

We presently carry general liability, excess liability, products liability and property insurance coverage in amounts that are customary for companies in our industry of comparable size and level of activity. However, our insurance policies contain 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 withy locally-authorized insurers licensed in countries where we conduct our clinical trials, before initiating clinical trials. We also expect to review and obtain additional product liability insurance coverage, if warranted, 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, general liability or product liability claim, even if such claim is within the limits of our insurance coverage or 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. Cost-containment measures, if implemented to affect the coverage or reimbursement of our products could have a material adverse effect on our ability to market our products profitably. 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.

Not applicable.

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.

We also maintain at our principal executive office an analytical and development laboratory that is predominantly involved in 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 executive offices that support the further development of our capillary aerosolization systems. The facility includes a controlled environment with two class 10,000 hoods (for activities requiring clean room procedures). We also use this laboratory for component parts and finished assembly inspection and storage.

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. As this early termination option could require us to move out of our Totowa facility as early as March 2013, 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 Capital Market under the symbol "DSCO." As of March 15, 2011, the number of stockholders of record of shares of our common stock was approximately 153. We were advised by Broadridge Financial Solutions, Inc., that, on October 25, 2010, the record date for our Annual Meeting of Stockholders, we had approximately 24,700 beneficial owners of shares of our common stock. As of March 15, 2011, there were 24,115,151 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 (adjusted for the 1-for-15 reverse stock split that was effective December 28, 2010).

	Low	High
First Quarter 2009	$ 13.65	$ 22.20
Second Quarter 2009	$ 10.65	$ 36.00
Third Quarter 2009	$ 4.88	$ 25.35
Fourth Quarter 2009	$ 9.15	$ 20.70
First Quarter 2010	$ 7.35	$ 12.58
Second Quarter 2010	$ 2.70	$ 9.30
Third Quarter 2010	$ 2.56	$ 5.10
Fourth Quarter 2010	$ 2.52	$ 5.40

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-month period ended December 31, 2010, we did not issue any unregistered shares of common stock or conduct any stock repurchases.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

INTRODUCTION

Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. You should review the "Forward Looking Statements" and "Risk Factors" sections of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in the Annual Report on Form 10-K.

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, 2010, and 2009.

- **Liquidity and Capital Resources**: this section provides a discussion of 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 neonatal populations. Our research and development efforts are currently focused on the management of respiratory distress syndrome (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.

We have filed a New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in 2009. The safety and efficacy of Surfaxin for the prevention of RDS in premature infants has previously been demonstrated in a large, multinational Phase 3 clinical program and we believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit Biological Activity Test (BAT). We have been conducting a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT. If successful, we believe that we could file a Complete Response in the third quarter of 2011, which after an anticipated six-month FDA review cycle, could lead to approval of Surfaxin for the prevention of RDS in premature infants in the first quarter of 2012. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for use in neonatal medicine. We are developing Surfaxin LS and Aerosurf for the prevention and/or treatment of RDS in premature infants for both the United States and all other major markets throughout the world.

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. We are conducting research and preclinical development with our KL_4 surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, Cystic Fibrosis, Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have conducted and are planning additional 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 of our KL_4 surfactant technology. We continue to assess an array of potential strategic alliances and financing opportunities to potentially accomplish our development and commercialization objectives. 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 focus on our RDS programs, primarily Surfaxin, and conserve our resources, predominantly by curtailing and pacing investments in our other 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, 2010, we had cash and cash equivalents of $10.2 million and three Committed Equity Financing Facilities (CEFFs), which would allow us to raise capital (subject to certain conditions, including minimum stock price and volume limitations), at our discretion, at such times and in amounts that we deem suitable to support our business plans (*see*, "– Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)"). Effective February 6, 2011, the December 2008 CEFF expired. Based on the closing market price of our common stock on March 15, 2011, the potential availability under our two remaining CEFFs is approximately $3.5 million. However, we agreed in connection with our February 2011 offering that we would not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in May 2011. During 2010, we raised aggregate gross proceeds of $30.6 million, including $16.5 million ($15.1 million net) and $10.0 million ($9.1 million net) from public offerings in February and June 2010, respectively; $2.2 million ($2.1 million net) and $0.5 million from offerings to PharmaBio in April 2010 and October 2010, respectively; and $1.4 million from draw downs on our 2010 CEFF.

On February 22, 2011, we completed a public offering resulting in gross proceeds of $23.5 million ($21.6 million net). *See*, "– Liquidity and Capital Resources – 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, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting neonatal 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 and Recent Accounting Pronouncements" in the Notes to Consolidated Financial Statements for the year ended December 31, 2010, in Part IV to this Annual Report on Form 10-K.

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.

Warrant accounting

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) 815 (ASC 815) as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Under ASC 815, registered common stock warrants that require the issuance of registered shares upon exercise and do not expressly preclude an implied right to cash settlement are accounted for as derivative liabilities. We classify these derivative warrant liabilities on the consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes pricing model to value the derivative warrant liability. Changes in the fair market value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

RESULTS OF OPERATIONS

The net loss for the years ended December 31, 2010, and 2009 was $19.2 million (or $1.65 per share) and $29.9 million (or $3.89 per share), respectively. Included in the net loss were stock-based compensation expenses of $1.4 million (or $0.12 per share), and $2.7 million (or $0.35 per share) for the years ended December 31, 2010 and 2009, respectively. In addition, the net loss includes $6.4 million and $0.4 million of income from the change in fair value of common stock warrant liability for the years ended December 31, 2010 and 2009, respectively.

Revenue

We did not record any revenues in 2010 or 2009.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. As many of our research and development activities form a foundation for the development of our KL_4 surfactant technology platform, they benefit more than a single project. For that reason, we cannot reasonably estimate the costs or our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) manufacturing development, (b) development operations, and (c) direct pre-clinical and clinical programs. We also track our research and development expenses by the following categories: (i) salaries and benefits, (ii) contracted services, (iii) rents and utilities, (iv) depreciation, (v) raw materials and supplies, (vi) contract manufacturing, (vii) stock-based compensation and (viii) other.

Research and development expenses for the years ended December 31, 2010 and 2009 were $17.1 million, and $19.1 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands)	**Year Ended December 31,**	
Research and Development Expenses:	**2010**	**2009**
Manufacturing development	$ 10,235	$ 9,118
Development operations	4,841	7,100
Direct pre-clinical and clinical programs	2,060	2,859
Total Research and Development Expenses [(1)]	$ 17,136	$ 19,077

(1) Included in research and development expenses are charges associated with stock-based employee compensation in accordance with the provisions of ASC Topic 718. For years ended December 31, 2010, and 2009, these charges were $0.5 million and $0.7 million, respectively.

For a description of the clinical programs included in research and development, *see*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine" in this Annual Report on Form 10-K.

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 expense, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities and analytical services, etc.

The $1.1 million increase in manufacturing development expenses in 2010 as compared to 2009 is primarily due to costs incurred in 2010 relating to a technology transfer of our Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturing organization (CMO) with expertise in lyophilized drug product formulation.

Manufacturing development expenses included charges of $0.2 million, and $0.4 million associated with stock-based employee compensation for the years ended December 31, 2010 and 2009, 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 and disposable dose delivery packets) and our novel patient interface system necessary to administer our KL_4 aerosolized surfactant for anticipated clinical development, including our planned Phase 2 clinical trials, and, if approved, commercial use and; (iv) pharmaceutical development activities. These costs include personnel, expert consultants, outside services to support regulatory, data management and device development activities, key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The $2.3 million decrease in development operations expenses in 2010 as compared to 2009 is primarily due to our ongoing efforts to conserve financial resources and limit investment in our KL_4 surfactant pipeline programs following receipt of the 2009 Complete Response Letter.

Development operations expenses included charges of $0.3 million and $0.3 million associated with stock-based employee compensation for the years ended December 31, 2010 and 2009, respectively.

Direct Pre-Clinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) pre-clinical activities, including toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, clinical drug supply and related external costs such as contract research consultant fees and expenses and (iii) activities related to addressing the items identified in the 2009 Complete Response Letter.

Direct pre-clinical and clinical program expenses in 2010 and 2009 include: (i) costs associated with activities to address the items identified in the 2009 Complete Response Letter; (ii) pre-clinical and preparatory activities for anticipated clinical trials for Surfaxin LS and Aerosurf for RDS in premature infants; and (iii) activities associated with the Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF.

The $0.8 million decrease in direct pre-clinical and clinical program expenses in 2010 as compared to 2009 is primarily due to the completion of the Phase 2 clinical trial for ARF in the first half of 2010. This decrease was partially offset by increased costs incurred in 2010 associated with activities to address the items identified in the 2009 Complete Response Letter.

In an effort to conserve our financial resources, we plan to continue to focus on our RDS programs, primarily Surfaxin, and limit investment in our other programs until we have secured appropriate strategic alliances and/or necessary capital. We also plan to meet with U.S. and European regulatory authorities to discuss the requirements for our regulatory packages, including potential trial design requirements, to prepare for our planned clinical trials.

Research and Development Expenses by Category

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

	2010	2009
Salaries & Benefits	$ 6,858	$ 8,693
Contracted Services	4,395	4,832
Rents & Utilities	1,442	1,310
Depreciation	1,207	1,235
Raw Materials & Supplies	1,009	1,466
Contract Manufacturing	990	–
Stock-Based Compensation	479	694
All Other	756	847
Total	$ 17,136	$ 19,077

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. Following receipt of the 2009 Complete Response Letter, 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 of 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 two-year period primarily due to our efforts to conserve our financial resources and limit our investment in our KL_4 surfactant pipeline programs following receipt of the 2009 Complete Response Letter.

Rents and utilities are associated with our leased manufacturing, laboratory and related facilities, including our manufacturing operations in Totowa, New Jersey.

Depreciation is primarily associated with leasehold improvements at our laboratories and headquarters in Warrington, Pennsylvania as well as manufacturing, and laboratory equipment, and leasehold improvements at our manufacturing operations in Totowa, New Jersey.

Contract manufacturing represents costs related to the technology transfer of the Surfaxin LS lyophilized manufacturing process to a cGMP compliant, third-party CMO with expertise in lyophilized formulations.

Raw materials and supplies consist of purchases of our active pharmaceutical ingredients for the manufacture of our KL_4 surfactant product candidates and supplies to support our manufacturing and laboratory operations, including component parts for the disposable dose delivery packets and patient interface and related componentry necessary to administer Aerosurf using our novel capillary aerosolization technology. The decrease in raw materials and supplies is primarily due to a reduction in raw material purchases in 2010 associated with our efforts to conserve our financial resources following receipt of the 2009 Complete Response Letter.

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

Research and Development Projects

A substantial portion of our cumulative losses to date, including approximately $36.2 million in the two-year period ended December 31, 2010, relate to investments in our research and development activities. Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are significant unknowns that may significantly impact cost projections and timelines. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty.

For a discussion of certain risks and uncertainties affecting our ability to estimate projections and timelines, *see*, "Item 1 – Business – Government Regulation;" and "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;" "– Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes;" "– Our clinical trials may be delayed, or fail, which will harm our business," "– Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business;" as well as elsewhere in this Annual Report on Form 10-K.

Our lead development projects are initially focused on the management of RDS in premature infants and include Surfaxin, Surfaxin LS and Aerosurf. We believe that these neonatal programs have the potential to greatly improve the management of RDS and expand the current RDS market worldwide. All of these potential products are either in regulatory review or clinical or pre-clinical development and none are available for commercial sale. While we anticipate that we will be able to file a Complete Response with the FDA with respect to Surfaxin for the prevention of RDS in premature infants in the third quarter of 2011, which could lead to potential approval of Surfaxin in the first quarter of 2012, there can be no assurance that we will be successful in securing such approval or that, if approved, we will be successful in commercializing Surfaxin and realizing a profit in the foreseeable future. We plan in 2011 to seek regulatory and scientific guidance from the FDA and EMA with respect to our planned clinical programs for Surfaxin LS and Aerosurf; however, our ability to move forward will depend upon the success of our efforts to secure strategic alliances and/or appropriate capital to fund these activities. Accordingly, we are unable to project when we might implement these programs, the pace of such implementation or the overall anticipated expense that we might incur.

