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, 2011

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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 o NO x

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

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

Indicate by check mark 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 x NO o

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

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	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 o NO x

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on The Nasdaq Capital Market under the symbol DSCO on June 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $54 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, 2012 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 21, 2012, 43,307,867 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 2011 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; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL4 surfactant-based pipeline and our capillary aerosol generator (CAG) and ventilator circuit / patient interface connectors for delivery of aerosolized medications, 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 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:

- the risk that, if we are unable for any reason to introduce, or, if there is a significant delay in the commercial introduction of, SURFAXIN® and AFECTAIR® in the United States and other markets as planned, we may have difficulty securing additional capital to sustain our operations, which could have a material adverse effect on our ability to continue our marketing and distribution efforts, research and development programs and operations;

- the risk that we may be unable to enter into strategic alliances or collaboration agreements to support the development of our KL4 surfactant pipeline products, beginning with SURFAXIN LS™ and AEROSURF®, and, if approved, commercialization of these products in markets outside the United States;

- risks relating to our lack of marketing and distribution capabilities, which we will have to develop internally and 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, drug product candidates and drug delivery technologies;

- risks relating to our ability to develop a successful sales and marketing organization to market SURFAXIN® and AFECTAIR® and our other product candidates, if approved, in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products or that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- risks relating to our ability to develop and manufacture drug products based on our KL_4 surfactant technology, drug-device combination products that use our capillary aerosol generator (CAG) technology, and medical devices, including our CAG devices and novel ventilator circuit / patient interface connectors, for commercialization of our approved products and for preclinical and clinical studies of our product candidates;

- 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 drug product substances, our drug products, CAG devices and ventilator circuit / patient interface connectors and related componentry, and other materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN® and the AFECTAIR® devices, as well as our research and development activities for our other product candidates;

- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug, combination drug-device product or medical device that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;

- risks related to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product and medical device candidates, including (i) drug and drug-device combination products that we are developing to address RDS in premature infants: SURFAXIN LS™ (our lyophilized (freeze-dried) dosage form of SURFAXIN®, and AEROSURF® (our initial aerosolized KL_4 surfactant using our CAG technology); and (ii) AFECTAIR®, a series of our novel ventilator circuit / patient interface connectors that we plan to introduce commercially in fourth quarter of 2012;

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

- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- risks relating to 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 and quality control release and stability tests to satisfy the requirements of the regulatory authorities;

- 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;

- the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;

- the risk that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;

- risks that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians 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 and medical device candidates;

- the risk that we may be unable to maintain compliance with continued listing requirements of The Nasdaq Capital Market®, including without limitation those relating to maintaining a minimum bid price, market capitalization and stockholders' equity, which could increase the probability that our stock will be delisted, which could cause our stock price to decline;

- risks that the unfavorable credit and economic environment will adversely affect our ability to fund our activities, that our Committed Equity Financing Facility (CEFF) and the ATM Program may be unavailable or may expire or be exhausted, and that additional equity financings could result in substantial equity dilution or result in a downward adjustment to the exercise price of five-year warrants that we issued in February 2011 (which contain price-based anti-dilution revisions);

- 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, biotechnology and medical technology 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 and biotechnology 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 as 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, 2011

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 specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug 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. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of inhaled therapies, including our aerosolized KL_4 surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We are implementing a plan that, if successful, is intended to result in the commercial introduction of SURFAXIN in the United States in the fourth quarter of 2012. *See*, "About SURFAXIN", "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – SURFAXIN for the Prevention of RDS in Premature Infants at High Risk for RDS." *See also*, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our KL_4 Surfactant Technology."

Our strategy is initially to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of RDS in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs, beginning with SURFAXIN and, if approved, SURFAXIN LS™ and AEROSURF®, have the potential to greatly improve the management of RDS and, collectively over time, to become the global standard of care for premature infants with RDS.

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing SURFAXIN LS with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States, the European Union and other major markets worldwide. *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 a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG) and our novel AFECTAIR® ventilator circuit / patient interface connectors. We are developing AEROSURF for premature infants with or at risk of RDS. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. As a consequence, neonatologists will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. For this reason, we believe that AEROSURF, if approved, potentially may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but are currently not treated. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – AEROSURF for RDS in Premature Infants."

AFECTAIR, a series of disposable ventilator circuit / patient interface connectors, was initially developed for use in the NICU as part of our AEROSURF development program. AFECTAIR devices simplify the delivery of inhaled therapies (including our aerosolized KL4 surfactant) to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. We initially developed a ventilator circuit / patient interface connector to be used with our CAG in the NICU. To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, we are developing AFECTAIR devices in different sizes for use in NICUs, pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. In February 2012, we successfully registered our initial AFECTAIR device, which is intended for use with jet nebulizers and other aerosol generators, in the United States as a Class I, exempt medical device. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients. We are implementing a regulatory and manufacturing plan that, if successful, is intended to result in the commercial introduction of the initial AFECTAIR device in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR DUO, in mid-2013.

We are preparing for the commercial introductions, beginning in late 2012, of SURFAXIN in the United States, and AFECTAIR in the United States and the European Union and other markets worldwide thereafter. To accomplish our objectives, in the United States, we plan to build our own, in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN. We also expect that our commercial and medical affairs organization will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN to efficiently support the introductions of SURFAXIN LS and AEROSURF, if approved. We also expect that our in-house organization will also work in a coordinated manner with a network of third-party distributors to execute the commercial introduction of the AFECTAIR devices.

In major markets outside the United States, an important priority is to secure the strategic resources to support the continued development and commercial introduction of our RDS products. A key goal for us in 2012 is to secure one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF development programs, and, if approved, to support the commercial introduction of these products in Europe and elsewhere. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other similar transaction.

BUSINESS STRATEGY

Our immediate goal is to successfully introduce SURFAXIN® in the United States and AFECTAIR® in the United States and the European Union. In addition, we plan to advance development of our other KL4 surfactant product candidates, SURFAXIN LS™ and AEROSURF®. Key elements of our strategy for achieving this goal include:

- In 2012, we plan to focus on the commercial introduction of SURFAXIN in the United States and the initial AFECTAIR device in the United States and potentially in the European Union. If successful, we also believe that we will be in a position to introduce the second AFECTAIR device, AFECTAIR DUO in both the United States and European Union in mid-2013.

    - For the launch of SURFAXIN in the United States, we plan to build our own in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN, and, if approved, our other KL4 surfactant products for RDS, SURFAXIN LS and AEROSURF. Our strategy will focus primarily on hospitals with NICUs that we believe currently represent a significant portion of the surfactant market in the United States. To execute this strategy, we expect to incur annual expenses of approximately $12 - 13 million for commercial and medical affairs capabilities. We believe that this strategy will provide us direct control over our U.S. sales and marketing activities, permit us to establish a strong presence in NICUs nationwide, and potentially optimize the economics of our business.

- We expect that our commercial and medical affairs organization will also support the planned commercial introduction of AFECTAIR in the United States. Many hospitals, including those that have adult ICUs, PICUs and critical care centers, as well as NICUs, will use AFECTAIR devices to benefit critical care patients. Accordingly, we plan to further support the launch of AFECTAIR in the United States and the European Union through arrangements with third-party distributors experienced in introducing respiratory medical products into hospitals. We expect that our commercial organization will work in a coordinated manner with our third-party distributors to assure that all hospitals with critical care facilities are aware of, and have access to, our AFECTAIR devices. We believe that AFECTAIR has the potential to become the standard of care for delivery of inhaled therapies and, after an up-take period following introduction, revenues in the U.S. and the five largest countries in the European Union (EU5) could potentially be between $50 million and $75 million in the fourth full year of sales, which could occur as early as 2016.

- We plan to support our network of AFECTAIR distributors with an in-house medical affairs staff that will be focused on medical education activities, publications and congresses. We have and will continue to conduct and sponsor studies evaluating the potential utility of AFECTAIR, including a series of studies with several inhaled therapies that have been or will be presented at medical congresses and medical meetings. We are pleased with the results of our early studies, and believe that AFECTAIR has the potential to address a considerable unmet medical need and become a new standard of care for the delivery of inhaled therapies to patients requiring ventilatory support.

- We plan to continue to focus our drug research and development activities 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 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 LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing SURFAXIN LS with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. In recent years, we slowed the pace of this program as we focused our efforts on securing regulatory approval for SURFAXIN in the United States and until we are able to secure the required capital to advance our program. In 2012, we plan to continue our preclinical work and expect to advance the ongoing technology transfer of our SURFAXIN LS manufacturing process to a contract manufacturer that manufactures in accordance with current good manufacturing practices (cGMP) established by the FDA and other international regulatory authorities, and that has expertise in lyophilized dosage forms. We plan to implement a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States, European Union and other major markets worldwide. We have discussed with the FDA a proposed development program and expect to engage in further discussions with the FDA after we have received regulatory guidance with respect to our planned development program in Europe. We believe, but need to confirm with the European Medicines Agency (EMA) and other relevant regulatory bodies, that we will have to conduct a Phase 3 clinical trial in Europe and will work with the FDA and EMA potentially to develop a single trial design that will support approval for SURFAXIN LS in the United States and the European Union. We believe that, over time, SURFAXIN and SURFAXIN LS, if approved, collectively 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, is a drug-device combination product that produces our KL_4 surfactant in aerosolized form using our CAG device and AFECTAIR ventilator circuit / patient interface connectors. In recent years, we also slowed the pace of this program as we focused our efforts on securing regulatory approval for SURFAXIN in the United States and until we are able to secure the required capital to advance our program. AEROSURF holds the promise to significantly expand the use of surfactant therapy in premature infants by providing neonatologists with a means of administering aerosolized KL_4 surfactant without the risks associated with the current method of administering surfactant by invasive endotracheal intubation and mechanical ventilation. In 2012, we plan to continue advancing our preclinical development activities for AEROSURF and, with the assistance of our own and third-party medical device engineers, we plan to optimize the design of the CAG device for use in our anticipated clinical program and, if approved, commercially. We also plan to seek regulatory guidance to inform our regulatory plan for the AEROSURF development and clinical programs.

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.

- An important priority for us is to manage and strengthen our long-term strategic and financial position to support the introduction of our approved products, advance our research and development programs, and maximize stockholder value.

  - We have managed, and plan to continue closely managing our expenditures in 2012, while focusing our resources on the initiatives outlined above. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support development and introduction of our products in various markets. There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other financing transaction.

  - We recently completed a public offering of 16,071,429 shares of our common stock, at a price to the public of $2.80 per share for gross proceeds of $45.0 million, and net proceeds to us of $42.1 million, after transaction-related fees and expenses, and before taking into account a 30-day option granted to the underwriters to purchase up to an additional 2,410,714 shares of common stock to cover over-allotments, if any.

- 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 our drug delivery technologies, including our CAG and ventilator circuit / patient interface connectors, 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 potentially may extend our exclusivity rights into the future.

- We have, and will continue to evaluate, and invest in, our quality systems and manufacturing capabilities, including at our drug manufacturing operations in Totowa, New Jersey, and our analytical and medical device development laboratories in Warrington, Pennsylvania. We plan to manufacture sufficient amounts of SURFAXIN drug product to meet our anticipated commercial requirements and to support SURFAXIN-related preclinical, clinical and formulation development activities for our other KL_4 surfactant product candidates. For AFECTAIR, we have entered into a Manufacturing and Supply Agreement with Lacey Manufacturing, a unit of Precision Engineered Products, LLC to manufacture and supply AFECTAIR devices for commercial sale. With respect to SURFAXIN LS, we are conducting a technology transfer of our lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in such dosage forms. For AEROSURF, we plan to collaborate with engineering device experts and use contract manufacturers to produce CAG devices and related components to meet our manufacturing requirements.

- While we are focused on advancing our lead KL4 surfactant and drug delivery technologies to treat critical care patients with respiratory disease, beginning with RDS, we believe that our KL4 surfactant technology has the potential to be developed into a broad product pipeline to address a variety of debilitating respiratory conditions and diseases. As our resources permit, we are conducting research and preclinical development activities potentially to address acute lung injury (ALI), and may in the future seek to address other diseases associated with inflammation of the lung, such as asthma and chronic obstructive pulmonary disease (COPD). In 2010, an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of our aerosolized KL4 surfactant in patients with cystic fibrosis (CF) concluded. We will consider supporting such independent initiatives that explore the utility of applying our KL4 surfactant to address CF and other respiratory diseases. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Cystic Fibrosis."

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: Annual Summary of Vital Statistics: 2006, *Pediatrics*, Martin et. al.; CDC National Vital Statistics, 2005; IMS Midas Data MAT, December 2010; HCUP Hospital Discharge data, 2008; Hospital Insurance Claim Database, 2009; Management and Outcomes of Very Low Birth Weight, *New England Journal of Medicine* (NEJM), 2008, Eichenwald, Stark; Market Intelligence Report on Number of ICU Beds in EU5 Countries;
The Cystic Fibrosis Foundation website; Vermont Oxford Network Data, 2006; and Discovery Labs Primary Market Research, December 2010 and May 2011; 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, and 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. In our KL4 surfactant, KL4 is a 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 KL4 surfactant and our CAG technology may expand the therapeutic options to treat previously unaddressed respiratory problems in a range of patient populations, from premature infants to adults. We plan to develop our aerosolized KL4 surfactant initially for RDS in premature infants and thereafter for a range of indications in neonatal, pediatric and adult critical care patient populations.

Our KL4 Surfactant Technology

Our proprietary KL4 surfactant technology produces a synthetic surfactant that is structurally similar to human pulmonary surfactant and contains a proprietary synthetic peptide, KL4 (sinapultide). KL4 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 dosage form (freeze-dried), 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 an affiliate of Johnson & Johnson, Inc. (J&J).

Our KL4 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 KL4 surfactant has also demonstrated in preclinical studies unique characteristics, including modulation of the inflammatory process, antimicrobial properties and is non-immunogenic. We believe these characteristics will be important attributes as we develop our KL4 surfactant technology pipeline potentially to address a broad range of respiratory conditions that represent significant unmet medical needs. Several preclinical studies assessing the potential advantages of our KL4 surfactant technology have been presented at major medical congresses and are summarized below:

- In October 2011, an AEROSURF® study was presented at the 2011 European Society for Paediatric Research Annual Meeting (ESPR). These data were initially presented at the 2011 *Pediatric Academic Societies* Annual Congress (PAS) in May 2011. This preclinical study was conducted to determine which dose of AEROSURF would produce the optimal physiologic response and demonstrated that AEROSURF significantly improved gas exchange ($p < 0.05$), pulmonary mechanics ($p < 0.05$) and lung structure integrity ($p < 0.05$), and reduced levels of inflammatory mediators in the lung ($p < 0.05$), in a dose-dependent manner, in the well-recognized preterm lamb model of RDS. The data also suggest that of the doses tested, AEROSURF delivered during a 20 to 30 minute dosing interval results in the most desirable overall dosing strategy.

- Also at the 2011 ESPR, data were presented from a study demonstrating that treatment with either bolus or aerosolized KL4 surfactant resulted in a significant improvement in lung function and survival when treating ALI in a preclinical model of ALI. These data were initially presented at the 2011 PAS. The objective of this study was to evaluate aerosolized KL4 surfactant in a piglet model with lung injury and subsequent reduced pulmonary function consistent with what is observed in humans with ALI. Piglets were randomized to receive either endotracheal bolus KL4 surfactant with extubation to continuous positive airway pressure (CPAP), aerosolized KL4 surfactant while on CPAP, or CPAP alone (control). Relative to control piglets on CPAP alone, treatment with either bolus or aerosolized KL4 surfactant resulted in a significant improvement in both oxygenation response ($p < 0.001$) and overall survival ($p < 0.05$) throughout the evaluation period, with the most robust response observed in the aerosolized KL4 surfactant treatment group. Piglets treated with aerosolized KL4 surfactant had reduced tissue levels of interleukin–8 (IL-8), a key marker of lung inflammation, compared with control piglets ($p < 0.03$).

- In December 2010, data were presented at the 2010 Annual Hot Topics in Neonatology Congress (Hot Topics) in Washington, DC demonstrating that AEROSURF 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 this preclinical study, preterm lambs were randomized to receive 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 IL-8, with marked differences following 20 minutes of AEROSURF 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 KL4 surfactant in an established porcine model of lung transplantation. The objective of this study was to assess the potential protective role of KL4 surfactant in reducing ischemia-reperfusion injury by administering KL4 surfactant to donor lungs prior to harvest and transplantation in an experimental pig lung transplant model. In transplanted donor lungs that were treated with KL4 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 KL4 surfactant may play an important protective role in minimizing lung damage triggered by ischemia-reperfusion injury following lung transplantation.

- In May 2010, preclinical data were presented at PAS that demonstrate that our initial lyophilized KL4 surfactant, SURFAXIN LS™, improves lung function and oxygenation while attenuating lung inflammation in the preterm lamb model of RDS. In one study, lyophilized KL4 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 KL4 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: 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 KL4 surfactant compared with those treated with comparator animal-derived surfactants ($p < 0.05$).

- In another preclinical study presented at the 2010 PAS, the effects of lyophilized KL4 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 KL4 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 KL4 surfactant. The study investigators concluded that lyophilized KL4 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 KL4 surfactant, which contains POPG, is the only exogenous surfactant in which POPG is a specified active pharmaceutical ingredient. This study further supports our belief that our KL4 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 at the 2009 PAS, data from a preclinical study was presented 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 KL4 surfactant in treating newborn piglets with severe ALI. The results demonstrated that piglets treated with KL4 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 preclinical 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 PAS, data were presented from animal preclinical 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.

- An *in vitro* study presented at the 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 PAS in May 2008, a preclinical study was presented that assessed the potential for KL4 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 KL4 would trigger anaphylaxis. Supporting our belief that our KL4 surfactant has nonimmunogenic properties, this study concluded that KL4 did not induce active or passive anaphylaxis in this animal model, even when the immune system was potentiated and sensitized.

- In May 2007, a preclinical study was presented at PAS, the objective of which was to determine the impact of SURFAXIN on cytokine-driven lung inflammation and focused specifically on the transforming growth factor-beta (TGF-beta) superfamily. In this study, SURFAXIN suppressed two central members of the TGF-beta superfamily (BMP10 and BMP15), which could have implications in reducing inflammation and fibrosis (scarring) of the lung in a variety of pulmonary diseases. Members of the TGF-beta superfamily are known to induce fibrosis (scar tissue formation) in the lung. These results support our developing our KL4 surfactant technology to potentially treat diseases in which respiratory inflammation plays an integral part, such as acute lung injury.

We believe that the foregoing preclinical studies demonstrate promising novel properties and attributes of our KL4 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 2011, the *Journal of Neonatal-Perinatal Medicine* (Volume 4, Number 2, 2011) published a post-hoc analysis of data from our pivotal SELECT and STAR Phase 3 clinical trials for SURFAXIN titled "Reintubation and risk of morbidity and mortality in preterm infants after surfactant replacement therapy." The article evaluated the consequences of reintubation and the potential effect of the choice of surfactant on reintubation rates and subsequent clinical outcomes in premature infants. The analysis indicates that, for preterm infants at risk for RDS who received prophylactic surfactant therapy and were extubated, infants who were reintubated had significantly higher rates of six major complications of prematurity, including bronchopulmonary dysplasia (BPD, a chronic lung condition), necrotizing enterocolitis (a severe intestinal condition often requiring surgery and loss of bowel), sepsis, and intraventricular hemorrhage (bleeding into the brain) is a highly predictive risk factor for mortality and major complications of prematurity. The analysis also indicates that infants treated with SURFAXIN had a significantly lower incidence of reintubation and a significantly higher incidence of survival without reintubation, compared with infants who received animal-derived surfactants Survanta and Curosurf, the current standard of care.

- In May 2010, results from a Phase 2a feasibility study that we previously conducted as part of our AEROSURF development program for the prevention of RDS in premature infants were published in the *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. In this feasibility study, aerosolized KL_4 surfactant was administered to seventeen infants within 30 minutes of birth using a commercially available aerosolization device via nasal CPAP (nCPAP) over a three-hour duration. Aerosolized KL_4 surfactant was generally safe and well tolerated with twelve (71%) of the infants requiring a single dose or aerosolized KL_4 surfactant. In addition, all infants survived through the assessment period (day 28 of life), fifteen (88%) infants survived with no evidence of BPD at day 28 of life, and five (29%) infants required intubation and mechanical ventilation (commonly known as CPAP failure). The study investigators concluded that our aerosolized KL_4 surfactant 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). 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.

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 acute respiratory failure (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 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.

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.

KL_4 Surfactant Drug Product – Dosage Form Flexibility

SURFAXIN is a liquid instillate that is administered using endotracheal intubation and mechanical ventilation, which is the same method of administration required for currently-approved animal-derived surfactants. Our KL_4 surfactant technology also can be produced in a lyophilized (freeze-dried) dosage form (SURFAXIN LS) that is resuspended to liquid form prior to administration. We have conducted several experiments that demonstrate that our lyophilized KL_4 surfactant retains the key characteristics of our liquid KL_4 surfactant (SURFAXIN). Relative to liquid instillate surfactants, we believe that our lyophilized dosage form may provide benefits, in a clinical setting, including:

- improved ease of use for healthcare practitioners, including
    - shortened preparation time due to potential elimination of drug product warming process prior to use; and
    - potential elimination or reduction of continuous cold chain storage and refrigeration requirements;

- potential improved product stability and extended shelf life; and

- relatively lower viscosity, which may aid and/or improve the distribution of KL_4 surfactant throughout the lung and potentially reduce the frequency of transient peri-dosing events typically observed during administration of surfactants;

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

Ventilator Circuit /Patient Interface Connectors and Related Componentry

In connection with our AEROSURF development program, we developed a novel ventilator circuit / patient interface connector for potential use with our CAG to treat premature infants with or at risk for RDS. Our ventilator circuit / patient interface connector simplifies the delivery any inhaled therapy to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. To benefit all critical care patients who require inhaled therapies and are receiving ventilatory support, we are developing a series of ventilator circuit / patient interface connectors, which are sized for use in NICUs, PICUs and ICUs and can be used with a variety of aerosol generating devices

The initial AFECTAIR® device has been designed for use with jet nebulizer aerosol generators and is currently registered in the United States as a Class I, exempt medical device. In the European Union, we believe that this device will be classified as a Class IIa device, which must be cleared for marketing in the European Union through a European conformity (CE) marking process. We are currently working with a regulatory services firm to obtain CE marking and believe that we will be cleared to market our initial AFECTAIR device in the European Union in fourth quarter of 2012.

We are developing a second AFECTAIR Device, AFECTAIR DUO, which is being designed for use with vibrating mesh nebulizers (VMN), metered dose inhalers (MDI) and other aerosol generator technologies. We believe that we will be in a position to register AFECTAIR DUO in the United States in fourth quarter of 2012 and in the European Union in mid-2013.