The status of our lead projects and our other pipeline candidates, including the potential timing and milestones for each, is discussed in "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine." *See also*, "Item 1 – Business – Business Strategy," and "Item 1A – Risk Factors – We may not successfully develop and market our products, and even if we do, we may not become profitable," "– 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."

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 in patient populations ranging from premature infants to adults. After we have completed Phase 2 proof-of-concept studies for each potential indication, if successful, we plan to assess the potential markets for these products and determine whether to seek strategic alliances or collaboration arrangements, or utilize other financial alternatives to fund their further development. At the present time, however, we continue to conserve our resources, predominantly by curtailing and pacing investments in these pipeline programs. *See*, "Item 1 – Business – Business Strategy," and "– Surfactant Replacement Therapy For Respiratory Medicine" in this Annual Report on Form 10-K.

Our ability to generate sufficient capital to support our product development activities and, if approved, commercialization plans, depends upon many factors, including the success of our efforts to secure one or more strategic alliances or other collaboration arrangements. We believe that our ability to successfully enter into meaningful strategic alliances will likely improve with any advances that we may make in finalizing our development efforts and filing the Complete Response for Surfaxin, and furthering our Surfaxin LS and Aerosurf programs leading to initiation of clinical trials. There can be no assurance, however, that we will be able to secure strategic partners or collaborators to support and provide expert advice to guide our activities, that our research and development projects will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

Ultimately, if we do not successfully develop and gain marketing approval for our drug product candidates, in the United States or elsewhere, we will not be able to commercialize, or generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

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, 2010 and 2009 were $8.4 million and $10.1 million, respectively. General and administrative expenses included charges of $0.9 million and $2.0 million associated with stock-based employee compensation for the years ended December 31, 2010 and 2009, respectively. Additionally, general and administrative expenses included charges of $1.0 million and $0.7 million for the years ended December 31, 2010 and 2009, respectively, associated with certain contractual cash severance obligations to our former President and Chief Executive Officer. Excluding the charges related to our severance obligation and charges associated with stock-based compensation, general and administrative expenses decreased $0.9 million for the year ended December 31, 2010 as compared to the same period in 2009.

Following receipt of the 2009 Complete Response Letter, we reassessed our business strategy and curtailed investment in developing our own commercial capabilities. We plan on continuing to assess strategic alliances and other collaborative arrangements for the development and/or commercialization of our KL_4 surfactant product candidates that potentially could provide financial support, development capabilities, and ultimately commercial expertise to advance our KL_4 technology. We also are assessing various financial alternatives that would provide infusions of capital and other resources needed to advance our KL_4 respiratory pipeline programs. There can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded.

In addition, following receipt of the 2009 Complete Response Letter, to conserve our cash resources, we reduced our workforce and implemented cost containment measures. 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.

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.

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."

Change in Fair Value of Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 - "Derivatives and Hedging – Contracts in Entity's Own Equity" (ASC 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued using the Black-Scholes pricing model at the date of initial issuance and each subsequent balance sheet date. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

The warrants that we issued in registered transactions in May 2009 and February 2010 generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, the warrant agreements do not expressly state that there is no circumstance that requires us to effect a net cash settlement of the warrant. Therefore, notwithstanding the availability of cashless exercise, generally accepted accounting principles establish that, in the absence of express agreement of the parties to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the issuer to provide freely-tradable shares in all circumstances. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that such an event would result in a cash settlement. Based on the terms of the warrant agreements and the applicable accounting guidance, we have classified the May 2009 and February 2010 warrants as derivative warrant liabilities.

The change in fair value of common stock warrant liability for the years ended December 31, 2010 and 2009 resulted in income of $6.4 million and $0.4 million, respectively, due primarily to a decrease in our common stock share price during the periods.

Other Income / (Expense)

Other income / (expense), net was ($0.1) million and ($1.0) million, for the years ended December 31, 2010 and 2009, respectively, as follows:

(Dollars in thousands)	**Year Ended December 31,**	
	2010	**2009**
Interest income	$ 13	$ 48
Interest expense	(357)	(1,096)
Other income / (expense)	275	5
Other income / (expense), net	$ (69)	$ (1,043)

Interest income consists of interest earned on our cash and cash equivalents. The decrease in interest income in 2010 and 2009 is due to a decline in our average cash and cash equivalents balance.

Interest expense consists of interest accrued on the loan with PharmaBio and under our equipment financing facilities. In addition, interest expense includes $0.2 million and $0.5 million, for the years ended December 31, 2010 and 2009, respectively, associated with the amortization of deferred financing costs for a warrant issued to PharmaBio in October 2006 as consideration for restructuring our loan in 2006. These costs were fully amortized as of April 2010. The decrease in interest expense in 2010 as compared to 2009 is primarily due to the maturing of our loan with PharmaBio in April 2010 and full repayment of the outstanding balance as of September 30, 2010.

Other income / (expenses) for 2010 primarily consist of grant proceeds received under the Patient Protection and Affordable Care Act of 2010 to reimburse costs incurred in 2009 to advance our aerosolized KL_4 Surfactant program for the prevention of neonatal RDS.

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, and, upon regulatory approval, also through sales revenue from our product candidates, beginning with Surfaxin for the prevention of RDS, if approved.

On November 30, 2010, we received written notification from Nasdaq that our common stock was subject to delisting because we had not regained compliance with the Listing Rule 5550(a)(2) ("Minimum Bid Price Rule") which requires that we maintain a minimum closing bid price of $1.00 per share, within the 180-day period grace period previously granted. We requested a hearing with a Nasdaq Hearing Panel, which stayed the delisting of our stock pending the Panel's review. On December 28, 2010, we implemented a 1-for-15 reverse stock split, after which the closing market price of our stock was above $1.00. On January 11, 2011, following our hearing, the Nasdaq Hearing Panel determined that we had regained compliance with the Minimum Bid Price Rule because our common stock had maintained a minimum closing bid price of $1.00 per share over a period of 10 consecutive trading days. Currently, our common stock continues to comply with all Nasdaq Listing Requirements for the Nasdaq Capital Market. In addition, effective December 28, 2010, we filed an amendment to our Certificate of Incorporation to reduce the number of authorized shares of common stock, par value $0.001 per share, from 380 million to 50 million. Both the reverse split and the reduction in authorized shares were approved by our stockholders at our Annual Meeting of Stockholders on December 21, 2010.

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 also considering other alternatives, including additional financings and other similar opportunities. There can be no assurance, however, 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. 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, 2010, we had cash and cash equivalents of $10.2 million and three Committed Equity Financing Facilities (CEFFs), which could allow us, at our discretion, to raise capital (subject to certain conditions, including minimum stock price and volume limitations) at a time and in amounts deemed suitable for us to support our business plans. Effective February 6, 2011, the December 2008 CEFF expired. Based on the closing market price of our common stock on March 15, 2011, the potential availability under our two remaining CEFFs is approximately $3.5 million. However, we agreed in connection with our February 2011 offering that we would not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in May 2011. During 2010, we raised aggregate gross proceeds of $30.6 million, including $16.5 million ($15.1 million net) and $10.0 million ($9.1 million net) from public offerings in February and June 2010, respectively; $2.2 million ($2.1 million net) and $0.5 million from offerings to PharmaBio in April 2010 and October 2010, respectively; and $1.4 million from draw downs on our 2010 CEFF. *See*, "– Committed Equity Financing Facilities (CEFFs)", and "– Financings Pursuant to Common Stock Offerings." On February 22, 2011, we completed a public offering of 10,000,000 shares of our common stock, five-year warrants to purchase 5,000,000 shares of our common stock (Five-Year Warrants), and fifteen month warrants to purchase 5,000,000 shares of our common stock (Short-Term Warrants), resulting in gross proceeds of $23.5 million ($21.6 million net). *See*, "– Financings Pursuant to Common Stock Offerings."

After taking our February 2011 financing into account, we believe that we have sufficient capital to fund our planned research and development activities to the end of the second quarter of 2012. Our plans include activities to potentially advance Surfaxin LS and Aerosurf towards planned Phase 3 and Phase 2 clinical trials, the filing the Complete Response and the potential approval of Surfaxin, which we anticipate could occur in the first quarter 2012.

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 "– 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

As of December 31, 2010, we had cash and cash equivalents of $10.2 million compared to $15.7 million as of December 31, 2009. Cash outflows before financings for the year ended December 31, 2010 consisted of $21.1 million used for ongoing operating activities, a one-time payment of $1.1 million to satisfy our severance obligations to our former President and Chief Executive Officer, and $11.3 million used for debt service (primarily payments of $10.6 million of principal and accrued interest to PharmaBio). We received net proceeds of $26.6 million from financings from stock offerings and $1.4 million from financings under our CEFFs during 2010.

Cash Flows Used in Operating Activities

Cash flows used in operating activities were $24.3 million and $27.4 million for the years ended December 31, 2010 and 2009, 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, fair value adjustment of common stock warrants, depreciation and changes in our accounts payable and accrued liabilities. *See*, "– Results of Operations."

Cash Flows From / (Used in) Investing Activities

Cash flows from / (used in) investing activities include capital expenditures of $0.1 million and $0.1 million for the years ended December 31, 2010 and 2009, respectively. Capital expenditures were primarily for laboratory and manufacturing equipment to support analytical, quality, manufacturing and development activities

Cash flows from / (used in) investing activities in 2009 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, 2010 and 2009, we did not have any available-for-sale marketable securities.

Cash Flows from Financing Activities

Cash flows from financing activities were $18.8 million and $18.3 million for the years ended December 31, 2010 and 2009, respectively, as summarized in the chart below:

(In millions)	Year Ended December 31, 2010	2009
Financings pursuant to common stock offerings	$ 26.6	$ 10.5
Financings under CEFFs	1.4	10.3
Debt service payments	(9.2)	(2.5)
Cash flows from financing activities, net	$ 18.8	$ 18.3

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

Committed Equity Financing Facilities (CEFFs)

Since 2006, we have entered into five 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 CEFFs. Each CEFF is available for a period of two to three years and, should we choose to raise funds under a CEFF, our ability to access funds at any time is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2010, we had three available CEFFs as follows: the CEFF dated June 11, 2010 (2010 CEFF), the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). Effective February 6, 2011, the December 2008 CEFF expired. The following table sets forth an overview of the "draw down" requirements and availability under each CEFF at December 31, 2010:

(in millions, except per share data and trading days)	Expiration	Minimum Price per Share 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, 2010	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008 CEFF	June 18, 2011	$ 1.15	90% of the closing market price on the	8	1.3	$ 60.0	0.9	$ 51.8
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60	day preceding the first day of draw down	6	1.0	$ 25.0	0.5	$ 17.7
2010 CEFF	June 11, 2013	$ 0.20	Threshold Price [3]	8	2.1	$ 35.0	1.6	$ 33.7

(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 price 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 under the June 2010 and May 2008 CEFFs, and 1/6th under December 2008 CEFF, respectively. Unless we and Kingsbridge agree otherwise, a minimum of three trading days must elapse between the expiration of any draw-down period and the beginning of the next draw-down period.

(3) Threshold Price is either (i) 90% of the closing market price of our common stock on the trading day immediately preceding the first trading day of the draw down period or (ii) a price that we specify at our sole discretion, but not less than $0.20 per share.