Several *in vitro* studies have suggested that AFECTAIR improves the delivery of inhaled therapies to patients on ventilatory support:

- In December 2011, data from an *in vitro* study were presented at the 2011 Hot Topics. The study was designed to compare the performance of the neonatal AFECTAIR device with a current SoC ventilator system in the delivery of nitric oxide under simulated neonatal ventilator conditions. The simulated breathing pattern was maintained within narrow ranges and the delivery of oxygen was not different between the study conditions. The investigators observed a 50 to 70 percent decrease in nitric oxide utilization requirements to achieve desired inhaled nitric oxide dose with the AFECTAIR device, compared with SoC ($p < 0.001$). The study investigators concluded that AFECTAIR significantly decreased the nitric oxide utilization requirements to achieve the desired inhaled nitric oxide concentration and that results of the study support further investigation of AFECTAIR in the delivery of other medical gases and with other ventilation methods.

- In November 2011, data from an *in vitro* study were presented at the *American Association for Respiratory Care* (AARC) Congress 2011. The objective of this study was to compare the dose of aerosolized albuterol sulfate delivered to lung simulator under various neonatal ventilator settings using the neonatal AFECTAIR device versus the current standard of care (SoC) delivery system. The investigators observed that use of AFECTAIR resulted in a statistically significant 6-to-14 fold increase ($p < 0.05$) in the delivery of aerosolized albuterol when compared with SoC, and concluded that potential clinical use of AFECTAIR may result in increased delivery of aerosolized medication to neonates receiving positive pressure ventilatory support.

- Also in November 2011, data were presented at AARC from a second *in vitro* study, the objective of which was to determine the particle size distribution (PSD) using the neonatal AFECTAIR device versus SoC delivery system to deliver aerosolized albuterol in a neonatal ventilatory circuit. PSD is an important determination for effective aerosolized medication delivery, where the 'optimal PSD' spans the human respirable range of 2-5 microns. The investigators observed PSD at or below the lower end of the respirable range when using the SoC delivery system. In contrast, the PSD observed using the AFECTAIR connector spanned the entire respirable range. These observations suggest that the potential clinical use of AFECTAIR may result in increased delivery and retention of aerosolized medication in the lung.

- Also in November 2011, data were presented at AARC from a third *in vitro* study, the objective of which was to determine if the neonatal AFECTAIR device impacts respiratory system resistance in a ventilator circuit, compared with SoC connectors currently used in ventilator circuits. The investigators observed that resistance measurements were similar between AFECTAIR and the SoC delivery system and concluded that AFECTAIR may be a comparably safe alternative to SoC in ventilator circuits.

- In May 2011, data from a study were presented at the 2011 PAS. This data was also presented in June 2011 at the 2011 *International Society for Aerosols in Medicine* (ISAM) Annual Meeting. The objective of this study was to assess our novel ventilator circuit / patient interface connectors. The data from this study suggests that the neonatal AFECTAIR device reduces gas dilution when administered during CPAP respiratory support without increasing flow resistance, potentially improving efficiency of aerosolized medications delivery to preterm neonates receiving positive pressure ventilator support.

We plan to continue to sponsor and support studies that explore the benefits of AFECTAIR devices. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients.

We are implementing a regulatory and manufacturing plan that, if successful, could position us to initiate the commercial introduction of the initial AFECTAIR device in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR DUO, in mid-2013. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients.

Capillary Aerosolization Technology

We have worldwide exclusive rights to our CAG technology through exclusive license agreements with Philip Morris USA Inc. (PMUSA) in the United States, and Philip Morris Products S.A. (PMPSA) in all territories outside of the United States. Each of these license agreements provides us with exclusive rights to the CAG 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 CAG technology for use with certain 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 CAG technology has the potential to enable targeted, upper respiratory, airway or alveolar delivery of therapies, and has been initially designed to produce high-quality aerosols for delivery to the lung. An aerosol is created by pumping KL_4 surfactant through a heated capillary, which converts the drug product to a vapor state. Upon exiting the capillary, the vapor stream cools and slows in velocity, yielding a dense aerosol with a defined particle size. With this technology, we believe that we may control and adjust the particle size through device modifications and potentially changes in drug formulation. In addition, because our KL_4 surfactant technology produces a surfactant that is designed to spread throughout 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 delivering the combined drug products into the lung more effectively than would be possible without our KL_4 surfactant. With the assistance of our own and third-party medical device engineers, we are currently optimizing the design of the CAG device for anticipated clinical development in our AEROSURF development program and, if approved, potential commercial use.

In studies conducted with our initial CAG device and our KL4 surfactant, we have generated an aerosol that:

- retains the surface-tension lowering properties of a functioning surfactant;
- retains the surfactant composition of our liquid KL4 surfactant;
- has a drug particle size believed to be suitable for deposition into the lung;
- is produced at rates that can deliver therapeutic dosages in a reasonable period of time, with consistent reproducible output. Preclinical studies presented at the 2007 PAS comparing our CAG technology to commercially-available aerosol devices indicated that our CAG device 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 nCPAP alone in an animal model of RDS.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

The only pulmonary surfactants commercially available today were introduced in the United States in the 1990's. All are animal-derived and are approved only for RDS in premature infants. These products have not been approved for other respiratory indications. SURFAXIN® is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We believe that our proprietary KL4 surfactant technology makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of respiratory problems, including those for which there are currently few or no approved therapies. Our potential programs include:

Respiratory Distress Syndrome in Premature Infants (RDS)

We are currently focused primarily on addressing RDS in premature infants, one of the most common serious respiratory problems facing premature infants in the NICU. 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 infants with RDS often require endotracheal intubation and mechanical ventilation to administer one of the currently available animal-derived surfactants (usually within the first hours of birth) and to provide respiratory support. Unfortunately, many infants relapse following initial surfactant therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, increasing their risk of developing further serious respiratory complications. Neonatologists generally try to avoid mechanically ventilating infants due to the perceived risks associated with intubation, such as the risk of trauma and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits of invasive surfactant administration clearly outweigh the associated risks. For all but the very low birth weight infants with severe RDS, a common ventilatory support treatment alternative to intubation and mechanical ventilation is nCPAP. Unfortunately, a significant number of infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation. Several recent published studies point toward a high rate of nCPAP failure in the neonatal population (Finer *et al*, "Early CPAP versus surfactant in extremely preterm infants," N Engl J Med 2010;362(21):1970-9 (Finer, *et al*, NEJM 2010); Morely *et al*, "Nasal CPAP or Intubation at Birth for Very Preterm Infants," N Engl J Med 2008;358:700-8 (Morely *et al*, NEJM 2008)). As it is not possible to ascertain in advance which patients will experience nCPAP failure, neonatologists are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy in the first hours of life.

We estimate that approximately 360,000 low birth weight premature infants are born annually in the United States and at risk for RDS (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, for either 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. 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 at High Risk for RDS

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. SURFAXIN represents the first synthetic, peptide-containing surfactant approved for use in neonatal medicine.

Our NDA for SURFAXIN was filed with the FDA in April 2004 and 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.

Post-hoc analysis of data from our SELECT and STAR Phase 3 clinical trials reveals that premature infants with RDS who were extubated after treatment with surfactant and who later 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 infants treated with SURFAXIN were observed to have a statistically significant lower incidence of reintubation than those infants treated with comparator surfactants, the clinical relevance of this finding has not been adequately established and, accordingly, warrants further study.

In April 2009, we received a Complete Response Letter (2009 Complete Response Letter) that focused primarily on the Chemistry, Manufacturing and Controls (CMC) section of our NDA, and in particular, on certain aspects of our fetal rabbit biological activity test (BAT, an important quality control release and stability test for SURFAXIN). The FDA did not question the quality of our clinical trial data or call for additional clinical trials demonstrating safety or efficacy. The FDA indicated that, in addition to certain items that were easily addressed, we needed to satisfy the FDA as to the final validation of the BAT and demonstrate whether the BAT can adequately reflect the biological activity of SURFAXIN throughout its shelf life and discriminate biologically active from inactive SURFAXIN drug product.

At an end-of-review meeting in June 2009, we presented additional data from studies using the preterm lamb model and the BAT. The FDA did not accept our analytical approach and indicated that 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. We believed that establishing the degree of consistency that the FDA required through preclinical experimentation using the animal models would represent a significant challenge. In September 2009, we discussed with the FDA our detailed plans to optimize the precision of, and thereafter to revalidate, the BAT. Following a successful revalidation of the BAT, we initiated our comprehensive preclinical program using the optimized BAT that involved performing a series of prospectively-designed, side-by-side preclinical studies (i.e., concordance studies) using multiple batches of SURFAXIN to demonstrate comparability between data generated from the BAT and from the preterm lamb model of RDS. *See*, "– Background for the Comprehensive Preclinical Program," below. The concordance studies were intended to support final validation of the BAT and to demonstrate comparability of SURFAXIN drug product used in the Phase 3 clinical program with SURFAXIN drug product to-be-manufactured for commercial use. The comprehensive preclinical program was also intended to provide support for final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of SURFAXIN drug product.

In December 2010, we received a communication from the FDA that directed us to increase the sample size of specified data sets by testing additional SURFAXIN batches. In December 2010, we began manufacturing additional SURFAXIN batches for use in the comprehensive preclinical program. *See also*, "– Business Operations – Manufacturing and Distribution – Precision Engineered Surfactant." We completed the comprehensive preclinical program and filed the Complete Response to the 2009 Complete Response Letter, on September 2, 2011. On March 6, 2012, the FDA granted marketing approval for SURFAXIN. We are now preparing for the commercial introduction of SURFAXIN in the United States, potentially in late 2012.

WARMING CRADLE®

To facilitate proper administration of SURFAXIN, we plan to make available to hospitals a dry block-warming device called a WARMING CRADLE that is designed to warm drug vials at the same temperature that is designated in the SURFAXIN prescribing information. The WARMING CRADLE is registered with the FDA as a Class I, exempt medical device. Our commercial organization will work with hospitals medical device control units to gain the appropriate clearances to make WARMING CRADLEs available to NICUs for use with SURFAXIN.

Background Regarding 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. To demonstrate comparability between the SURFAXIN clinical drug product and the to-be-manufactured SURFAXIN drug product, we replicated studies in the well-established preterm lamb model using the to-be-manufactured SURFAXIN drug product that previously had been conducted using the SURFAXIN clinical drug product. These studies demonstrated to the FDA's satisfaction comparability between the SURFAXIN clinical drug product and the to-be-manufactured drug product. Since we sought to use the BAT to demonstrate biological activity in our SURFAXIN drug product, rather than the preterm lamb model, we needed to correlate data generated using the preterm lamb model to 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.

SURFAXIN LS™ – Lyophilized SURFAXIN® for RDS in Premature Infants

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing SURFAXIN LS with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States, the European Union and other major markets worldwide.

In 2012, we plan to continue the technology transfer of our SURFAXIN LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized drug products. This initiative was slowed in 2011 to conserve resources while we focused our efforts on the potential approval of SURFAXIN. We also plan to seek further regulatory and scientific guidance with respect to the planned SURFAXIN LS development program. Our objective is to develop SURFAXIN LS for the United States and other major markets worldwide. If we are successful in harmonizing the requirements of the FDA and the EMA, we expect to conduct a single Phase 3 clinical trial to gain regulatory approval for SURFAXIN LS in the United States and the European Union. We anticipate initiating the clinical program, potentially in late 2013, but only after we have secured appropriate strategic alliances and/or necessary capital.

AEROSURF® for RDS in Premature Infants

AEROSURF is a drug-device combination product that produces our KL_4 surfactant in aerosolized form using our CAG and drug delivery technologies. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. In many cases today, neonatologists will not treat infants who could benefit from surfactant therapy if the perceived potential benefits of surfactant therapy are outweighed by the risks associated with such invasive administration procedures.