Each draw down is limited in amount as follows:

- May 2008 CEFF – the lesser of 3.0% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $10 million
- December 2008 CEFF – the lesser of 1.5% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $3 million
- 2010 CEFF – Kingsbridge is obligated to purchase ("Obligated Amount") in a draw down the amount determined under one of two methodologies that we choose at our discretion, subject to a limit of the lesser of 3.5% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $15 million. The methodologies for determining the Obligated Amount are:

Methodology 1 – based on Threshold Price	**Obligated Amount**
Threshold Price is:	
Greater than $90.00 per share	$ 7,250,000
Greater than or equal to $75.00 but less than $90.00 per share	$ 6,500,000
Greater than or equal to $60.00 but less than $75.00 per share	$ 4,250,000
Greater than or equal to $45.00 but less than $60.00 per share	$ 3,500,000
Greater than or equal to $30.00 but less than $45.00 per share	$ 2,750,000
Greater than or equal to $18.75 but less than $30.00 per share	$ 2,000,000
Greater than or equal to $11.25 but less than $18.75 per share	$ 1,350,000
Greater than or equal to $7.50 but less than $11.25 per share	$ 1,000,000
Greater than or equal to $3.75 but less than $7.50 per share	$ 500,000
Greater than or equal to $3.00 but less than $3.75 per share	$ 350,000

Methodology 2

Under this method, the Obligated Amount is equal to: 8 (the trading days in the draw down period) multiplied by the adjusted average trading volume of our common stock (calculated as the average daily trading volume of the prior 40 trading days excluding the 5 trading days with the highest trading volume and the 5 trading days with the lowest trading volume) multiplied by the Threshold Price multiplied by 0.1985.

In addition, the 2010 CEFF provides that in connection with any draw down notice we may, in our sole discretion, include a request that Kingsbridge purchase an amount that is in addition to the Obligated Amount (a supplemental amount). Kingsbridge may in its sole discretion choose to purchase all or a portion of any supplemental amount that we designate. If we designate a supplemental amount, we may also designate a separate threshold price for that supplemental amount, provided that the supplemental amount, when aggregated with all other amounts drawn under the 2010 CEFF, may not exceed the total commitment amount available under the 2010 CEFF. If Kingsbridge elects to purchase any of the supplemental amount, we will sell to Kingsbridge the corresponding number of shares at a price equal to the greater of (i) the daily VWAP of our common stock on the applicable trading day, or (ii) the supplemental amount threshold price designated by us, in either case less the applicable discount determined in the same manner as for the Obligated Amount.

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 in the draw down period 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%

Daily VWAP	% of VWAP	Applicable Discount
December 2008 CEFF		
Greater than $7.25 per share	94%	6%
Less than or equal to $7.25 but greater than $3.85 per share	92%	8%
Less than or equal to $3.85 but greater than $1.75 per share	90%	10%
Less than or equal to $1.75 but greater than or equal to $1.10 per share	88%	12%
Less than or equal to $1.10 but greater than or equal to $.60	85%	15%
2010 CEFF		
Greater than $6.00 per share	95.62%	4.38%
Greater than or equal to $5.00 but less than $6.00 per share	95.25%	4.75%
Greater than or equal to $4.00 but less than $5.00 per share	94.75%	5.25%
Greater than or equal to $3.00 but less than $4.00 per share	94.25%	5.75%
Greater than or equal to $2.00 but less than $3.00 per share	94.00%	6.00%
Greater than or equal to $1.25 but less than $2.00 per share	92.50%	7.50%
Greater than or equal to $0.75 but less than $1.25 per share	91.50%	8.50%
Greater than or equal to $0.50 but less than $0.75 per share	90.50%	9.50%
Greater than or equal to $0.25 but less than $0.50 per share	85.00%	15.00%
Greater than or equal to $0.20 but less than $0.25 per share	82.50%	17.50%

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 current and prior CEFFs, we issued the following warrants to Kingsbridge, all of which are exercisable, in whole or in part, for cash, except in limited circumstances and none of which have been exercised as of December 31, 2010:

- On May 22, 2008, a warrant to purchase up to 55,000 shares of our common stock at an exercise price of $37.59 per share, expiring in November 2013.
- On December 22, 2008, a warrant to purchase up to 45,000 shares of our common stock at an exercise price of $22.70 per share, expiring in May 2014.
- On June 11, 2010, a warrant to purchase up to 83,333 shares of our common stock at an exercise price of $6.69 per share. The warrant expires in December 2015 and is exercisable, in whole or in part, for cash, except in limited circumstances.
- On April 17, 2006, a warrant to purchase up to 32,667 shares of our common stock at an exercise price equal to $84.29 per share, expiring in October 2011.
- In 2004, a warrant to purchase up to 25,000 shares of our common stock at an exercise price equal to $181.12 per share, which expired unexercised in January 2010.

CEFF Financings

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	74	$ 1,563	$ 21.21
July 31, 2008	66	1,500	22.69
October 17, 2008	61	1,313	21.55
November 20, 2008	15	250	16.95
January 2, 2009	32	500	15.66
January 16, 2009	28	438	15.68
February 18, 2009	57	1,000	17.50
March 31, 2009	68	1,094	16.17
October 13, 2009	37	606	16.27
	438	$ 8,264	

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	54	$ 1,000	$ 18.60
May 7, 2009	85	1,000	11.78
September 23, 2009	120	1,583	13.24
October 13, 2009	127	1,800	14.14
October 21, 2009	140	1,900	13.57
	526	$ 7,283	

The financings that we completed under the 2010 CEFF are:

(in thousands, except per share data) Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
October 4, 2010	351	$ 973	$ 2.77
November 4, 2010	166	432	2.60
January 24, 2011	314	991	3.16
	831	$ 2,396	

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.

On February 22, 2011, we completed a public offering of 10,000,000 shares of our common stock, five-year warrants to purchase 5,000,000 shares of our common stock, and fifteen-month warrants to purchase 5,000,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock, a five-year warrant to purchase one half share of common stock, and a fifteen-month warrant to purchase one half share of common stock, at a public offering price of $2.35 per unit, resulting in gross proceeds to us of $23.5 million ($21.6 million net). The fifteen-month warrants expire in May 2012 and are exercisable at a price per share of $2.94. The five-year warrants expire in February 2016 and are exercisable at a price per share of $3.20. In addition to other adjustments, described below, the exercise price of the five-year warrants will be subject to adjustment if we issue or sell common stock or securities convertible into common stock (in each case, subject to certain exceptions) at a price (determined as set forth in the warrant) that is less than the exercise price of the warrant.

On October 12, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, pursuant to which PharmaBio agreed to purchase 158,730 shares of our common stock and warrants to purchase an aggregate of 79,365 shares of common stock, sold as units with each unit consisting of one share of common stock and one warrant to purchase one-half of a share of common stock, at an offering price of $3.15 per unit. The offering resulted in gross proceeds to us of $0.5 million. The warrants generally will expire in October 2015 and are immediately exercisable, subject to an aggregate beneficial ownership limitation, at an exercise price per share of $4.10 per share. If exercised in full, the warrants would result in additional proceeds to us of approximately $0.325 million. In addition, upon 20 days' written notice to the holder of the warrant, we may redeem any or all of the warrants at any time within 20 days following the occurrence of a "trading threshold" (as defined below) at a per-warrant redemption price of $0.001. A "trading threshold" will be deemed to have occurred on any date that the reported volume weighted average price (VWAP) for five of the immediately preceding seven consecutive trading days exceeds $6.75, provided that the minimum average daily trading volume of our common stock during the seven-day period is at least 33,333 shares (the price and volume criteria being adjusted to take into account any share dividend, share split or other similar transaction that may occur on or after the issuance).

On June 22, 2010, we completed a public offering of 2,380,952 shares of our common stock, five-year warrants to purchase 1,190,474 shares of our common stock, and nine-month warrants to purchase 1,190,474 shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a five-year warrant to purchase one half share of common stock, and a nine-month warrant to purchase one half share of common stock, at a public offering price of $4.20 per unit, resulting in gross proceeds to us of $10 million ($9.1 million net). The five-year warrants expire on June 22, 2015 and are immediately exercisable, subject to an aggregate beneficial ownership limitation, at a price per share of $6.00. The nine-month warrants, which were immediately exercisable, subject to an aggregate beneficial ownership limitation, at a price per share of $4.20, expired on March 22, 2011.

On April 27, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, pursuant to which PharmaBio agreed to purchase 270,154 shares of common stock and warrants to purchase an aggregate of 135,077 shares of common stock, sold as units with each unit consisting of one share of common stock and one warrant to purchase one-half share of common stock, at an offering price of $8.14 per unit. The offering resulted in gross proceeds to us of $2.2 million ($2.1 million net). The warrants generally expire in April 2015 and have been exercisable since October 28, 2010, subject to an aggregate beneficial ownership limitation of 9.9%, at a price per share of $10.59.

In February 2010, we completed a public offering of 1,833,333 shares of our common stock and warrants to purchase 916,669 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase one-half share of common stock, at a public offering price of $9.00 per unit, resulting in gross proceeds to us of $16.5 million ($15.1 million net). The warrants expire in February 2015 and are immediately exercisable, subject to an aggregate share ownership limitation, at a price per share of $12.75.

In May 2009, we completed a registered direct offering of 933,333 shares of our common stock and warrants to purchase 466,667 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 $12.15 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 $17.25.

With respect to the warrants issued in connection with the foregoing offerings, the exercise price and number of shares of common stock issuable upon exercise are subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants are also subject to adjustment if we engage in a "Fundamental Transaction" (such as consolidation or merger, sale or disposal of substantially all of our assets, and among others as defined in the form of the warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not otherwise available for the resale of the warrant shares, the holder may exercise on a cashless basis.

As of December 31, 2010, $74.5 million remained available under the 2008 Shelf Registration Statement for potential future offerings. After taking into account the public offering we completed in February 2011, approximately $51.0 million remains available under the 2008 Shelf Registration Statement for potential future offerings. If the aggregate market value of our common stock held by non-affiliates remains below $75.0 million, the number of securities that we may offer and sell pursuant to this and any subsequent shelf registration statement within any 12 calendar month period will be limited to one-third of the aggregate market value of our common stock held by non-affiliates.

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 PharmaBio Development, Inc.

On April 28, 2010, we restructured our $10.6 million loan with PharmaBio Development Inc (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. (Quintiles). The related Payment Agreement and Loan Amendment dated April 27, 2010 (PharmaBio Agreement) provided for payment in cash of (a) an aggregate of $6.6 million, representing $4.5 million in outstanding principal and $2.1 million in accrued interest, and (b) of the remaining $4 million principal amount under the loan, $2 million of which became due and were paid on each of July 30, 2010 and September 30, 2010. Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation warrants to purchase an aggregate of 159,574 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities. As of December 31, 2010, all of our obligations related to the loan with PharmaBio were paid in full.

For the years ended December 31, 2010 and 2009, we incurred interest expense associated with the PharmaBio loan of $0.3 million and $0.8 million, respectively. Interest expense for the years ended December 31, 2010 and 2009 include $0.2 million and $0.5 million, respectively, of amortization of deferred financing costs for warrants issued to PharmaBio in 2006 in consideration for restructuring the loan.

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, 2010 and 2009 was as follows:

(in thousands)	2010	2009
GE Business Financial Services, Inc.		
Short-term	$ 51	$ 538
Long-term	-	65
Total	51	603
Pennsylvania Machinery and Equipment Loan		
Short-term	63	59
Long-term	296	363
Total	359	422
Other Capitalized Leases		
Short-term	22	-
Long-term	5	-
Total	27	-
Total Short-term	136	597
Total Long-term	301	428
Total	$ 437	$ 1,025

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 and we have not received any new funding since November 2008. Advances to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our prior facility was 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 1% prepayment penalty. 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.

Principal payments under the Facility were $0.6 million and $2.4 million for the years ended December 31, 2010 and 2009, respectively. Interest expense under the Facility was $33,000 and $0.2 million for the years ended December 31, 2010 and 2009, respectively. The remaining outstanding loan balance under the Facility was $51,000 as of December 31, 2010, with the final payment anticipated in September 2011.

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, may be adjusted to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Contractual Commitments

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. 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 14 employees subject to a collective bargaining arrangement which expires on December 3, 2011. *See*, "Item 1 – Business – Business Operations – Manufacturing and Distribution," and "Item 2 – Properties."

Rent expense under all leases for the years ended December 31, 2010 and 2009 was $1.0 million and $1.1 million, respectively.