AEROSURF, if approved, may be administered through less-invasive nCPAP, and is being developed to potentially reduce or eliminate the need for intubation and mechanical ventilation. We believe that AEROSURF holds the promise to significantly expand the use of our KL_4 surfactant in neonatal respiratory medicine by potentially providing neonatologists with a means to administer KL_4 surfactant to infants without subjecting them to the invasive procedures associated with administration of currently approved surfactants.

In 2005, prior to the initiation of our AEROSURF program, we completed and announced the results of our first pilot Phase 2 clinical study of our 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. We have since conducted or sponsored a number of studies evaluating AEROSURF and our aerosolized KL_4 surfactant drug product. *See*, "Business – Proprietary Platform – Surfactant and Aerosol Technologies – Our KL_4 Surfactant Technology."

We are currently developing AEROSURF using our CAG technology. See, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Device Technology – Capillary Aerosolization Technology." With our own in-house and third-party medical device engineers, we are optimizing the design of the CAG for anticipated clinical development and potential commercial use. We have continued to conduct certain developmental and preclinical activities to support our regulatory package, and we have met with and received guidance from the FDA with respect to the design of our planned Phase 2 clinical program. We plan in 2012 to focus on finalizing the clinical / potential commercial device design of our CAG, and seeking further regulatory guidance with respect to our AEROSURF development program. If successful, we plan to initiate a Phase 2 clinical trial for AEROSURF in premature infants with or at risk for RDS in the second half of 2013, but only after we have secured appropriate strategic alliances and/or necessary capital.

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."

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.

We believe that our proprietary aerosolized KL_4 surfactant technology may be used to address debilitating respiratory disorders such as ALI and, possibly in the future, CF and COPD. As resources permit, we may invest in or support third-party studies of these indications. If a proof-of-concept should be established, we will then 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 invest or support studies in these indications, that any such efforts will be successful, or that we will be able to conclude any such strategic alliance, collaboration arrangement or secure any 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.

For a discussion of our Phase 2 clinical trial assessing whether SURFAXIN treatment could decrease the duration of mechanical ventilation in children with acute respiratory failure (ARF), *see*, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our KL_4 Surfactant Technology – Acute Respiratory Failure / Acute Lung Injury." For a discussion of preclinical proof of concept studies, *see*, "– Proprietary Platform – Surfactant and Aerosol Technologies – Our KL_4 Surfactant Technology."

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 KL4 surfactant has unique attributes, including potential modulation of the inflammatory process and anti-microbial properties, that, when combined with a potential ability to enhance mucus clearance may be an effective treatment for COPD, potentially improving outcomes for these very ill patients.

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 results in the production of 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 KL4 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 was designed as a double-blind, randomized study to evaluate whether aerosolized KL4 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 KL4 surfactant. The trial demonstrated that aerosolized KL4 surfactant delivery to CF patients was feasible, generally safe and well tolerated and was not associated with serious adverse events. Both aerosolized KL4 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 KL4 surfactant specifically targeting airway mucus adhesion. Additionally, in 2010 the FDA granted us orphan drug designation for the treatment of CF with KL4 surfactant.

We believe that our novel synthetic, peptide-containing surfactant has unique attributes, potentially including anti-microbial properties, modulation of the inflammatory process, and lack of immunogenicity, 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. While our near-term plans are focused on treating RDS in a critical care setting, we will continue to support investigator-initiated studies that explore the utility of using our KL4 surfactant to treat CF and other diseases.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are initially focused on developing our proprietary KL4 surfactant, CAG, and aerosol delivery technologies into a series of pipeline programs that would support a significant critical care franchise, initially focused on RDS in premature infants, and complimented by our aerosol delivery technologies. 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 2012 and focus our development resources on our RDS pipeline drug programs, primarily to advance our SURFAXIN LS™ and AEROSURF® programs towards the initiation of clinical programs in second half of 2013; on finalizing the design of our AFECTAIR® and AFECTAIR DUO devices; and preclinical studies examining the utility and potential benefits of the AFECTAIR devices. For our RDS programs, we are considering potential strategic alliances that could 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 KL4 surfactant technology. To accomplish our objectives, we also would consider various financial alternatives and collaboration arrangements that would provide infusions of capital and other needed resources. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives or collaboration arrangement will be successfully concluded. Until we secure sufficient strategic and financial resources to support the continuing development of our pipeline programs and support our operations, we will continue to focus our resources on RDS programs and pace investments in potential non-RDS pipeline programs accordingly.

We will continue to consider supporting investigator-initiated studies, and may invest opportunistically in studies of other potential KL4 surfactant pipeline programs that would target adult and other indications, such as ALI and CF. We believe that these programs could represent significant market opportunities. If we were able to demonstrate proof-of-concept for any of these indications, we would consider whether to develop these products through potential strategic alliances or collaboration arrangements, or utilize other financial alternatives to fund their further development and commercialization, if approved. There can be no assurance that we will pursue such investments or, if we do, that we will succeed in demonstrating proof of concept or entering into any such alliance.

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 preclinical 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, biostatistics, and trial and data management capabilities. We analyze and report on our clinical trial data, supported by third-party technology systems and independent consultants. We 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;
- 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 to support development of our CAG and aerosol delivery technologies. In addition to our own design engineering team, we plan to work with consulting design engineers, medical device experts and other third-party collaborators to advance the development of our CAG for use in our AEROSURF clinical trials and, if approved, commercial application;
- quality operations capabilities to assure compliance with applicable regulations;
- manufacturing capabilities to manufacture SURFAXIN® and our liquid KL4 surfactant for use in preclinical studies. We also plan to rely on contract manufacturing organizations (CMOs) to produce our lyophilized dosage form of our KL4 surfactant and to manufacture and assemble our AFECTAIR devices. We plan to rely on third-party manufacturers to manufacture and assemble our CAG systems and related components; and
- our own analytical and testing laboratories, research and medical device development laboratory, and KL4 surfactant manufacturing facilities and related capabilities. We also rely on a number of third-party analytical and testing laboratories to support our research activities and provide certain laboratory services.

Research and development costs are charged to operations as incurred. During the years ended December 31, 2011, and 2010, our research and development expenses were $17.2 million, and $17.1 million, respectively.

Manufacturing and Distribution

KL4 Surfactant

Our KL4 surfactant products, 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 drug products are manufactured by combining raw materials, such as KL4, 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 over the next 12 to 36 months. Our risk of losing a source of supply is somewhat mitigated by the fact that we generally maintain a minimum six-month 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. As we prepare for the commercial introduction of SURFAXIN, we will need to identify service providers to support labeling, packaging, warehousing and other services for our SURFAXIN drug product.

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 are configured to produce 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 KL4 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 preclinical, clinical and commercial supply of SURFAXIN and possibly other KL4 surfactant liquid drug product candidates. We also are conducting a technology transfer of the SURFAXIN LS dosage form manufacturing process to a cGMP-compliant contract manufacturer with expertise in lyophilized formulations.

In connection with our efforts to respond to the 2009 Complete Response Letter that we received from the FDA, in December 2010, we began manufacturing additional SURFAXIN batches for use in the comprehensive preclinical program. In January 2011, quality control testing performed by us indicated that two newly manufactured SURFAXIN batches did not meet one of the pre-specified release specifications. In accordance with our quality assurance procedures and manufacturing practices, we conducted an investigation to determine why the SURFAXIN batches did not meet specification and, if appropriate, to implement a corrective action and preventative action plan. While we identified certain differences in the batches, we did not confirm a definitive root cause of the failures. *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." Following the investigation, we implemented a process improvement and continued to manufacture SURFAXIN batches for use in the comprehensive preclinical program, which batches successfully met all specifications, including the specifications that the two unacceptable batches did not meet. In January 2012, 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.

Our manufacturing operation also includes our analytical and quality systems. We have consolidated all of our in-house analytical, quality and development activities in our analytical and development laboratory at our headquarters in Warrington, Pennsylvania. Activities conducted there include release and stability testing of raw materials as well as clinical and commercial drug product supply of SURFAXIN and our other drug product candidates, if approved. We also perform development work with respect to our lyophilized and aerosolized KL4 surfactant dosage forms as well as other potential formulations of our KL4 surfactant technology. In addition, we have a microbiology laboratory at our Totowa facility to support the manufacture 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.

In addition, to further support our development activities and quality programs, we work with a number of third-party institutions and laboratories that perform various studies as well as quality release and stability testing and other activities related to our KL4 surfactant development and manufacturing activities. Among these, our BAT release and stability testing is conducted at a laboratory owned by the University of California, San Diego, School of Medicine, Department of Pediatrics. At the present time, several of these laboratories are single source providers. We are implementing a plan to identify and potentially qualify additional sources to meet our key release testing and stability requirements.

CAG Device and Related Componentry and Aerosol Delivery Devices

AEROSURF, our initial aerosolized KL4 surfactant, combines our KL4 surfactant technology with our CAG technology. We are developing and, if approved, will commercialize 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 also plan to develop our aerosolized KL4 surfactant to address a broad range of serious respiratory conditions.

To develop our CAG technology, we have worked in the past with selected component manufacturers and an integrator to manufacture and integrate our initial prototype CAG system. We are currently focused on developing an optimized, clinic-ready CAG device to meet regulatory and ease-of-use design requirements and prepare for planned Phase 2 and later Phase 3 clinical trials. We expect to rely on third-party contract manufacturers to manufacture and assemble the CAG device and related components to support our preclinical experiments, planned clinical studies and potential commercialization of AEROSURF, if approved. 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 CAG devices and disposable components 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."

AFECTAIR® Devices

For the manufacture of AFECTAIR devices, in February 2012, we entered into a supply agreement with Lacey Manufacturing Company, a division of Precision Products, LLC ("Lacey"), to manufacture our initial AFECTAIR devices. Lacey operates a cGMP-compliant manufacturing facility and has significant experience with the mold injection process required to manufacture AFECTAIR devices. Pursuant to the Agreement, Lacey will manufacture AFECTAIR and AFECTAIR DUO medical devices. In addition to providing manufacturing support, Lacey will label, package, and prepare AFECTAIR devices for shipment. We currently plan to direct ship ordered goods to distributors from Lacey and expect to warehouse an inventory of AFECTAIR devices at one of our facilities.

The initial term of our Agreement with Lacey is the shorter of three years from the date of the first order for commercial product or four years from the effective date. The term may be extended by written agreement of the parties. Among other rights to terminate the Agreement, either party may terminate the Agreement upon 30 days written notice to the other party if we, after a good faith effort, are unable to agree on (i) go-forward planning steps to complete development of one or both AFECTAIR Devices, or (ii) key terms, including, without limitation, pricing or order volume requirements. We will retain ownership of all equipment, molds and tooling and other capital assets purchased by Lacey to manufacture AFECTAIR Devices on our behalf. In connection with any termination of the Agreement, Lacey is obligated to cooperate and provide us reasonable assistance to transfer all equipment, inventory and materials to any successor manufacturing site or to such other location that the Company may designate in writing.

Distribution

We are currently manufacturing SURFAXIN as a liquid instillate that requires cold-chain storage and distribution. We arranged for ASD Specialty Healthcare, Inc. to act as our sole wholesaler for SURFAXIN and the WARMING CRADLE in the United States. This arrangement was originally put in place in 2006 and continues to be available to us. Under our agreement with ASD, we expect that ASD will provide certain promotional and marketing activities, maintain inventory, shipping and certain compliance and regulatory activities.

Our collaboration with Esteve provides that Esteve has responsibility for distribution of specified KL4 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.