Former CEO Commitment

In connection with the resignation in August 2009 of Robert J. Capetola, Ph.D., our former President, Chief Executive Officer and member of our Board, we entered into a separation agreement and general release (Separation Agreement) dated August 13, 2009, that provided, among other things, for periodic severance payments through the earlier of (i) May 3, 2010 (Severance Period) or (ii) the date, if ever, of a Corporate Transaction (defined below). Under the Separation Agreement, if a "Corporate Transaction" not involving a change of control were to occur during the Severance Period, Dr. Capetola would become entitled to receive an additional severance payment of up to $1,580,000, reduced by the sum of the aggregate cash severance amounts already paid under the Separation Agreement. A "Corporate Transaction" was defined to include one or more public or private financings completed during the Severance Period and resulting in cash proceeds (net of transaction costs) to us of at least $20 million. From August 13, 2009 through February 23, 2010, we raised approximately $21.0 million of aggregate net proceeds, including approximately $5.9 million from financings under our CEFFs and $15.1 million from a public offering that was completed on February 23, 2010. Accordingly, on March 3, 2010, we paid to Dr. Capetola an additional $1.06 million (less withholding), representing $1.58 million reduced by the sum of the cash severance amounts previously paid under the Separation Agreement, which totaled approximately $0.52 million. At this time, our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due to Dr. Capetola.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2010 or 2009, or for the periods then ended.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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

Our Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow for timely decisions regarding required disclosures, and 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 Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010. 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, 2010.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

(c) Changes in internal controls

Other than the remediation efforts described below, 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, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In our internal control report for our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, our management was unable to conclude that we had maintained effective internal control over financial reporting as of September 30, 2010 and identified a material weakness regarding our process and procedures related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments. Upon a reassessment of those financial instruments in light of generally accepted accounting principles, we determined that we should have accounted for registered warrants that we issued in May 2009 and February 2010 as derivative liabilities instead of equity. As a result, to reclassify the affected warrants as derivative liabilities, in November 2010, we filed restatements of our consolidated financial statements for the periods ended from June 30, 2009 through June 30, 2010. To address this material weakness, we took the following remedial actions during the quarter ended December 31, 2010 to enhance our process to identify and correctly apply developments in accounting standards specifically relating to improve our understanding of the nuances of increasingly complex accounting standards relating to the initial classification and subsequent accounting of derivative securities as liabilities or equity instruments:

- we improved access to accounting literature, research materials and documents; and

- we have provided for increased communication among our legal and finance personnel and third-party professionals with whom we consult regarding complex accounting applications.

As a result of these remedial actions, our management concluded that it has remediated the material weakness related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

Except as set forth below, the information required by Items 10 through 14 of Part III is incorporated herein by reference to our definitive proxy statement or an amendment to this annual report on Form 10-K, in either case, to be filed with the Securities and Exchange Commission within 120 days after the end of our 2010 fiscal year.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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 31, 2011

By: /s/ W. Thomas Amick
W. Thomas Amick, Chairman of the Board
and Chief Executive Officer

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

Signature	Name & Title	Date
/s/ W. Thomas Amick	W. Thomas Amick Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 31, 2011
/s/ John G. Cooper	John G. Cooper President and Chief Financial Officer (Principal Financial Officer)	March 31, 2011
/s/ John Tattory	John Tattory Vice President, Finance and Controller (Principal Accounting Officer)	March 31, 2011
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 31, 2011
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 31, 2011
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	March 31, 2011
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 31, 2011
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 31, 2011

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), as amended as of December 28, 2010..	Filed herewith.
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	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.
4.3	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
4.4	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.
4.5	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.
4.6	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.
4.7	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.
4.8	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.

Exhibit No.	Description	Method of Filing
4.9	Warrant Agreement dated June 11, 2010 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 June 14, 2010
4.10	Form of Five-Year Warrant issued on June 22, 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010
4.11	Form of Short-Term Warrant issued on June 22, 2010	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010
4.12	Warrant Agreement, dated as of October 12, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 13, 2010
4.13.	Form of Voting Agreement between RSA Holders and Discovery dated November 12, 2010	Filed herewith
4.14	Form of Five-Year Warrant issued on February 22, 2011	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
4.15	Form of Short Term Warrant issued on February 22, 2011	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
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/A, as filed with the SEC on April 18, 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 year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.3 +	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.
10.4 +	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.
10.5*	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).

Exhibit No.	Description	Method of Filing
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.
10.9*	Form of Stock Issuance Agreement, dated as of October 30, 2007, between 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*	Form of Restricted Stock Award (RSA) Agreement dated September 27, 2010	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 1, 2010.
10.11*	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.
10.12*	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.
10.13*	Renewal of Interim CEO Agreement dated July 2, 2010 between W. Thomas Amick and Discovery	Incorporated by reference to Exhibit 10.8 to Discovery's Quarterly Report on Form 10-Q dated June 30, 2010, as filed with the SEC on August 9, 2010.
10.14*	Employment Agreement dated as of October 18, 2010 by and between W. Thomas Amick and Discovery.	Incorporated by reference to Exhibit 10.5 to Discovery's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, as filed with the SEC on November 15, 2010.
10.15*	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.
10.16*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between John G. Cooper and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008.

Exhibit No.	Description	Method of Filing
10.17*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and David L. Lopez, Esq., CPA	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.18*	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.
10.19+	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.
10.20+	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.
10.21	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 year ended December 31, 2005, as filed with the SEC on March 16, 2006.
10.22	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.
10.23	Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.24	Payment Agreement and Loan Amendment (amending the Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006) dated April 27, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.25	Third Amended Promissory Note dated April 27, 2010 (amending and restating the Second Amended Promissory Note dated as of October 25, 2006), payable to PharmaBio	Incorporated by reference to Exhibit 1.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.26	Securities Purchase Agreement dated April 27, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 1.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.

Exhibit No.	Description	Method of Filing
10.27	Securities Purchase Agreement dated October 12, 2010 by and between PharmaBio and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 13, 2010.
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.
10.30	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.
10.31	Registration Rights Agreement, dated as of May 22, 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.
10.32	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.
10.33	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 December 15, 2008.
10.34	Common Stock Purchase Agreement dated as of June 11, 2010, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
10.35+	Supply Agreement dated as of December 22, 2010 between by and between Corden Pharma (formerly Genzyme Pharmaceuticals LLC) 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 29, 2010.
21.1	Subsidiaries of Discovery.	Filed herewith.
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 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

See notes to consolidated financial statements

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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. 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. We were not engaged to perform an audit of the company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluation 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

March 31, 2011
Philadelphia, PA

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,211	$ 15,741
Prepaid expenses and other current assets	285	233
Total current assets	10,496	15,974
Property and equipment, net	3,467	4,668
Restricted cash	400	400
Other assets	174	361
Total assets	$ 14,537	$ 21,403
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,685	$ 1,294
Accrued expenses	3,286	3,446
Common stock warrant liability	2,469	3,191
Loan payable, including accrued interest	-	10,461
Equipment loans and capitalized leases, current portion	136	597
Total current liabilities	7,576	18,989
Equipment loans and capitalized leases, non-current portion	301	428
Other liabilities	634	690
Total liabilities	8,511	20,107
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 50,000 authorized; 13,822 and 8,446 shares issued, 13,801 and 8,425 shares outstanding	14	8
Additional paid-in capital	385,521	361,622
Accumulated deficit	(376,455)	(357,280)
Treasury stock (at cost); 21 shares	(3,054)	(3,054)
Total stockholders' equity	6,026	1,296
Total liabilities & stockholders' equity	$ 14,537	$ 21,403

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,	
	2010	**2009**
Revenue	$ –	$ –
Expenses:		
Research & development	17,136	19,077
General & administrative	8,392	10,120
Total expenses	25,528	29,197
Operating loss	(25,528)	(29,197)
Change in fair value of common stock warrant liability	6,422	369
Other income / (expense):		
Interest and other income	288	39
Interest and other expense	(357)	(1,082)
Other income / (expense), net	(69)	(1,043)
Net loss	$ (19,175)	$ (29,871)
Net loss per common share - basic and diluted	$ (1.65)	$ (3.89)
Weighted average number of common shares outstanding - basic and diluted	11,602	7,680

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2010 and 2009

(In thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock Shares	Treasury Stock Amount	Accumulated Other Comprehensive Income/(Loss)	Total
Balance – January1, 2009	**6,773**	**$ 6**	**$ 341,389**	**$ (327,409)**	**(21)**	**$ (3,054)**	**$ 1**	**$ 10,933**
Comprehensive loss:								
Net loss	–	–	–	(29,871)	–	–	–	(29,871)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	(1)	(1)
Total comprehensive loss	–	–	–	–	–	–	–	(29,872)
Issuance of common stock, restricted stock awards	1	–	–	–	–	–	–	–
Issuance of common stock, 401(k) employer match	23	–	290	–	–	–	–	290
Issuance of common stock, May 2009 financing	933	1	6,904	–	–	–	–	6,905
Issuance of common stock, CEFF financings	716	1	10,356	–	–	–	–	10,357
Stock-based compensation expense	–	–	2,683	–	–	–	–	2,683
Balance – December 31, 2009	**8,446**	**$ 8**	**$ 361,622**	**$ (357,280)**	**(21)**	**$ (3,054)**	**$ –**	**$ 1,296**
Comprehensive loss:								
Net loss	–	–	–	(19,175)	–	–	–	(19,175)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	–
Total comprehensive loss	–	–	–	–	–	–	–	(19,175)
Issuance of common stock, restricted stock awards	155	–	–	–	–	–	–	–
Issuance of common stock, 401(k) employer match	61	1	223	–	–	–	–	224
Issuance of common stock, February 2010 financing	1,833	2	9,379	–	–	–	–	9,381
Issuance of common stock, April 2010 financing	270	–	2,105	–	–	–	–	2,105
Issuance of common stock, June 2010 financing	2,381	2	9,092	–	–	–	–	9,094
Issuance of common stock, October 2010 financing	159	–	452	–	–	–	–	452
Issuance of common stock, CEFF financings	517	1	1,242	–	–	–	–	1,243
Stock-based compensation expense	–	–	1,406	–	–	–	–	1,406
Balance – December 31, 2010	**13,822**	**$ 14**	**$ 385,521**	**$ (376,455)**	**(21)**	**$ (3,054)**	**$ –**	**$ 6,026**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,	
	2010	**2009**
Cash flow from operating activities:		
Net loss	$ (19,175)	$ (29,871)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,549	1,992
Stock–based compensation and 401(k) match	1,634	2,973
Fair value adjustment of common stock warrants	(6,422)	(369)
Gain on sale of equipment	(16)	–
Changes in:		
Prepaid expenses and other current assets	(52)	392
Accounts payable	391	(817)
Accrued expenses	(166)	(1,867)
Other assets	4	(1)
Other liabilities and accrued interest on loan payable	(2,017)	153
Net cash used in operating activities	(24,270)	(27,415)
Cash flow from investing activities:		
Purchase of property and equipment	(101)	(147)
Restricted cash	–	200
Proceeds from sale or maturity of marketable securities	–	2,047
Net cash provided by / (used in) investing activities	(101)	2,100
Cash flow from financing activities:		
Proceeds from issuance of securities, net of expenses	27,977	20,820
Principal payments of loan payable	(8,500)	–
Principal payments under equipment loan and capital lease obligations	(636)	(2,508)
Net cash provided by financing activities	18,841	18,312
Net decrease in cash and cash equivalents	(5,530)	(7,003)
Cash and cash equivalents – beginning of year	15,741	22,744
Cash and cash equivalents – end of year	$ 10,211	$ 15,741
Supplementary disclosure of cash flows information:		
Interest paid	$ 2,123	$ 208
Non-cash transactions:		
Unrealized gain / (loss) on marketable securities	–	(1)
Equipment acquired through capitalized lease	48	–

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 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 normal respiratory function and survival. 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 KL_4 surfactant 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 neonatal populations. Our research and development efforts are currently focused on the management of RDS in premature infants. We believe that Surfaxin, Surfaxin LS and Aerosurf, have the potential to greatly improve the management of RDS. We have filed a New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009 (2009 Complete Response Letter). The safety and efficacy of Surfaxin for the prevention of RDS in premature infants has previously been demonstrated in a large, multinational Phase 3 clinical program and we believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit Biological Activity Test (BAT). We have been conducting a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT. We believe that we could file a Complete Response in the third quarter of 2011, which could lead to approval of Surfaxin for the prevention of RDS in premature infants in the first quarter 2012.

We are developing Surfaxin LS (our initial lyophilized KL_4 surfactant) and Aerosurf (our initial aerosolized KL_4 surfactant) for the prevention and or treatment of RDS in premature infants for both the United States and all other major markets throughout the world. 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. In that regard, during 2010 an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and effectiveness (via improvement in mucociliary clearance) of aerosolized KL_4 surfactant in patients with Cystic Fibrosis concluded and we also completed a Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF). 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 conducted and are planning additional 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 of our KL_4 surfactant technology. We continue to assess an array of potential strategic alliances and financing opportunities to potentially accomplish our development and commercialization objectives. 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 focus on our RDS programs, primarily Surfaxin, and conserve our resources, predominantly by curtailing and pacing 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 Committed Equity Financing Facilities (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.

Since receipt of the 2009 Complete Response Letter, we have implemented cost-containment measures to conserve cash, including by reducing our workforce and limiting investments in our pipeline programs. We plan to continue closely managing our expenditures in 2011 and focus our financial resources on our RDS programs, primarily activities in support of the potential approval of Surfaxin.

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, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting neonatal 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.

As of December 31, 2010, we had cash and cash equivalents of $10.2 million and three Committed Equity Financing Facilities (CEFFs), which could allow us, at our discretion, to raise capital (subject to certain conditions, including minimum stock price and volume limitations) at a time and in amounts deemed suitable for us to support our business plans. Effective February 6, 2011, the December 2008 CEFF expired. Based on the closing market price of our common stock on March 15, 2011, the potential availability under our two remaining CEFFs is approximately $3.5 million. However, we agreed in connection with our February 2011 offering that we would not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in May 2011. During 2010, we raised aggregate gross proceeds of $30.6 million, including $16.5 million ($15.1 million net) and $10.0 million ($9.1 million net) from public offerings in February and June 2010, respectively; $2.2 million ($2.1 million net) and $0.5 million from offerings to PharmaBio in April 2010 and October 2010, respectively; and $1.4 million from draw downs on our 2010 CEFF. *See*, Note 10 – Stockholders Equity and, in our Annual Report on Form 10-K for the year-ended December 31, 2010 (Annual Report on Form 10-K), "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."

On February 22, 2011, we completed a public offering resulting in gross proceeds of $23.5 million ($21.6 million net). *See*, Note 18 – Subsequent Events.

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.

Reverse Stock Split

The accompanying consolidated financial statements reflect a 1-for-15 reverse split of our common stock that was approved by our Board of Directors and stockholders and made effective by an amendment to our Amended and Restated Certificate of Incorporation, as amended, on December 28, 2010. All share and per share information herein that relates to our common stock has been retroactively restated to reflect the reverse stock split.

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 cash and cash equivalents as amounts on hand, on deposit in financial institutions and all highly liquid marketable securities purchased with a maturity of three months or less.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities and restricted cash. The fair values of our 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, 2010 and December 31, 2009.

Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which we believe 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, 2010 and 2009, 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 proceeds are recorded as revenue upon receipt of funds, provided that grants received in respect of prior expenses are recorded as "Other income."

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

Stock-based compensation is accounted for under the fair value recognition provisions of Accounting Standards Codification (ASC) Topic 718 *"Stock Compensation." See*, Note 11 – Stock Options and Stock-based Employee Compensation, for a detailed description of our recognition of stock-based compensation expense.

Warrant accounting

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. In compliance with applicable securities law, registered common stock warrants that require the issuance of registered shares upon exercise and do not expressly preclude an implied right to cash settlement are accounted for as derivative liabilities. We classify these derivative warrant liabilities on the consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes pricing model to value the derivative warrant liability. Changes in the fair market value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

Income taxes

We account 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. 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, 2010 and 2009 are as follows:

(in thousands)	December 31, 2010	2009
Net loss	$ (19,175)	$ (29,871)
Change in unrealized (losses)/gains on marketable securities	–	(1)
Comprehensive loss	$ (19,175)	$ (29,872)

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, 2010 and 2009, 5.3 million and 2.1 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants. 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 October 2009, the Financial Accounting Standards Board ("FASB") issued amendments to the accounting and disclosure guidance for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and the scope of what constitutes a non-software deliverable. The impact of the adoption of these amendments will depend on the nature of the arrangements that we conclude subsequent to adoption.

In January 2010, an amendment to the FASB fair value guidance was issued. This amendment requires disclosures of transfers into and out of Levels 1 and 2, more detailed roll forward reconciliations of Level 3 recurring fair value measurements on a gross basis, fair value information by class of assets and liabilities, and descriptions of valuation techniques and inputs for Level 2 and 3 measurements. The adoption of this amendment had no impact on our consolidated financial statements as this change is disclosure-only in nature.

In April 2010, the FASB issued guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The amendments provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. We do not expect the implementation of this standard to have a material impact on our consolidated balance sheet and results of operations.

Note 4 – 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 and liabilities measured at fair value on a recurring basis are categorized in the table below as of December 31, 2010 and 2009:

(in thousands)	Fair Value December 31, 2010	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money markets	$ 9,690	$ 9,690	$ –	$ –
Certificate of deposit	600	600	–	–
Total Assets	$ 10,290	$ 10,290	$ –	$ –
Liabilities				
Common stock warrant liability	$ 2,469	$ $ –	$ –	$ 2,469

(in thousands)	Fair Value December 31, 2009	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money markets	$ 14,690	$ 14,690	$ –	$ –
Certificate of deposit	600	600	–	–
Total Assets	$ 15,290	$ 15,290	$ –	$ –
Liabilities				
Common stock warrant liability	$ 3,191	$ –	$ –	$ 3,191

The following table summarizes the activity of Level 3 inputs measured on a recurring basis for the year ended December 31, 2010:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2009	$ 3,191
Issuance of common stock warrants	5,700
Change in fair value of common stock warrant liability	(6,422)
Balance at December 31, 2010	$ 2,469

Note 5 – Restricted Cash

Restricted cash consists of a security deposit held by our bank as collateral for 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 terms of the lease agreement the required restricted cash balance as of December 31, 2010 and 2009 was $400,000 and $600,000, respectively. The notional amount of the letter of credit (and the related security deposit) will remain at $400,000 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 6 –Property and Equipment

Property and equipment as of December 31, 2010 and 2009 was comprised of the following:

(in thousands)	December 31, 2010	2009
Equipment	$ 7,418	$ 7,265
Furniture	801	791
Leasehold improvements	2,838	2,838
Subtotal	11,057	10,894
Accumulated depreciation and amortization	(7,590)	(6,226)
Property and equipment, net	$ 3,467	$ 4,668

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 consist of construction of an analytical and development laboratory in our Warrington, Pennsylvania headquarters, which was completed in 2007. 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 expense on property and equipment for the years ended December 31, 2010 and 2009 was $1.4 million and $1.4 million, respectively.

Note 7 –Accrued Expenses

Accrued expenses as of December 31, 2010 and 2009 were comprised of the following:

(in thousands)	December 31, 2010	2009
Accrued compensation [(1)]	$ 760	$ 1,792
Accrued manufacturing	796	393
Accrued research and development	689	478
Accrued accounting and legal fees	395	254
All other accrued expenses	646	529
Total accounts payable and accrued expenses	$ 3,286	$ 3,446

(1) Accrued compensation primarily consists of potential employee incentive arrangements (pursuant to plans approved by our Board) and employees' unused earned vacation. As of December 31, 2009 accrued compensation also included contractual severance arrangements for our former President and Chief Executive Officer which were paid in the first quarter of 2010.

Note 8 –Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The warrants that we issued in registered transactions in May 2009 and February 2010 generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, the warrant agreements do not expressly state that there is no circumstance that requires us to effect a net cash settlement of the warrant. Therefore, notwithstanding the availability of cashless exercise, generally accepted accounting principles establishes that, in the absence of express agreement of the parties to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the issuer to provide freely-tradable shares in all circumstances. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that an event would result in a cash settlement. Based on the terms of the warrant agreements and the applicable accounting guidance, the May 2009 and February 2010 warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value using the Black-Scholes option pricing model. Changes in the estimated fair value of the warrants are reported in the Consolidated Statement of Operations as the "Change in fair value of common stock warrant."

Note 9 –Debt

Loan Payable – PharmaBio Development Inc.

On April 28, 2010, we restructured our $10.6 million loan with PharmaBio Development Inc. The related Payment Agreement and Loan Amendment dated April 27, 2010 (PharmaBio Agreement) provided for payment in cash of (a) an aggregate of $6.6 million, representing $4.5 million in outstanding principal and $2.1 million in accrued interest, and (b) of the remaining $4 million principal amount under the loan, $2 million of which became due and were paid on each of July 30, 2010 and September 30, 2010. Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation warrants to purchase an aggregate of 159,574 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities.

As of December 31, 2010, all of our obligations related to the loan with PharmaBio were paid in full.

For the years ended December 31, 2010 and 2009, we incurred interest expense associated with the PharmaBio loan of $0.3 million and 0.8 million, respectively. Interest expense for the years ended December 31, 2010 and 2009 include $0.2 million and $0.5 million, respectively, of amortization of deferred financing costs for warrants issued to PharmaBio in 2006 in consideration for restructuring the loan.

Equipment Loans

Our equipment loan liabilities as of December 31, 2010 and 2009 are as follows:

(in thousands)	**2010**	**2009**
GE Business Financial Services, Inc.		
Short-term	$ 51	$ 538
Long-term	–	65
Total	51	603
Pennsylvania Machinery and Equipment Loan		
Short-term	63	59
Long-term	296	363
Total	359	422

(in thousands)	2010	2009
Capitalized Leases		
Short-term	22	-
Long-term	5	-
Total	27	-
Total Short-term	136	597
Total Long-term	301	428
Total	$ 437	$ 1,025

For the years ended December 31, 2010 and 2009, we incurred interest expense associated with our equipment loans of $0.1 million and $0.2 million, respectively.

Equipment Financing Facility with GE Business Financial Services Inc.

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide us a $12.5 million facility (Facility) to fund our capital programs. The right to draw under this Facility expired and we have not received any new funding since November 2008. Advances to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our prior facility was 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 1% prepayment penalty. 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.

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

On October 12, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, pursuant to which PharmaBio agreed to purchase 158,730 shares of our common stock and warrants to purchase an aggregate of 79,365 shares of common stock, sold as units with each unit consisting of one share of common stock and one warrant to purchase one-half of a share of common stock, at an offering price of $3.15 per unit. The offering resulted in gross proceeds to us of $0.5 million. The warrants generally will expire in October 2015 and are immediately exercisable, subject to an aggregate beneficial ownership limitation, at an exercise price per share of $4.10 per share. If exercised in full, the warrants would result in additional proceeds to us of approximately $0.325 million. In addition, upon 20 days' written notice to the holder of the warrant, we may redeem any or all of the warrants at any time within 20 days following the occurrence of a "trading threshold" (as defined below) at a per-warrant redemption price of $0.001. A "trading threshold" will be deemed to have occurred on any date that the reported volume weighted average price (VWAP) for five of the immediately preceding seven consecutive trading days exceeds $6.75, provided that the minimum average daily trading volume of our common stock during the seven-day period is at least 33,333 shares (the price and volume criteria being adjusted to take into account any share dividend, share split or other similar transaction that may occur on or after the issuance).

On June 22, 2010, we completed a public offering of 2,380,952 shares of our common stock, five-year warrants to purchase 1,190,474 shares of our common stock, and nine-month warrants to purchase 1,190,474 shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a five-year warrant to purchase one half share of common stock, and a nine-month warrant to purchase one half share of common stock, at a public offering price of $4.20 per unit, resulting in gross proceeds to us of $10 million ($9.1 million net). The five-year warrants expire on June 22, 2015 and are immediately exercisable, subject to an aggregate beneficial ownership limitation, at a price per share of $6.00. The nine-month warrants, which were immediately exercisable, subject to an aggregate beneficial ownership limitation, at a price per share of $4.20, expired on March 22, 2011.