To distribute AFECTAIR, we plan to complement the activities of our own commercial team with a network of distributors in the United States, and also plan to have a network of distributors in the European Union and elsewhere. We expect that our distributors will be regional and will have a focus and expertise in distributing hospital-based medical device products.

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 KL4 surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Esteve will pay us a transfer price on sales of our KL4 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, in consideration of Esteve returning commercialization rights in portions of the territory originally licensed to Esteve, including key European markets and Latin America (Former Esteve Territories), we agreed to pay to Esteve 10% of any cash up front and milestone fees (up to a maximum of $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 KL4 surfactant products 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 seek strategic alliances and other collaborative arrangements for the development and/or commercialization of our KL4 surfactant product candidates, with a current focus on the development and, if approved, commercialization of SURFAXIN LS and AEROSURF in the European Union and other markets outside the United States. We seek 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 help us maximize the potential of these KL4 surfactant programs. We also would consider various financial alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 respiratory pipeline programs. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives or collaboration arrangement 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 KL4 surfactant, CAG and ventilator circuit / patient interface connector technologies 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 KL4 surfactant technology, including SURFAXIN®, is based on the proprietary synthetic peptide KL4 (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 J&J and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, for, with 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 KL4 surfactant product candidates. 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 in the range of 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 provides that the license will expire, on a country-by-country basis, upon the payment of royalties for all licensed products for the longest of (i) ten years beginning on the date of the first commercial sale of the first commercial product in such country or (ii) expiration of the last licensed patent containing a valid claim covering a licensed product in such country; or for countries in the European Union in which royalties are paid only by virtue of licensed know-how, upon the payment of royalties ending on the earlier of (i) the date on which the licensed know-how becomes public or (ii) the tenth anniversary of the first commercial sale of the first licensed product in any 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 United States 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. 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. 5,741,891; 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).

The patent term of U.S. Patent No. 5,407,914 has been extended until November 17, 2012 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. 5,741,891 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.

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 KL4-Related Patents and Patent Rights

We have been active in seeking patent protection for our innovations relating to new dosage forms, formulations and methods of manufacturing and delivering synthetic peptide containing pulmonary surfactants. Our patent activities have focused particularly on improved dosage forms 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 entered national phase), 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 entered national phase), 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 entered national phase), 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 entered national phase) 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 2008, we restructured our December 2005 strategic alliance with PMUSA 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 CAG 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).

Under the license agreements, 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 CAG 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 CAG 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 CAG technology that are made under the license agreements. With these proprietary rights, we believe that our aerosolized KL4 surfactant can be developed to potentially address a broad range of serious respiratory conditions. We are developing AEROSURF® to treat premature infants with or at risk for RDS using the CAG technology.

Capillary Aerosolization Technology Patents and Patent Rights

We currently hold exclusive licenses to the CAG technology both in and outside of the United States for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions. In addition, under the U.S. License Agreement, our license to use the CAG technology includes certain 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 that we plan to market under the trademark AFECTAIR®. 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 ventilation circuit adaptor 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 Technologies."

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."

Trademarks

AEROSURF®, AFECTAIR®, AFECTAIR® DUO, SURFAXIN®, SURFAXIN LS™, and WARMING CRADLE® are our registered and common law trademarks.

Trade Secrets

In addition to our patent exclusivities, we rely on trade secrets to protect and maintain our competitive position. We take measures to protect and maintain our trade secrets and know-how licensed to us or developed by us by entering in confidentiality agreements with third parties. Our trade secrets and know-how include information related to manufacturing processes for our drug products and devices, analytical methods and procedures, research and development activities, provisional patent applications, as well as certain information provided to FDA that was not made public which relates to our regulatory activities and clinical trials.

Other Regulatory Designations

New Drug Product Exclusivity

SURFAXIN is expected to receive at least three years of marketing exclusivity as a new drug product based on the new data from the SELECT and STAR clinical trials. In addition, the FDA has indicated that our SURFAXIN drug product also qualifies as a "new molecular entity," which we expect will provide extended marketing exclusivity from three to five years. However, we will have to await the final determination by the FDA.

Orphan Drug and Orphan Medicinal Product Designations

"Orphan Drugs" are pharmaceutical products that are intended to address 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 indication for SURFAXIN is for the prevention, rather than treatment, of RDS, we filed a request with the FDA to allow for application of this designation to SURFAXIN. We recently were advised by the FDA that our request has been denied. If we develop SURFAXIN LS for the treatment of RDS, this orphan drug designation will apply for that indication. 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, (ii) our KL_4 surfactant for the treatment of ALI in adults (which in this circumstance encompasses ARDS), and (iii) our KL_4 surfactant for the treatment of CF.

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 process of 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. As a result, larger companies with greater financial resources will likely have a competitive advantage over us.

Drug Product Regulations

Development Activities: To gain regulatory approval of our KL4 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."

Preclinical 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 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 connection with our efforts to gain FDA marketing approval for SURFAXIN, in January 2012, the FDA conducted a Pre-approval Inspection of our Totowa, NJ manufacturing operations and our analytical and testing laboratory in Warrington, PA, and other of the quality assurance/quality control facilities for SURFAXIN including those of our third-party raw material suppliers and testing laboratories. On February 24, 2012, the FDA issued an EIR recommending approval of our Totowa, NJ manufacturing operations for the manufacture of SURFAXIN. 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: In addition to seeking regulatory approval to market our products in the United States, we also will 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 Regulations (QSR), to ensure that the device is in compliance with applicable performance standards. Although cGMP and QSR 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 QSR may present unique problems and manufacturing challenges.

Medical Device Products

To varying degrees, each of the regulatory agencies having oversight over medical devices, including the FDA and comparable foreign regulators, has laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of medical devices. In the United States, medical device products are subject to regulation that is intended to calibrate regulatory requirements to the issues of safety and efficacy presented by specific devices. Medical devices are classified into one of three classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements that apply to them are: (i) Class I General Controls, with exemptions and without exemptions, (ii) Class II General Controls and Special Controls, with exemptions and without exemptions, and (iii) Class III General Controls and Premarket Marketing authorization. The class to which a device is assigned determines the process that applies for gaining marketing authorization. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Marketing authorization.

Exempt Class I Medical Device: Prior to marketing an exempt Class I medical device, the manufacturer must register its establishment, list the generic category or classification name of the medical device being marketed and pay a registration fee. We have consulted with our regulatory experts and believe that AFECTAIR® qualifies as an exempt Class I medical device. We therefore plan to comply with the registration requirements applicable to Class I medical devices. Once registered, we would be required to update and renew our registration annually.

510(k) Clearance Process: If for any reason, the FDA determines that AFECTAIR is a Class II medical device, we would have to obtain FDA clearance, before marketing AFECTAIR in the U.S., through the 510(k) clearance process. We believe that if we are required to seek marketing authorization using the 510(k) clearance process, we will be able to complete the process and launch AFECTAIR within the time frames set forth above. The 510(k) clearance process is available if we can demonstrate that AFECTAIR is substantially equivalent to a legally marketed medical device. In this process, we would be required to submit data that supports our equivalence claim. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute AFECTAIR. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness.

Pre-market Marketing Authorization: A more rigorous and time-consuming process applicable to Class III medical devices, known as pre-market marketing authorization (PMA), would require us to independently demonstrate that AFECTAIR is safe and effective. We would do this by collecting data regarding design, materials, bench and animal testing, and human clinical data for the medical device. The FDA will authorize commercial release of a Class III medical device if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on benefit outweighing risk for the population intended to be treated with the device. This process is much more detailed, time-consuming and expensive than the 510(k) clearance process. We do not believe that we will be required to file an application for PMA.

CE Marking Process: The European Union has comparable regulations to the FDA for the registration or marketing authorization of medical devices. We believe that in the European Union AFECTAIR will be classified as a Class IIa device, which will require us to obtain a “CE mark” by filing a statement of registration. We must first seek a review of a third-party “Notified Body” that will conduct an audit to ensure that our manufacturers and we are in compliance with applicable quality regulations, and, if the audit is successful, will certify the product for a CE mark. We are working with a regulatory services firm to obtain CE marking. The regulatory services firm will assist us with compiling the required technical file, labeling review, a clinical evaluation report to support CE marking, design control and quality system implementation, subcontractor audit and general regulatory consulting. In addition, in the European Union we will have to designate a single Authorized Representative located in the European Union to interact with the local authorities and respond to technical document requests. The Authorized Representative will be responsible for preparing supplemental submissions to member states that have additional requirements for marketing authorization.

Other Regulatory Requirements: *Pervasive and Continuing Regulation*

After a device is placed on the market, numerous regulatory requirements may apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulation (“QSR”), which is the medical device term for good manufacturing practices, requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a significant change in the safety or efficacy of our cleared devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval or post-clearance restrictions or conditions, including post-approval or post-clearance study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations.

Advertising and promotion of drugs and medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of certain companies have been the subject of enforcement action brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities will take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. In addition to this domestic US regulatory scheme, there are numerous additional regulatory considerations pertaining to medical devices in foreign jurisdictions.

SURFAXIN is our first approved drug product in the United States and AFECTAIR is our first approved medical device in the United States. None of our other 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 these products. 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, CAG 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 address 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 21, 2012, we have 73 employees, 70 of which are full-time, three 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, 2012. 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) of 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 that are not presently known to us or that we currently deem immaterial may also impair our business operations. The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time. If any of the following risks actually occurs, our business prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you could lose all or part of your investment.

We may fail in the development and commercialization of our products.

Although we have regulatory clearance to market SURFAXIN® and AFECTAIR®, they are not currently available for sale and we have no other products approved for marketing. We are implementing a plan intended to result in the commercial introduction of SURFAXIN and AFECTAIR in late 2012. We are conducting research and development on our other product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products.

We may experience a delay in, or be unable to achieve, the commercial introduction of, SURFAXIN and AFECTAIR in the United States and other markets as planned, or we may not successfully develop and market our other KL4 surfactant and aerosol delivery pipeline products. Our long-term viability will be impaired if we experience a significant delay or failure to successfully commercialize our approved products or obtain regulatory approval for and 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, which could have a material adverse effect on our ability to continue our marketing and distribution efforts, research and development programs and operations.

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

Until we are able to generate sufficient revenues from the sale of SURFAXIN and AFECTAIR, we will need substantial additional funding to support our commercial operations and our ongoing research and development activities and our operations. Our current plans are to focus our resources on our lead drug product and device development programs, SURFAXIN LS™ and AEROSURF®, and on being in a position to initiate key clinical programs after we have secured the necessary capital. 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.

As of December 31, 2011, we have an accumulated deficit of approximately $397.4 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. As of December 31, 2011, we had cash and cash equivalents of $10.2 million. In the first quarter 2012, we received net proceeds of approximately $50.3 million from financings and the exercise of warrants to purchase shares of our common stock. We expect our cash outflows in 2012 to increase as we invest in our commercial and medical affairs organization and prepare for the commercial introduction of our approved products.

Our ability to fund our research and development activities in the future is dependent upon our ability to generate revenues from the sale of approved products and raise additional capital to fund our research and development and commercial programs and meet our obligations on a timely basis. We are seeking strategic alliances to support the development of SURFAXIN LS and AEROSURF and, if approved, to commercialize these product candidates in the European Union and other markets outside the United States. Even if we are successful in generating revenues from the sale of approved products, we will likely not have sufficient cash flow and liquidity to fund our research and development programs, and will require additional capital through strategic alliances and other financing alternatives. If we are unable to successfully raise the necessary additional capital, we will likely not have sufficient cash flow and liquidity to fund our research and development programs, which will force 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 challenges accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for our CEFF and our ATM Program (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.