On April 27, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, pursuant to which PharmaBio agreed to purchase 270,154 shares of common stock and warrants to purchase an aggregate of 135,077 shares of common stock, sold as units with each unit consisting of one share of common stock and one warrant to purchase one-half share of common stock, at an offering price of $8.14 per unit. The offering resulted in gross proceeds to us of $2.2 million ($2.1 million net). The warrants generally expire in April 2015 and have been exercisable since October 28, 2010, subject to an aggregate beneficial ownership limitation of 9.9%, at a price per share of $10.59.

In February 2010, we completed a public offering of 1,833,333 shares of our common stock and warrants to purchase 916,669 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase one-half share of common stock, at a public offering price of $9.00 per unit, resulting in gross proceeds to us of $16.5 million ($15.1 million net). The warrants expire in February 2015 and are immediately exercisable, subject to an aggregate share ownership limitation, at a price per share of $12.75.

In May 2009, we completed a registered direct offering of 933,333 shares of our common stock and warrants to purchase 466,667 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 $12.15 per unit, resulting in gross proceeds to us of $11.3 million ($10.5 million net). The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of $17.25.

The foregoing offerings were issued pursuant to our 2008 Universal Shelf. *See*, this note – Common Shares Reserved for Future Issuance – Universal Shelf Registration Statements – 2008 Universal Shelf. With respect to the warrants issued in connection with the foregoing offerings, the exercise price and number of shares of common stock issuable upon exercise are subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants are also subject to adjustment if we engage in a “Fundamental Transaction” (such as consolidation or merger, sale or disposal of substantially all of our assets, and among others as defined in the form of the warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not otherwise available for the resale of the warrant shares, the holder may exercise on a cashless basis.

Committed Equity Financing Facilities (CEFFs)

Since 2006, we have entered into five 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 CEFFs. Each CEFF is available for a period of two to three years and, should we choose to raise funds under a CEFF, our ability to access funds at any time is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2010, we had three available CEFFs as follows: the CEFF dated June 11, 2010 (2010 CEFF), the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). Effective February 6, 2011, the December 2008 CEFF expired. The following table sets forth an overview of the "draw down" requirements and availability under each CEFF at December 31, 2010:

(in millions, except per share data and trading days)	Expiration	Minimum Price per Share 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, 2010	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008 CEFF	June 18, 2011	$ 1.15	90% of the closing market price on the	8	1.3	$ 60.0	0.9	$ 51.8
Dec. 2008 CEFF	Feb. 6, 2011	$ 0.60	day preceding the first day of draw down	6	1.0	$ 25.0	0.5	$ 17.7
2010 CEFF	June 11, 2013	$ 0.20	Threshold Price [3]	8	2.1	$ 35.0	1.6	$ 33.7

(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 price 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 under the June 2010 and May 2008 CEFFs, and 1/6th under December 2008 CEFF, respectively. Unless we and Kingsbridge agree otherwise, a minimum of three trading days must elapse between the expiration of any draw-down period and the beginning of the next draw-down period.

(3) Threshold Price is either (i) 90% of the closing market price of our common stock on the trading day immediately preceding the first trading day of the draw down period or (ii) a price that we specify at our sole discretion, but not less than $0.20 per share.

Each draw down is limited in amount as follows:

- May 2008 CEFF – the lesser of 3.0% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $10 million
- December 2008 CEFF – the lesser of 1.5% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $3 million
- 2010 CEFF – Kingsbridge is obligated to purchase ("Obligated Amount") in a draw down the amount determined under one of two methodologies that we choose at our discretion, subject to a limit of the lesser of 3.5% of the closing market value of the outstanding shares of our common stock at the time of the draw down or $15 million. The methodologies for determining the Obligated Amount are:

Methodology 1 – based on Threshold Price	Obligated Amount
Threshold Price is:	
Greater than $90.00 per share	$ 7,250,000
Greater than or equal to $75.00 but less than $90.00 per share	$ 6,500,000
Greater than or equal to $60.00 but less than $75.00 per share	$ 4,250,000
Greater than or equal to $45.00 but less than $60.00 per share	$ 3,500,000
Greater than or equal to $30.00 but less than $45.00 per share	$ 2,750,000
Greater than or equal to $18.75 but less than $30.00 per share	$ 2,000,000
Greater than or equal to $11.25 but less than $18.75 per share	$ 1,350,000
Greater than or equal to $7.50 but less than $11.25 per share	$ 1,000,000
Greater than or equal to $3.75 but less than $7.50 per share	$ 500,000
Greater than or equal to $3.00 but less than $3.75 per share	$ 350,000

Methodology 2

Under this method, the Obligated Amount is equal to: 8 (the trading days in the draw down period) multiplied by the adjusted average trading volume of our common stock (calculated as the average daily trading volume of the prior 40 trading days excluding the 5 trading days with the highest trading volume and the 5 trading days with the lowest trading volume) multiplied by the Threshold Price multiplied by 0.1985.

In addition, the 2010 CEFF provides that in connection with any draw down notice we may, in our sole discretion, include a request that Kingsbridge purchase an amount that is in addition to the Obligated Amount (a supplemental amount). Kingsbridge may in its sole discretion choose to purchase all or a portion of any supplemental amount that we designate. If we designate a supplemental amount, we may also designate a separate threshold price for that supplemental amount, provided that the supplemental amount, when aggregated with all other amounts drawn under the 2010 CEFF, may not exceed the total commitment amount available under the 2010 CEFF. If Kingsbridge elects to purchase any of the supplemental amount, we will sell to Kingsbridge the corresponding number of shares at a price equal to the greater of (i) the daily VWAP of our common stock on the applicable trading day, or (ii) the supplemental amount threshold price designated by us, in either case less the applicable discount determined in the same manner as for the Obligated Amount.

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 in the draw down period 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%

Daily VWAP	% of VWAP	Applicable Discount
2010 CEFF		
Greater than $6.00 per share	95.62%	4.38%
Greater than or equal to $5.00 but less than $6.00 per share	95.25%	4.75%
Greater than or equal to $4.00 but less than $5.00 per share	94.75%	5.25%
Greater than or equal to $3.00 but less than $4.00 per share	94.25%	5.75%
Greater than or equal to $2.00 but less than $3.00 per share	94.00%	6.00%
Greater than or equal to $1.25 but less than $2.00 per share	92.50%	7.50%
Greater than or equal to $0.75 but less than $1.25 per share	91.50%	8.50%
Greater than or equal to $0.50 but less than $0.75 per share	90.50%	9.50%
Greater than or equal to $0.25 but less than $0.50 per share	85.00%	15.00%
Greater than or equal to $0.20 but less than $0.25 per share	82.50%	17.50%

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 current and prior CEFFs, we issued the following warrants to Kingsbridge, all of which are exercisable, in whole or in part, for cash, except in limited circumstances:

- On May 22, 2008, a warrant to purchase up to 55,000 shares of our common stock at an exercise price of $37.59 per share, expiring in November 2013.
- On December 22, 2008, a warrant to purchase up to 45,000 shares of our common stock at an exercise price of $22.70 per share, expiring in May 2014.
- On June 11, 2010, a warrant to purchase up to 83,333 shares of our common stock at an exercise price of $6.69 per share. The warrant expires in December 2015 and is exercisable, in whole or in part, for cash, except in limited circumstances.
- On April 17, 2006, a warrant to purchase up to 32,667 shares of our common stock at an exercise price equal to $84.29 per share, expiring in October 2011.
- In 2004, a warrant to purchase up to 25,000 shares of our common stock at an exercise price equal to $181.12 per share, which expired unexercised in January 2010.

CEFF Financings

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	74	$ 1,563	$ 21.21
July 31, 2008	66	1,500	22.69
October 17, 2008	61	1,313	21.55
November 20, 2008	15	250	16.95
January 2, 2009	32	500	15.66
January 16, 2009	28	438	15.68
February 18, 2009	57	1,000	17.50
March 31, 2009	68	1,094	16.17
October 13, 2009	37	606	16.27
	438	$ 8,264	

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	54	$ 1,000	$ 18.60
May 7, 2009	85	1,000	11.78
September 23, 2009	120	1,583	13.24
October 13, 2009	127	1,800	14.14
October 21, 2009	140	1,900	13.57
	526	$ 7,283	

The financings that we completed under the 2010 CEFF are:

(in thousands, except per share data) Completion Date	Shares Issued	Gross Proceeds	Discounted Average Price Per Share
October 4, 2010	351	$ 973	$ 2.77
November 4, 2010	166	432	2.60
January 24, 2011	314	991	3.16
	831	$ 2,396	

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, 2010 and 2009, the match resulted in the issuance of 61,158 and 23,126, 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, 2010	December 31, 2009	Exercise Price	Expiration Date
PharmaBio – October 2010 Financing	79	-	$ 4.10	10/13/2015
Investor Warrants – June 2010 Financing	1,190	-	$ 4.20	6/22/2015
Investor Warrants – June 2010 Financing	1,190	-	$ 6.00	3/22/2011
Kingsbridge – 2010 CEFF	83	-	$ 6.69	12/11/2015
PharmaBio – April 2010 Financing	135	-	$ 10.59	4/30/2015
Investor Warrants – February 2010 Financing	917	-	$ 12.75	2/23/2015
Investor Warrants – May 2009 Financing	467	467	$ 17.25	5/13/2014
Kingsbridge – December 2008 CEFF	45	45	$ 22.70	6/12/2014
Kingsbridge – May 2008 CEFF	55	55	$ 37.59	11/22/2013
Private Placement – 2006	154	154	$ 47.70	11/22/2011

(in thousands, except price per share data)	December 31, 2010	December 31, 2009	Exercise Price	Expiration Date
Quintiles - 2006 Loan Restructuring	-	100	$ 53.70	10/26/2013
Class C Investor Warrants - 2006 CEFF	33	33	$ 84.29	10/17/2011
Quintiles - 2004 Partnership Restructuring	-	57	$ 107.85	11/3/2014
Class B Investor Warrants - 2004 CEFF	-	25	$ 181.12	1/6/2010
Class A Investor Warrants – 2003	-	54	$ 103.20	9/19/2010
Total	4,348	990		

Common shares reserved for potential future issuance upon exercise of stock options or granting of additional equity incentive awards

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 and awards outstanding and available for future issuance as of December 31, 2010 and 2009 are as follows:

(in thousands)	As of December 31, 2010	As of December 31, 2009
2007 Plan		
Outstanding	564	446
Available for Future Grants	3	121
Total	567	567
1998 Plan		
Outstanding	533	620
Available for Future Grants	–	–
Total	533	620
Total Outstanding	1,097	1,066
Total Available for Future Grants	3	121
Total	1,100	1,187

The 1998 Plan was suspended upon approval of the 2007 Plan in June 2007; therefore, no shares are 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, 2010, $74.5 million remained available under the 2008 Shelf Registration Statement for potential future offerings. After taking into account the public offering we completed in February 2011, approximately $51.0 million remains available under the 2008 Shelf Registration Statement for potential future offerings. If the aggregate market value of our common stock held by non-affiliates remains below $75.0 million, the number of securities that we may offer and sell pursuant to this and any subsequent shelf registration statement within any 12 calendar month period will be limited to one-third of the aggregate market value of our common stock held by non-affiliates. *See*, in this note – Registered Public Offering and Private Placements, for offerings made pursuant to the 2008 Universal Shelf.

Common shares reserved for potential future issuance under CEFF arrangements

As of December 31, 2010, we had reserved for potential future financings under our CEFFs:

(in thousands)		Potential future issuance as of December 31,	
	Expiration	**2010**	**2009**
May 2008 CEFF	June 18, 2011	851	851
December 2008 CEFF	February 6, 2011	475	475
2010 CEFF	June 11, 2013	1,589	-

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

As of December 31, 2010 and 2009, we had 58,018 and 9,162 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 or granting of additional equity incentive awards. 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 566,667 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.

Awards 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 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 determines. 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 director is entitled to automatic option grants on specified dates as follows: (i) options to purchase 2,667 shares on the date of first election or appointment to the board and (ii) options to purchase 2,000 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. There were 154,333 RSAs granted under the 2007 Plan during 2010. These RSA's vest, for non-officer employees, on the first anniversary of the grant date for and, for officers, on the earliest of (i) the second anniversary of the grant date; (ii) FDA marketing approval of Surfaxin; or (iii) the effective date of a strategic alliance or collaboration agreement as determined by the Board of Directors. Under the 1998 Plan, in 2007, 3,800 RSAs were granted to certain employees for no cash consideration. These RSAs when granted vested on the date that Surfaxin for the prevention of RDS in premature infants first becomes widely commercially available; however, in 2009, the Committee amended the vesting provisions to provide for vesting on the third anniversary of the date of grant date, which, depending up on the date of grant, occurred between December 2009 and January 2010. As of December 31, 2010 and 2009, there were 154,333 and 1,834 unvested restricted stock awards outstanding, respectively.

Under the 2007 Plan, as of December 31, 2010, options to purchase 409,529 shares of common stock were outstanding and 3,000 shares were available for potential future grants. As of December 31, 2009, options to purchase 445,836 shares of common stock were outstanding and 120,831 shares were available for potential future grants. Under the 1998 Plan, options to purchase 533,426 and 619,847 shares of common stock were outstanding as of December 31, 2010 and 2009, respectively. No shares are available for future grants under the 1998 Plan.

A summary of option activity under the 2007 Plan and 1998 Plan during the periods ended December 31, 2010 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, 2008	$ 12.15 – $156.45	1,147	$ 55.73	
Granted	$ 7.35 – $17.70	20	11.70	
Exercised	—	—	—	
Forfeited or expired	$ 12.15 – $137.55	(102)	39.47	
Outstanding at December 31, 2009	$ 7.35- $156.45	1,065	$ 56.46	
Granted	$ 2.55 - $5.85	20	3.19	
Exercised	—	—	–	
Forfeited or expired	$ 5.40 - $137.55	(142)	51.93	
Outstanding at December 31, 2010	$ 2.55 – $156.45	943	$ 56.06	5.4
Exercisable at December 31, 2010	$ 2.55 – $156.45	879	$ 58.79	5.2

Based upon application of the Black-Scholes option-pricing formula described below, the weighted-average grant-date fair value of options and awards granted during the years ended December 31, 2010 and 2009 was $2.48 and $8.43, respectively. There were no options exercised during the years ended December 31, 2010 and 2009, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2010 is $5,000, $0 and $0, respectively.

A summary of the status of our nonvested shares issuable upon exercise of outstanding options and changes during 2010 is presented below:

(shares in thousands)	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2009	158	$ 16.65
Granted	20	3.19
Vested	(91)	16.80
Forfeited	(23)	16.86
Non-vested at December 31, 2010	64	$ 10.05

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2010:

(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
$2.55 - $7.35	23	$ 3.89	8.94 Years	4	$ 7.35	8.67 Years
$7.36 – $18.15	68	$ 17.25	7.93 Years	53	$ 17.02	7.92 Years
$18.16 – $29.85	171	$ 27.61	6.44 Years	143	$ 27.46	6.44 Years
$29.86 – $49.05	432	$ 39.59	5.42 Years	430	$ 39.62	5.42 Years
$49.06 – $156.45	249	$ 119.56	3.68 Years	249	$ 119.56	3.68 Years
	943			879		

Stock-Based Compensation

We recognized compensation expense in accordance with Accounting Standards Codification (ASC) Topic 718, *"Stock Compensation,"* for the years ended December 31, 2010 and 2009, of $1.4 million and $2.7 million, respectively.

Stock-based compensation expenses was classified as follows:

(in thousands)	December 31, 2010	December 31, 2009
Research and development	$ 479	$ 649
General and administrative	931	2,035
Total	$ 1,410	$ 2,684

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.

	December 31, 2010	December 31, 2009
Weighted average expected volatility	112%	99%
Weighted average expected term	4.9 years	4.7 years
Weighted average risk-free interest rate	1.47%	1.7%
Expected dividends	–	–

The total fair value of the underlying shares of the options vested during 2010 and 2009, equals $1.5 million and $5.6 million, respectively. As of December 31, 2010, there was $1.0 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 0.9 years.

On August 13, 2009, Robert J. Capetola, Ph.D., our former President and Chief Executive Officer and a member of our Board, resigned his position. Under the terms of a related separation agreement, all of Dr. Capetola's outstanding RSAs and options immediately vested and all such RSAs and options remain exercisable to the end of their stated terms. During 2009, we 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 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 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.

Under license agreements with Philip Morris USA Inc. (PMUSA) and a former affiliate of PMUSA, Philip Morris Products S.A. (PMPSA), we hold exclusive worldwide licenses to our capillary aerosolization technology 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), and an exclusive license in the United States 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. 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, including sales of aerosol devices and related components that are not based on the capillary aerosolization technology (unless 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, we are obligated to make milestone payments aggregating up to $2,500,000 and royalties. In addition, we have paid $450,000 to date for milestones that have been achieved.

Note 13 – Cost Containment Measures

Following receipt of the 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. 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 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, 2010, all payments relating to these items had been made.

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
2009 Charge	$ 554	$ 74	$ 628
2009 Payments / Adjustments	(554)	(45)	(599)
Liability as of December 31, 2009	$ –	$ 29	$ 29
Payments / Adjustments	–	(29)	(29)
Liability as of December 31, 2010	$ –	$ –	$ –

Note 14 – Commitments

Future payments due under contractual obligations at December 31, 2010 are as follows:

(in thousands)	2011	2012	2013	2014	2015	There-after	Total
Equipment loan obligations[1]	152	85	85	85	70	-	$ 477
Operating lease obligations	1,146	1,166	320	150	–	–	2,782
Total	$ 1,298	$ 1,251	$ 405	$ 235	$ 70	$ –	$ 3,259

[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. 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 14 employees subject to a collective bargaining arrangement which expires on December 3, 2011. For a discussion of our manufacturing strategy, *see*, "Item 1 – Business – Business Operations – Manufacturing and Distribution," in our Annual Report on Form 10-K.

Rent expense under all of these leases for the years ended December 31, 2010 and 2009 was $1.0 million and $1.1 million, respectively.

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, 2010 and 2009 is as follows:

(in thousands)	December 31, 2010	2009
Income tax benefit, statutory rates	$ 6,519	$ 10,156
State taxes on income, net of Federal benefit	1,206	423
Research and development tax credit	656	756
Employee Related	(2,562)	(1,471)
Other	18	107
Income tax benefit	5,837	9,971
Valuation allowance	(5,837)	(9,971)
Income tax benefit	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2010 and 2009, are as follows:

(in thousands)	December 31, 2010	2009
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 132,994	$ 126,291
Research and development tax credits	8,447	7,893
Compensation expense on stock	5,126	4,730
Charitable contribution carryforward	7	6
Other accrued	607	1,635
Depreciation	2,493	2,341
Capitalized research and development	1,932	2,069
Total long-term deferred tax assets	151,606	144,965
Long-term deferred tax liabilities	–	–
Net deferred tax assets	151,606	144,965
Less: valuation allowance	(151,606)	(144,965)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2010 and 2009 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, 2010 and 2009, we had available carryforward net operating losses for Federal tax purposes of $329.7 million and $315.5 million, respectively, and a research and development tax credit carryforward of $8.4 million and $7.9 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2030. Approximately $5.6 million of the $329.7 net operating loss carryforwards expire prior to 2013.

At December 31, 2010, we had available carryforward Federal and State net operating losses of $5.2 million and $0.4 million, respectively, related 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.

At December 31, 2010 and 2009, we had available carryforward losses of approximately $319.9 million and $291.4 million, respectively, for state tax purposes. Of the $319.9 state tax carryforward losses, $290.8 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.

Note 17 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2010 and 2009. The operating results for any quarter are not necessarily indicative of results for any future period.

2010 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues	$ –	$ –	$ –	$ –	$ –
Expenses:					
Research and development	4,133	4,363	4,727	3,913	17,136
General and administrative	2,932	1,865	1,476	2,119	8,392
Total expenses	7,065	6,228	6,203	6,032	25,528
Operating loss	(7,065)	(6,228)	(6,203)	(6,032)	(25,528)
Change in fair value of common stock warrant liability	1,230	5,519	(365)	38	6,422
Other expense, net	(223)	(84)	(16)	254	(69)
Net loss	$ (6,058)	$ (793)	$ (6,584)	$ (5,740)	$ (19,175)
Net loss per common share - basic and diluted	$ ($0.66)	$ (0.07)	$ (0.51)	$ (0.42)	$ (1.65)
Weighted average number of common shares outstanding	9,180	10,695	12,945	13,525	11,602

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)
Change in fair value of common stock warrant liability	-	(1,323)	(1,662)	3,354	369
Other expense, net	(297)	(264)	(244)	(238)	(1,043)
Net loss	$ (9,000)	$ (9,231)	$ (8,853)	$ (2,787)	$ (29,871)
Net loss per common share - basic and diluted	$ (1.32)	$ (1.23)	$ (1.11)	$ (0.33)	$ (3.89)
Weighted average number of common shares outstanding	6,806	7,514	8,000	8,376	7,680

Note 18 – Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2010 up through the date we issued these financial statements. During this period we did not have any material recognized subsequent events, however, there were two nonrecognized subsequent events described below:

On January 26, 2011 we completed a financing under our 2010 CEFF resulting in proceeds of approximately $1.0 million from the issuance of 314,179 shares of our common stock at an average price per share, after applicable fees and discounts of $3.16. *See*, Note 10 – Stockholders Equity.

On February 22, 2011, we completed a public offering of 10,000,000 shares of our common stock, five-year warrants to purchase 5,000,000 shares of our common stock, and fifteen-month warrants to purchase 5,000,000 shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a five-year warrant to purchase one half share of common stock, and a fifteen-month warrant to purchase one half share of common stock, at a public offering price of $2.35 per unit, resulting in gross proceeds of $23.5 million ($21.6 million net). The fifteen-month warrants expire in May 2012 and are exercisable at a price per share of $2.94. The five-year warrants expire in February 2016 and are exercisable at a price per share of $3.20. In addition to other customary adjustments, the exercise price of the five-year warrants will be subject to adjustment if we issue or sell common stock or securities convertible into common stock (in each case, subject to certain exceptions) at a price (determined as set forth in the warrant) that is less than the exercise price of the warrant. This offering was made pursuant to our 2008 Universal Shelf.

CERTIFICATE OF AMENDMENT TO
THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
DISCOVERY LABORATORIES, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Discovery Laboratories, Inc. a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Discovery Laboratories, Inc. (the “Corporation”), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 6, 1992 under the name Ansan, Inc.

2. That at a meeting of the Board of Directors of the Corporation, resolutions were duly adopted setting forth proposed amendments to the Amended and Restated Certificate of Incorporation of the Corporation, declaring said amendments to be advisable and calling a meeting of the stockholders of the Corporation for consideration thereof.

3. That such amendments were duly adopted in accordance with the provisions of Section 242 of the General Corporation Law by the Board of Directors and stockholders of the Corporation, and that such amendments are set forth in this Certificate of Amendment.

4. That upon the effectiveness of this Certificate of Amendment as set forth in paragraph 5 below, Article FOURTH of the Amended and Restated Certificate of Incorporation is amended and restated to read as follows:

The total number of shares of all classes of stock which the Corporation shall have the authority to issue is 55,000,000 consisting of 50,000,000 shares of common stock, par value $0.001 per share (the “Common Stock”), and 5,000,000 shares of preferred stock, par value $0.001 per share (the “Preferred Stock”).

On December 28, 2010, at 12:01 a.m. Eastern Time (the “Effective Time”), each fifteen (15) shares of the Common Stock, par value $0.001 per share (the “Common Stock”), issued and outstanding immediately prior to the Effective Time shall automatically be combined into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof, subject to the treatment of fractional share interests as described below (the “Reverse Stock Split”). No fractional shares will be issued as a result of the Reverse Stock Split. Instead, stockholders who otherwise would be entitled to receive a fractional share of Common Stock as a consequence of the Reverse Stock Split will be entitled to receive cash in an amount equal to the product obtained by multiplying (i) the closing sale price of our Common Stock on the business day immediately preceding the effective date of the Reverse Stock Split as reported on the The Nasdaq Capital Market® by (ii) the number of shares of our Common Stock held by the stockholder that would otherwise have been exchanged for the fractional share interest. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional share interests as described above.