To support the commercialization of SURFAXIN® and AFECTAIR®, we plan to establish our own commercial and medical affairs organization, enter into distribution arrangements and, in markets outside the United States, seek one or more strategic alliances to support the development and, if approved, commercialization of our KL4 surfactant products and AFECTAIR devices. If we enter into distributor arrangements or strategic alliances, we may be required to transfer rights to our products and will be exposed to risks associated with the transfer of control to third parties.

To support the commercial introduction of SURFAXIN and AFECTAIR in the United States, we plan to establish our own commercial and medical affairs organization. In addition, we expect to enter into distribution and / or co-marketing arrangements to support the introduction of AFECTAIR in a broad range of critical care facilities, including in NICUs, PICUs and ICUs. In major markets outside the United States, we plan to seek one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF development programs, and, if approved, to support the commercial introduction of these products in Europe and elsewhere. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). We have also considered various other financial alternatives that could potentially provide infusions of capital and other resources needed to advance our KL4 surfactant 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 available opportunities with a view to maintaining and strengthening our financial and operational position. Moreover, consideration and planning of such strategic alliances 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 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 our KL4 surfactant 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. In addition, we may not be able to enter into marketing and sales agreements for our KL4 surfactant pipeline products on acceptable terms, if at all, in territories not covered by the Esteve agreement, or for any of our other drug product candidates. If Esteve or we 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.

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 in the United States, we plan to develop our own commercial and medical affairs capabilities, which could increase the cost to commercialize our products. We also plan to seek third-party distribution arrangements and marketing alliances, particularly to support the commercialization of AFECTAIR® in the United States and in markets outside the United States, which could require us to give up rights to our drug product candidates.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing capabilities. We plan to establish and primarily rely on own, in-house, specialty respiratory critical care commercial organization to market SURFAXIN, and, if approved, SURFAXIN LS and AEROSURF, in the United States. We expect that our commercial organization will also support the commercial introduction of AFECTAIR. Commercializing our drug product candidates in the United States on our own will likely cause our commercialization costs to increase, but will potentially avoid the transfer of rights to our products or drug product candidates. Developing an internal commercial and medical affairs capabilities is potentially a difficult, expensive and time-consuming process and requires a substantial capital investment. Recruiting, training and retaining qualified personnel will be critical to our success. Competition for such personnel can be 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 incentives to retain our sales force. If we are unable to successfully attract and motivate a commercial team to support the introduction and sale of our products, we will have difficulty selling, maintaining and increasing the sales of our products, which could have a material adverse effect on our business.

Even with our own commercial organization to support the launch of SURFAXIN in the United States, we may also need to enter into co-marketing arrangements with third parties where our own personnel are neither well situated nor large enough to achieve maximum penetration in the market. In addition, we may seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA. We may not be successful in entering into any co-marketing arrangements, and the terms of any co-marketing arrangements may not be favorable to us. In addition, if we enter into co-marketing arrangements or market and sell additional products directly, we may need to further expand our commercial staff and incur additional expense.

We also plan to rely on third-party distributors to distribute, or enter into marketing alliances to sell, our AFECTAIR devices in the United States and internationally. 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 are not successful in finalizing such arrangements, we may not have sufficient funds to successfully commercialize SURFAXIN or any other potential product in the United States or elsewhere. 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 products;
- 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 fail to establish or secure commercial and medical affairs 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, our third-party distributors and we 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 our sales force, 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 products that we bring to market, including SURFAXIN and AFECTAIR, 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 SURFAXIN and AFECTAIR and 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;
- our ability to gain access to the entire market through our distributor arrangements;
- the rate of preterm births;
- the willingness of the target patient population to try new products and of physicians to prescribe our products;
- the willingness of the target hospitals to accept and employ the WARMING CRADLE
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

If our business development activities are unsuccessful, our business could suffer and our financial performance could be adversely affected.

As part of our long-term growth strategy, we are engaged in business development activities intended to develop strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other opportunities. Such opportunities may result in substantial investments. Our success in developing products or expanding into new markets from such activities will depend on a number of factors, including our ability to find suitable opportunities for investment, alliance or acquisition; whether we are able to complete an investment, alliance or acquisition on terms that are satisfactory to us; the strength of our underlying technology, products and our ability to execute our business strategies; any intellectual property and litigation related to these products or technology; and our ability to successfully execute the investment, alliance or acquisition into our existing operations, including to fund our share of any in-process research and development projects. If we are unsuccessful in our business development activities, we may be unable to meet our financial targets and our financial performance could be adversely affected.

Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Any failure to comply could adversely affect our business, financial condition and results of operations.

Our products and our operations are regulated by numerous government agencies, both inside and outside the United States. Our drug product candidates and medical devices must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third-party providers must be approved and licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. In addition, requirements of the FDA and other regulatory authorities may change; implementing additional compliance requirements may increase our costs, or force us or our third-party providers to suspend production, which could result in a shortage of our approved product or delays in the commercial introduction of our new product candidates, if approved.

The sales and marketing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, other healthcare related laws, antitrust and other competition laws. The Department of Justice (DOJ) also has increased its focus on the enforcement of the U.S. Foreign Corrupt Practices Act (FCPA), particularly as it relates to the conduct of pharmaceutical companies. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers. The laws and standards governing the promotion, sale and reimbursement of our products and those governing our relationships with healthcare providers and governments can be complicated, are subject to frequent change and may be violated unknowingly. We are developing compliance programs, including policies, training and various forms of monitoring, designed to address these risks. However, these programs and policies may not always protect us from conduct by individual employees, well meaning or otherwise, that violate these laws. Violations or allegations of violations, of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

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, we must receive regulatory approvals for each product. The FDA and foreign regulators, such as the EMA, 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. We received the 2009 Complete Response Letter for this NDA. Following a number of exchanges with the FDA, we conducted a comprehensive preclinical program that consisted of a series of prospectively-designed, side-by-side preclinical studies employing our optimized BAT and the well-established preterm lamb model of RDS. These time-consuming studies were 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 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 at High Risk for RDS."

To gain approval of SURFAXIN LS and AEROSURF, we expect to conduct a clinical program and are working to be in a position to initiate a Phase 2 clinical trial for AEROSURF and a Phase 3 clinical trial for SURFAXIN LS in late 2013. We believe that our success in gaining approval for SURFAXIN in the United States may facilitate our efforts to gain regulatory approval for SURFAXIN LS and AEROSURF. However, there can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise. There can be no assurance that we will be successful in gaining regulatory approval for SURFAXIN LS and / or AEROSURF, if at all, within our expected time frame.

If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected.

Even assuming that we have gained 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 has approved SURFAXIN for marketing in the United States. Our development programs for SURFAXIN LS and AEROSURF are in the preclinical stage, with clinical trials potentially anticipated in late 2013. Foreign regulators have not yet approved any of our products under development for marketing. Without regulatory approval, we will not be able to market these 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.

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 KL4 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 KL4 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 continuing research and development KL4 surfactant programs for SURFAXIN LS™ and AEROSURF® 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 preclinical and clinical trials of our KL4 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 devices and related components and related services necessary to manufacture our KL4 surfactant product candidates;
- provide for sufficient manufacturing capabilities, at our manufacturing operations in Totowa and with third-party contract manufacturers, to produce sufficient drug product, including for SURFAXIN-related studies, SURFAXIN LS and AEROSURF, and CAG devices and related materials to meet our preclinical 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 KL4 surfactant pipeline 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 KL4 surfactant development programs, SURFAXIN LS and AEROSURF, through the initial preclinical phase of development, we plan to conduct Phase 2 and/or Phase 3 clinical trials, potentially beginning in late 2013. However, before we will initiate a clinical program, we will have to secure 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 Data and Safety Monitoring Committee (DSMC), 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 our SAB, the DSMC, any regulator or we 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 DSMC recommendation, or business reasons.

In addition to our planned clinical programs to support SURFAXIN LS and AEROSURF, we also may initiate or support clinical studies evaluating other KL4 surfactant pipeline products. 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.

Marketing authorization to promote, manufacture and/or sell AFECTAIR® will be limited and subject to continuing review.

We have successfully registered our initial AFECTAIR in the United States. We expect to register this device in the European Union in 2012. Even if regulatory clearance of this product is granted in the European Union, or if regulatory clearance of any subsequent AFECTAIR device is granted, such clearance will be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions, including some of those listed above. It is also possible that other federal, state or foreign enforcement authorities will take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Due to these legal constraints, our distributors' sales and marketing efforts will focus only on the general technical attributes and benefits of AFECTAIR and the FDA cleared indications for use. We plan to conduct a series of studies evaluating the utility of AFECTAIR in delivering specific inhaled therapies, but there can be no assurance that our efforts will be successful, or even if successful, that we will be able to expand our label to include the additional indications.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of AFECTAIR, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with AFECTAIR, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market or regulatory enforcement actions.

Failure to complete the development of our CAG device and related componentry in a timely manner, if at all, would have a material adverse effect on our efforts to develop AEROSURF®, our other aerosolized KL4 surfactant products, and our business strategy.

Since early 2008, we have been responsible for development of our proprietary CAG technology, including finalizing the design of an optimized CAG device that is 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 a CAG device 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. We have medical device engineering staff with industry experience in developing medical devices, and plan to work 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 a clinic-ready CAG system for use in our planned clinical trials and, potentially, for later versions of the CAG systems, it would impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 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 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 AEROSURF or other aerosolized KL_4 surfactant products.

The realization of any of the foregoing risks 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 current good manufacturing practices (cGMP) and Quality 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. In January 2011, quality control testing performed by us indicated that two newly manufactured SURFAXIN batches did not meet one of the pre-specified release specifications. In accordance with our quality assurance procedures and manufacturing practices, we conducted an investigation to determine why the SURFAXIN batches did not meet specification and, if appropriate, to implement a corrective action and preventative action plan. While we identified certain differences in the batches, we did not confirm a definitive root cause of the failures. Following the investigation, we implemented a process improvement and continued to manufacture SURFAXIN batches for use in the comprehensive preclinical program, which batches successfully met all specifications, including the specifications that the two unacceptable batches did not meet. In this instance, our efforts appear to have been successful. In January 2012, the FDA completed a pre-approval inspection (PAI) of our manufacturing facility and issued an Establishment Inspection Report indicating an approval recommendation for the commercial manufacture of SURFAXIN.

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 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 could have a material adverse effect on our ability to commercialize SURFAXIN and potentially adversely affect our clinical research activities.

We currently do not have a back-up facility. Any interruption of our manufacturing operations at Totowa, NJ, could result in a shortage of our commercial drug supply of SURFAXIN and could affect our preclinical and clinical development activities. 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. Under certain conditions, we may be unable to produce SURFAXIN at the required volumes or to appropriate standards, if at all. If we are unable to successfully maintain our manufacturing capabilities and at all times comply with cGMP, it will adversely affect our efforts to commercialize SURFAXIN and have an adverse effect on our sales.

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 assembly 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 CAG device subcomponent parts or assembled 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.

Relying exclusively on third parties to manufacture certain of our drug product candidates and medical devices exposes us to risks that may delay our research and development activities, regulatory approval and commercialization of our drug product candidates.

While we manufacture our SURFAXIN liquid instillate at our facilities in Totowa, NJ, we plan to depend upon third-party manufacturers to manufacture SURFAXIN LS, our lyophilized dosage form of SURFAXIN, AFECTAIR devices and our CAG. Our anticipated future reliance on third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;
- Third-party manufacturers might be unable to manufacture our products in the volume and to our specifications to meet our clinical needs and, if approved, commercial needs;
- Contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with cGMP and / or quality system regulations (QSR) and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements;
- Each of these risks could delay our development programs, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues;

If we fail to identify or maintain relationships with manufacturers and assemblers of our CAG devices, the timeline of our plans for the development and, if approved, commercialization of AEROSURF® and our other aerosolized KL4 surfactant products could suffer. We are exposed to similar risks with respect to the manufacture of our AFECTAIR® devices.

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 CAG technology and to assemble 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 ventilator circuit / patient interface connectors must be packaged. 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 to develop our initial prototype CAG device. We are currently focused on developing an optimized CAG 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 that we identify may not be able to consistently manufacture and assemble, if at all, the subcomponents of our CAG systems to our specified standards. In addition, we may not be able to identify qualified additional or replacement manufacturers and assemblers to manufacture subcomponents and assemble our optimized CAG system and, if developed, later versions of our CAG 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 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 and assemblers that have the required expertise to produce our CAG devices as and when needed, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL4 surfactant, including AEROSURF.

Our relationship with Lacey exposes us to similar risks. We are reliant upon Lacey for, among other things, the manufacture, packaging and labeling of our AFECTAIR devices. These activities must be performed to specifications and in compliance with the QSR of the FDA and foreign regulators. Lacey is obligated to cooperate with us in the event of any release of defective product, including those that results in product recalls or other similar events. If Lacey is unable to manufacture to our specifications, or if Lacey fails to comply with the QSRs of the FDA or foreign regulators, it could have a material adverse effect on our development and commercial activities and our financial condition and prospects.

The cost of materials required for the manufacture of AFECTAIR® may increase or be higher than anticipated.

The components of AFECTAIR are manufactured from high-quality medical grade materials that are generally recognized as safe. Suppliers of these materials, due to a change in their pricing policies or an increase in raw materials costs, might charge us increasingly higher than anticipated prices. In turn, we might experience diminishing profit margins or remain unprofitable indefinitely.

Issues with product quality could have an adverse effect upon our business, subject us to regulatory actions and costly litigation and cause a loss of customer confidence in our products or us.

Our success depends upon the quality of our products. Our future revenues will depend upon our ability to develop, maintain, and continuously improve our quality management program, including an objective and systematic process for monitoring and the evaluation of key effectiveness indicators. Quality and safety issues may occur with respect to any of our products. We are dependent upon third-party suppliers, manufacturers and service providers to support our development and commercialization activities. Third-party suppliers are required to comply with our quality standards. Failure of a third-party supplier to provide compliant raw materials or supplies could result in delays or other quality-related issues. A quality or safety issue could have an adverse effect on our business, financial condition and results of operations and may result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in our current or future products or us, which may result in the loss of sales and difficulty in commercializing our products.

AFECTAIR® product inadequacies could lead to recalls and harm our reputation, business and financial results.

The design, manufacture and marketing of our medical device products involve certain inherent risks. Our products must be designed, manufactured and marketed to specific product specifications. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining marketing authorization, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory clearance. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field alert or action, known as a recall, for a product if any material deficiency in a device is found. A government mandated or voluntary recall by us or our third-party manufacturers or suppliers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. We are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Under the FDA medical device reporting regulation, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Failure in our information technology systems could disrupt our operations and cause the loss of confidential information, customers and business opportunities.

As we prepare for the commercialization of our first approved products, we will need extensive information technology (IT) systems in virtually all aspects of our business, including billing, customer service, logistics and management of clinical trial and medical data management. Our technology systems are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Our success will depend, in part, on the continued and uninterrupted performance of our IT systems. IT systems may be vulnerable to damage, disruptions and shutdown from a variety of sources, including telecommunications or network failures, human acts and natural disasters. They also may be subject to physical or electronic intrusions, computer viruses, unauthorized tampering and similar disruptive problems. Likewise, data privacy breaches by employees and others with permitted access to our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Along with our new systems, we plan to take precautionary measures to prevent unanticipated problems. Nevertheless, we may experience damages to our systems, system failures and interruptions and unauthorized disclosure of confidential information, and our data could be compromised.

There can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition of the company. In addition, there can be no assurances that a significant implementation issue may not arise as we continue to implement new systems and consolidate or replace existing (legacy) systems.

If we experience systems problems, they may interrupt our ability to operate. If we experience systems problems, or if we experience unauthorized disclosure of confidential information, it could adversely affect our reputation, result in a loss of customers and revenues and cause us to suffer financial damage, including significant costs to alleviate or eliminate the problem.

If we do not adequately forecast customer demand for our approved products, including SURFAXIN® and AFECTAIR®, our business could suffer. We are also subject to risks associated with doing business globally.

The timing and amount of customer demand and the commercial requirements to meet changing customer demand are difficult to predict. We may not be able to accurately forecast customer demand for our products and product candidates, starting with SURFAXIN and AFECTAIR, or to respond effectively to unanticipated increases in demand. This could have an adverse effect on our business. If we overestimate customer demand, or attempt to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity.

In addition, the current economic conditions may result in reduced demand for our products, increased pricing pressure, longer sales cycles, and slower adoption rates for our products. Conditions in the healthcare industry, including lower healthcare utilization, cost containment efforts by governments and other payers for healthcare services and other factors may result in weaker overall customer demand and increased pricing pressure for our products. The current economic conditions may also adversely affect our suppliers, which could affect our ability to manufacture and sell our products.

We expect to offer certain of our products in the European Union and elsewhere, which subjects us to risks associated with doing business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, increasingly complex labor environments, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of U.S. or local laws, including the FCPA, pricing restrictions, economic and political instability, diminished or insufficient protection of intellectual property, and disruption in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our business could have an adverse effect on our business, financial condition or results of operations.

Our CEFF and ATM Program may become unavailable to us if we do not comply with their conditions.

Except for our CEFF and ATM Program (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 CEFF and ATM Program, we will not be able to issue any portion of the shares potentially available for issuance thereunder and these programs may expire unutilized. In addition, our ability to utilize the ATM Program or 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 CEFF but are triggered by financings under the ATM Program or any new CEFF. In that event, the potential dilutive effect of a financing could be increased if the applicable purchase price of such financing is less than the exercise price of the warrants, which could result in a decline in the market price of our stock.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our CEFF and ATM Program, 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 will require 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 CEFF and the ATM Program has, and the issuance of shares upon exercise of the warrants we issued to Kingsbridge in connection with our CEFFs 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 ATM Program, we will pay Lazard a commission equal to three percent of the aggregate purchase price. If we access the CEFF, 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 Facility (CEFF)." Furthermore, to the extent that Kingsbridge sells to third parties the shares of our common stock that we sell to Kingsbridge under the CEFF, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or other similar transactions. This could contribute to a decline in the stock price of our common stock.

We also filed a universal shelf registration statement with the SEC on Form S-3 (File No. 333-174786) on June 8, 2011 (which was declared effective shortly thereafter) for the proposed offering from time to time of up to $200 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 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 21, 2012, we had 43,307,867 shares of common stock issued and outstanding. In addition, as of December 31, 2011, approximately (i) 13.0 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 2.4 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 342,833 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, 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.

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 12-month period ended December 31, 2011, the price of our common stock ranged between $1.44 and $4.18. 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, 2011, the average daily trading volume in our common stock, was approximately 389,347 shares, and the average number of transactions per day, was approximately 796. 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 were ultimately determined to be meritless or unsuccessful, they would involve substantial costs and a diversion of management attention and resources, which could negatively affect 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. 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 days. 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 were 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.

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. Government and other healthcare 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.

Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products may be subject to price controls in several of the world's principal markets, including many countries within the European Union. In the United States, where pricing levels for our products are substantially established by third-party payers, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

The implementation of the 2010 Health Care Reform Law in the United States may adversely affect our business.

The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010, generally known as the Health Care Reform Law, significantly expands health insurance coverage to uninsured Americans and changes the way health care is financed by both governmental and private payers. We expect expansion of access to health insurance may increase the demand for our products, but other provisions of the Health Care Reform Law could affect us adversely. We also expect that further federal and state proposals for healthcare reform are likely. The changes contemplated by the health care reform law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, any changes that lower reimbursements for our products could adversely affect our business and results of operations.

The Health Care Reform Law establishes new reporting and disclosure requirements for pharmaceutical and medical device manufacturers. Data collection obligations were to commence in January 2012, and reporting requirements are to be implemented in 2013. On December 14, 2011, the Centers for Medicare and Medicaid Services issued proposed regulations to implement these provisions and sought substantial comments, thereby apparently delaying the January 1, 2012 start of information collection. These proposed regulations are broadly drafted and still subject to change, and it is possible that when these regulations are finalized, our contract manufacturers or we will be subject to these reporting requirements. In addition, several states require pharmaceutical and/or device companies to report expenses relating to the marketing and promotion of products as well as gifts and payments to individual practitioners in the states, or prohibit certain marketing related activities. Other states, such as California, Nevada, Massachusetts and Connecticut, require pharmaceutical and/or device companies to implement compliance programs or marketing codes. Wholesale distributors are covered by the laws in certain of these states. In others, it is possible that we will be subject us to the state's reporting requirements and prohibitions. Compliance activities with respect to these measures could increase our costs and adversely affect business operations.

The Health Care Reform Law contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of medical devices by manufacturers and importers beginning in 2013, and a fee on branded prescription drugs that was implemented in 2011, both of which may affect sales of our products. As U.S. net sales are expected to be a significant portion of our worldwide net sales in the coming years, this additional tax burden may have a material, negative impact on our results of operations and our cash flows. The Health Care Reform Law also mandates pharmacy benefit manager transparency regarding rebates, discounts and price concessions with respect to drug benefits under Medicare Part D, and in 2014 with respect to drug benefits offered through qualified health plans offered through state exchanges, which could affect pricing and competition.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, are continuing in many countries where we plan to do business, including the United States.

The Health Care Reform Law establishes the Independent Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. These proposals automatically will be implemented unless Congress enacts alternative proposals that achieve the same savings targets. Further, the legislation calls for a Center for Medicare and Medicaid Innovation that will examine alternative payment methodologies and conduct demonstration programs. The legislation provides for extensive health insurance reforms, including the elimination of pre-existing condition exclusions and other limitations on coverage, fixed percentages on medical loss ratios, expansion in Medicaid and other programs, employer mandates, individual mandates, creation of state and regional health insurance exchanges, and tax subsidies for individuals to help cover the cost of individual insurance coverage. The legislation also permits the establishment of accountable care organizations, a new healthcare delivery model. While the ultimate impact of the legislation on the healthcare industry is unknown, it is likely to be extensive and may result in significant change. Our failure to adapt to these changes could have a material adverse effect on our business.

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 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.

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 will need to hire additional qualified personnel to support (i) the commercialization of SURFAXIN and AFECTAIR, and (ii) the advancement of our SURFAXIN LS and AEROSURF development programs. In particular, over the next 12 months, we expect to hire approximately 50 new employees primarily in the areas of field based sales and marketing, medical affairs, regulatory affairs, and quality control and assurance. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately $8.0 million. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant, and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

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.

As of December 31, 2011, we had employment agreements with four executive officers, including Chief Executive Officer; President and Chief Financial Officer and Treasurer; Senior Vice President and 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 February 2012, we provided notice of non-renewal for these agreements. In addition, in May 2010, we entered into retention agreements with five other executive officers under which each officer is provided certain severance benefits, based on title. These agreements also expire in May 2012. Prior to the May 2012 expiration date for the executive officer agreements, the Compensation Committee of our Board of Directors expects to review market and other compensation data, as well as other information that the Committee may request, with a view to entering into new agreements with our executive officers. 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.

As we prepare for the commercialization of our approved products, we will need to attract candidates to join our management, commercial, medical affairs and development teams, although there can be no assurances that we will be successful in that endeavor. 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. 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 in the future to seek stockholder approval for additional authorizations to support the use of equity incentives. 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.