5. This Certificate of Amendment shall become effective on December 28, 2010 at 12:01 a.m. Eastern Time.

6. Except as set forth in this Certificate of Amendment, the Amended and Restated Certificate of Incorporation, as previously amended, remains in full force and effect.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this 27th day of December 2010.

By: /s/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and
Chief Executive Officer

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

DISCOVERY LABORATORIES, INC.

(Pursuant to Sections 228, 242, and 245 of the
General Corporation Law of the State of Delaware)

The Corporation was originally incorporated on November 6, 1992, under the name “Ansan, Inc.”

ARTICLE ONE

The name of the corporation (hereinafter called the “Corporation”) is Discovery Laboratories, Inc.

ARTICLE TWO

The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE THREE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

ARTICLE FOUR

Authorization. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 385,000,000 consisting of 380,000,000 shares of common stock, par value $.001 per share (the “Common Stock”), and 5,000,000 shares of preferred stock, par value $.001 per share (the “Preferred Stock”).

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance.

ARTICLE FIVE

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors shall have the power, both before and after receipt of any payment for any of the Corporation's capital stock, to adopt, amend, repeal or otherwise alter the Bylaws of the Corporation without any action on the part of the stockholders; provided, however, that the grant of such power to the Board of Directors shall not divest the stockholders of nor limit their power to adopt, amend, repeal, or otherwise alter the Bylaws.

ARTICLE SIX

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

ARTICLE SEVEN

The Corporation reserves the rights to adopt, repeal, rescind or amend in any respect any provisions contained in this Certificate of Incorporation in the manner now or hereafter prescribed by applicable law, and all rights conferred on stockholders herein are granted subject to this reservation.

ARTICLE EIGHT

A director of the Corporation shall, to the fullest extent permitted by the General Corporation Law of the State of Delaware as it now exists or as it may hereafter be amended, not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article EIGHT, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article EIGHT, shall eliminate or reduce the effect of this Article EIGHT in respect of any matter occurring or any cause of action, suit or claim that, but for this Article EIGHT, would accrue or arise prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE NINE

This Amended and Restated Certificate of Incorporation was duly adopted in accordance with the provisions of Section 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Discovery Laboratories, Inc., has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 9th day of December 2009.

DISCOVERY LABORATORIES, INC.

By: /s/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and interim Chief Executive Officer

VOTING AGREEMENT

THIS VOTING AGREEMENT (the "**Agreement**") is made and entered into as of this __ day of November, 2010, by and among Discovery Laboratories, Inc., a Delaware corporation (the "**Company**"), and _____ ("**Participant**").

RECITALS

WHEREAS, pursuant to the terms of the Company's 2007 Long-Term Incentive Plan ("**Plan**"), on September __, 2010, the Company issued to Participant a grant consisting of ____,000 shares of restricted stock ("**Shares**"). Under the terms of the related award agreement between the Company and Participant (the "**RSA Agreement**"), at the discretion of the Company, Participant may be required to execute a stockholders agreement with respect to the voting rights associated with the Shares, in such form as shall be determined by the Company.

WHEREAS, in accordance with the RSA Agreement, the parties now desire to set forth their agreements and understandings with respect to how the Shares will be voted.

NOW, THEREFORE, the parties agree as follows:

1. Voting of the Shares; Irrevocable Proxy.

1.1. Acknowledgement. Participant hereby acknowledges and agrees that, until such time as (a) the Shares become fully vested in accordance with the terms of the RSA Agreement, or (b) Participant forfeits the Shares pursuant to Section 4 of the RSA Agreement, the Company shall have the right to vote, or cause to be voted, all Shares of Participant, including any additional Shares that may be made subject to this Agreement under Section 4.1 of this Agreement, with respect to all matters that may be brought for a vote before the stockholders of the Company, either at a meeting of stockholders or by written consent, including, without limitation: election or removal of directors; ratification of the appointment of the Company's independent auditors; amendments to, or restatements of, the Company's Amended and Restated Certificate of Incorporation; approval of executive compensation arrangements, including compensation and employee benefit plans; and approval of transactions involving a change of control of the Company or the issuance of shares of capital stock of the Company, including strategic alliances and financings, and mergers, acquisitions, business combinations and other similar transactions.

1.2. Irrevocable Proxy. Participant hereby constitutes and appoints the Chief Executive Officer of the Company ("CEO"), or if the Company does not have a CEO, the individual performing the functions of a CEO, with full power of substitution, as the proxy of Participant with respect to the Shares, including any additional Shares made subject to this Agreement under Section 4.1 of this Agreement, and hereby authorizes the Company's CEO to represent and vote all of the Shares, in his or her discretion, in accordance with the recommendations of the Company's Board of Directors, and to vote all of the Shares, in his or her discretion, upon such other business as may properly come up for a vote of the Company's stockholders, by consent or at a meeting of stockholders or any adjournments or postponements thereof. The proxy granted pursuant to the immediately preceding sentence is given in consideration of the agreements and covenants of the Company under the RSA Agreement and, as such, is coupled with an interest and shall be irrevocable unless and until this Agreement terminates or expires pursuant to Section 3 of this Agreement. Participant hereby revokes any and all previous proxies with respect to the Shares and shall not hereafter, unless and until this Agreement terminates or expires, purport to grant any other proxy or power of attorney with respect to any of the Shares or enter into any agreement (other than this Agreement), arrangement or understanding with any person, directly or indirectly, to vote, grant any proxy or give instructions with respect to the voting of any of the Shares.

1.3. Stock Splits, Stock Dividends, etc. In the event of any issuance of shares of Common Stock or other voting securities of the Company hereafter to Participant with respect to the Shares (including, without limitation, in connection with any stock split, stock dividend, recapitalization, reorganization, or the like), such additional shares of Common Stock or other voting securities shall be deemed to be Shares and shall immediately upon issuance become subject to this Agreement.

1.4. No Liability for Voting or not Voting Shares. Under no circumstances shall the Company or the individual proxy designated under Section 1.2 of this Agreement have any liability as a result of voting or not voting the Shares in accordance with the provisions of this Agreement.

1.5. Manner of Voting. The Company may vote the Shares pursuant to this Agreement in any manner permitted by applicable law. If for any reason, the proxy provided in Section 1.2 of this Agreement shall be deemed unenforceable either in a particular circumstance or for all purposes, then, Participant hereby agrees to vote the Shares in accordance with any written instructions provided by the Company and, in the absence of such written shares, to vote the Shares "for" each proposal that is recommended by the Board of Directors of the Company.

2. Term.

2.1. This Agreement shall be effective as of the date hereof and shall continue in effect until, and shall terminate effective upon, the earlier to occur of (a) vesting of all Shares in accordance with the RSA Agreement, and (b) the effective date of any termination or expiration of the RSA Agreement.

3. Remedies.

3.1. Specific Enforcement. Participant acknowledges and agrees that the Company will be irreparably damaged in the event that Participant fails to comply with the terms of this Agreement. Accordingly, it is agreed that the Company shall be entitled to an injunction to prevent breaches of this Agreement, and to specific enforcement of this Agreement and its terms and provisions in any action instituted in any court of the United States or any state having subject matter jurisdiction.

3.2. Remedies Cumulative. All remedies, either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

3.3. Delays or Omissions. No delay or failure to exercise any right, power or remedy available to the Company under this Agreement, upon any breach of Participant, shall impair any such right, power or remedy of the Company; nor shall it be construed to be a waiver of, or an acquiescence in, any such breach of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default previously or thereafter occurring.

4. Miscellaneous.

4.1. Transfers. Each transferee or assignee of any Shares subject to this Agreement shall continue to be subject to the terms hereof, and, as a condition precedent to the Company's consenting to such transfer, each transferee or assignee shall agree in writing to be subject to the terms of this Agreement.

4.2. Successors and Assigns. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

4.3. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to its principles of conflicts of laws.

4.4. Counterparts; Facsimile. This Agreement may be executed and delivered by facsimile signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

4.5. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

4.6. Notices. Any notice required to be given or delivered to the Company under the terms of this Agreement shall be in writing and addressed to the Company at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: Legal Department, or to such other address as shall be provided in writing to Participant. Any notice required to be given or delivered to Participant shall be in writing and addressed to the most recent address of Participant, as set forth in the books and records of the Company. All notices shall be deemed effective one day after being sent by Federal Express or similar overnight delivery or three days after being mailed registered or certified mail, postage prepaid, and properly addressed to the party to be notified.

4.7. Amendment, Modification or Waiver. This Agreement may be amended or modified and the observance of any term hereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only by a written instrument executed by the party against whom any such amendment, waiver or modification is intended to be charged.

4.8. Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision.

4.9. Entire Agreement. This Agreement constitutes the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties are expressly canceled.

4.10. Further Assurances. Participant agrees to cooperate with the Company, and at the request of the Company, to execute and deliver any further instruments or documents and to take all such further action as the Company may reasonably request in order to carry out the intent of the parties under this Agreement.

4.11. Severability. Whenever possible, each provision in this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be held to be prohibited by or invalid under applicable law, then (a) such provision shall be deemed amended to accomplish the objectives of the provision as originally written to the fullest extent permitted by law and (b) all other provisions of this Agreement shall remain in full force and effect.

4.12. Dispute Resolution. Any unresolved controversy or claim arising out of or relating to this Agreement, except as otherwise provided in this Agreement, shall be submitted to arbitration by one arbitrator mutually agreed upon by the parties, and if no agreement can be reached within thirty (30) days after names of potential arbitrators have been proposed by the American Arbitration Association (the "**AAA**"), then by one arbitrator having reasonable experience in Delaware law corporate governance matters and who is chosen by the AAA. The arbitration shall take place in Doylestown, Pennsylvania, in accordance with the AAA rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction thereof. There shall be limited discovery prior to the arbitration hearing as follows: (a) exchange of witness lists and copies of documentary evidence and documents relating to or arising out of the issues to be arbitrated, (b) depositions of all party witnesses and (c) such other depositions as may be allowed by the arbitrators upon a showing of good cause. Depositions shall be conducted in accordance with the Pennsylvania Code of Civil Procedure, the arbitrator shall be required to provide in writing to the parties the basis for the award or order of such arbitrator, and a court reporter shall record all hearings, with such record constituting the official transcript of such proceedings. Each party will bear its own costs in respect of any disputes arising under this Agreement. Each of the parties to this Agreement consents to personal jurisdiction for any equitable action sought in the U.S. District Court for the Eastern District of Pennsylvania or any court of the Commonwealth of Pennsylvania having subject matter jurisdiction.

[Signatures appear on the following page]

IN WITNESS WHEREOF, the parties have executed this Voting Agreement as of the date first written above.

Discovery Laboratories, Inc.

By: _____
Name: _____
Title: _____

PARTICIPANT

_____
Name: _____

EXHIBIT 21.1

Subsidiaries of Registrant

1. Acute Therapeutics, Inc.

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., the 1996 Stock Option/Stock Issuance Plan of Discovery Laboratories, Inc., and the 1996 Stock Option/ Stock Issuance Plan of Acute Therapeutics, Inc.

(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, Form S-8 No. 333-164470, Form S-8 No. 333-165809, and Form S-8 No. 333-169662) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our report dated March 31, 2011, with respect to the consolidated financial statements 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, 2010.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 31, 2011

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 31, 2011

/s/ W. Thomas Amick

W. Thomas Amick, Chairman of the Board and
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Annual Report on Form 10-K of Discovery Laboratories, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)**)** for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including our consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2011

/s/ John G. Cooper

John G. Cooper
President and Chief Financial Officer

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, 2010 (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 31, 2011

/s/ W. Thomas Amick
W. Thomas Amick, Chairman of the Board
and Chief Executive Officer

/s/ John G. Cooper
John G. Cooper
President and
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.