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.

The parties licensing technologies to us and we 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 J&J 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 extended the term of our most important patent until November 2012, 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 CAG 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 CAG 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."

Our technology platform is based solely on our proprietary KL$_4$ surfactant technology, our novel CAG technology, and our novel ventilator circuit / patient interface connectors.

Our technology platform is based on the scientific rationale of using our KL$_4$ surfactant technology, our CAG 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.

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 J&J, 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.

Moreover, although our four 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, if any should resign, we may not be successful in enforcing our noncompetition agreements with them.

The failure to prevail in litigation or the costs of litigation, including securities class action, product liability 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.

Our business activities, including manufacturing and marketing our drug products and medical devices also exposes us to liability risks. Using our drug product candidates or medical devices in clinical trials may expose us to product liability claims. For our products that are approved for commercial sale, the risk of product liability claims is increased. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. In addition, we may be subject to product liability claims involving our AFECTAIR and other medical devices and alleged 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 also may arise.

The design, manufacture and marketing of SURFAXIN and the AFECTAIR devices involve an inherent risk of product liability claims. There are a number of factors that could result in an unsafe condition or injury to a patient, including manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information. Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time.

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. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We may need to obtain additional product liability insurance coverage, including with locally-authorized insurers licensed in countries where we market our approved products or conduct our clinical trials, before initiating clinical trials; 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.

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 KL4 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.

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.

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.

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 KL4 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 CAG 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. This lease expires in December 2014, subject to the landlord's right, in certain circumstances and upon two years' prior notice, to terminate the lease early. In addition, depending upon the timing of the notice, if we satisfy certain financial conditions at the time, the landlord would be obligated to make early termination payments to us. We are assessing our alternatives upon early termination or expiration of this lease and are developing a long-term manufacturing strategy that could include (i) subject to the landlord's agreement, potentially renegotiating our current lease, (ii) building or acquiring additional manufacturing capabilities to support product development and commercial production of our KL4 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. MINE SAFETY DISCLOSURE.

Not applicable.

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 21, 2012, we had 137 stockholders of record of shares of our common stock. We also have been advised by Broadridge Financial Solutions, Inc. that, as of March 26, 2012, there are approximately 23,421 beneficial owners of our common stock whose positions are held in street name. As of March 21, 2012, there were 43,307,867 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 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
First Quarter 2011	$ 1.71	$ 4.18
Second Quarter 2011	$ 1.79	$ 2.95
Third Quarter 2011	$ 1.93	$ 2.70
Fourth Quarter 2011	$ 1.44	$ 2.01

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

Effective as of March 18, 2011, we entered into an exchange agreement with a former employee pursuant to which we issued a warrant to purchase 30,000 shares of our common stock (warrant shares) in exchange for the return of options to purchase 123,334 shares of our common stock (surrendered options) that had been issued pursuant to our 2007 Long-Term Incentive Plan (2007 Plan). The warrant expires on March 18, 2016 and is exercisable at a price per share of $3.20. The warrant is excisable for cash only, except that the warrant may be exercised as a cashless exercise (as defined in the warrant) (i) if we determine to permit cashless exercise in our sole discretion, or (ii) if an exemption from registration under the Securities Act of 1933, as amended (the Act) and applicable state laws is not available for resale of the warrant shares to be received by the warrant holder upon exercise of the warrant unless the warrant is exercised as a cashless exercise. The exercise price, number of shares of common stock and/or the amount and/or type of property issuable upon exercise of the warrant are subject to adjustment in the event we declare or enter into transactions affecting our capital stock, as provided in the warrant. The warrant was issued in reliance upon the exemption from securities registration provided by Section 3(a)(9) and/or Section 4(2) of the Act. We received no cash proceeds in connection with this transaction.

During the 12-month period ended December 31, 2011, we did not 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, 2011 and 2010.

- **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 specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug 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. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of inhaled therapies, including our aerosolized KL_4 surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We are implementing a plan that, if successful, is intended to result in the commercial introduction of SURFAXIN in the United States in fourth quarter of 2012.

Our strategy is initially to focus the development of our KL_4 surfactant and aerosol technologies to improve the management of RDS in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs, beginning with SURFAXIN and, if approved, SURFAXIN LS™ and AEROSURF®, have the potential to greatly improve the management of RDS and, collectively over time, to become the global standard of care for premature infants with RDS.

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing SURFAXIN LS with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States, the European Union and other major markets worldwide.

AEROSURF is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG) and our novel AFECTAIR® ventilator circuit / patient interface connectors. We are developing AEROSURF for premature infants with or at risk of RDS. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. As a consequence, neonatologists will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. For this reason, we believe that AEROSURF, if approved, potentially may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but are currently not treated.

AFECTAIR, a series of disposable ventilator circuit / patient interface connectors, was initially developed for use in NICUs as part of our AEROSURF development program. AFECTAIR devices simplify the delivery of inhaled therapies (including our aerosolized KL4 surfactant) to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. We initially developed a ventilator circuit / patient interface connector to be used with our CAG in the NICU. To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, we are developing AFECTAIR devices in different sizes for use in NICUs, pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. In February 2012, we successfully registered our initial AFECTAIR device, which is intended for use with jet nebulizers and other aerosol generators, in the United States as a Class I, exempt medical device. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients. We are implementing a regulatory and manufacturing plan that, if successful, is intended to result in the commercial introduction of the initial AFECTAIR device in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR DUO, in mid-2013.

We are preparing for the commercial introductions, beginning in late 2012, of SURFAXIN in the United States, and AFECTAIR in the United States and the European Union and other markets worldwide thereafter. To accomplish our objectives, in the United States, we plan to build our own, in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN. We expect that our commercial and medical affairs organization will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN to efficiently support the introductions of SURFAXIN LS and AEROSURF, if approved. We also expect that our in-house organization will also work in a coordinated manner with a network of third-party distributors to execute the commercial introduction of the AFECTAIR devices.

In major markets outside the United States, an important priority is to secure the strategic resources to support the continued development and commercial introduction of our RDS products. A key goal for us in 2012 is to secure one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF development programs, and, if approved, to support the commercial introduction of these products in Europe and elsewhere. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other similar transaction.

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 KL4 pipeline programs.

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, 2011, 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, pharmaceutical and device 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 Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. We classify 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 or trinomial pricing models, depending on the applicable terms of the warrant agreement, to value the derivative warrant liabilities. 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." *See*, "– Results of Operations – Change in Fair Value of Common Stock Warrant Liability.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the years ended December 31, 2011, and 2010 was $21.0 million (or $0.93 per share) and $19.2 million (or $1.65 per share), respectively. Included in the net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $3.6 million and $6.4 million for the years ended December 31, 2011 and 2010, respectively.

The operating loss for the years ended December 31, 2011 and 2010 was $24.5 million and $25.5 million, respectively. The operating loss includes $2.2 million and $2.8 million for non-cash items related to depreciation and stock-based compensation for the years ended December 31, 2011 and 2010, respectively. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was $22.4 million and $22.7 million, respectively, for the years ended December 31, 2011 and 2010.

Grant Revenue

For the year ended December 31, 2011, we recognized revenue of $0.6 million, for funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL_4 surfactant for RDS. We did not recognize any grant revenues in 2010.

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 and drug delivery technologies, 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 and product development, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. We also track research and development by major expense category as follows: (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, 2011 and 2010 were $17.2 million, and $17.1 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands)

Research and Development Expenses[1]:	Year Ended December 31, 2011	2010
Manufacturing and product development	$ 12,359	$ 11,739
Medical and regulatory operations	3,452	3,337
Direct preclinical and clinical programs	1,419	2,060
Total Research and Development Expenses	$ 17,230	$ 17,136

[1] Certain 2010 expenses have been reclassified to conform to 2011 presentation.

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.4 million and $1.7 million for the years months ended December 31, 2011 and 2010, 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 and Product Development

Manufacturing and product development includes: (i) the cost of our manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and commercial drug supply for our KL4 surfactant products, in conformance with current good manufacturing practices (cGMP); (ii) design and development activities related to the development and manufacture of our CAG for use in our preclinical programs, our anticipated clinical programs, and, if approved, commercial use, (iii) design and development activities related to our novel ventilator circuit / patient interface connectors, including our AFECTAIR® and AFECTAIR DUO devices, and; (iv) pharmaceutical development activities, including development of a lyophilized dosage form of our KL4 surfactant. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

The $0.6 million increase in manufacturing and product development expenses in 2011 as compared to 2010 is primarily due to costs associated with the manufacture of SURFAXIN® batches needed to execute the comprehensive preclinical program that we conducted to respond to the 2009 Complete Response Letter, partially offset by a reduction in costs associated with the technology transfer of our SURFAXIN LS™ lyophilized manufacturing process to a third-party contract manufacturer.

Manufacturing and product development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.2 million and $1.4 million, respectively, for the years ended December 31, 2011 and 2010.

Medical and Regulatory Operations

Medical and regulatory operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; and (ii) medical affairs activities to provide scientific and medical education support in connection with our KL4 surfactant and aerosol delivery technologies programs; These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Medical and regulatory operations expenses in 2011 are comparable to 2010, primarily due to our efforts to conserve financial and other resources while we focused our efforts on securing marketing authorization for SURFAXIN.

Medical and regulatory operations expenses include non-cash charges associated with stock-based compensation and depreciation of $0.2 million and $0.3 million for the years months ended December 31, 2011 and 2010, respectively.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) activities related to responding to the 2009 Complete Response Letter; (ii) preclinical activities, including preparatory activities for the anticipated clinical trials for SURFAXIN LS and AEROSURF® for RDS in premature infants, toxicology studies and other preclinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; and (iii) 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), including, in 2010, activities related to the completion of the Phase 2 clinical trial evaluating the use of SURFAXIN in children up to two years of age suffering with Acute Respiratory Failure (ARF).

The $0.6 million decrease in direct preclinical and clinical program expenses in 2011 as compared to 2010 is primarily due to expenses associated with the completion of the Phase 2 ARF clinical trial incurred in 2010.

In an effort to focus our financial resources, we plan to focus our drug research and development activities on the management of RDS in premature infants and specifically in our SURFAXIN LS and AEROSURF development programs to advance them towards initiation of our planned Phase 2 and Phase 3 clinical trials, respectively. 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. If successful, we plan to initiate the planned AEROSURF Phase 2 and SURFAXIN LS Phase 3 clinical programs in late 2013, after we have secured one or more strategic alliances and/or necessary capital, our SURFAXIN LS Phase 3 clinical program in late 2013. As resources permit, we may make limited investments in non-RDS programs, including potentially acute lung injury (ALI), chronic obstructive pulmonary disorder (COPD) and cystic fibrosis (CF).

Research and Development by Major Expense Category

We also track our research and development by major expense category as shown in the following table:

	2011	2010
Salaries & Benefits	$ 8,231	$ 6,858
Contracted Services	3,317	4,395
Raw Materials & Supplies	1,871	1,009
Rents & Utilities	1,531	1,442
Depreciation	1,141	1,207
Contract Manufacturing	143	990
Stock-Based Compensation	289	479
All Other	707	756
Total	$ 17,230 17,280	$ 17,136

The increase in salaries and benefits in 2011 as compared to 2010 is primarily due to increased benefit costs, employee incentive payments and employee severance costs.

Contracted services include the cost of preclinical 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. The decrease in 2011 as compared to 2010 is primarily due to costs in 2010 related to the completion of the Phase 2 ARF clinical trial and a decrease in outside laboratory testing related to activities to address the 2009 Complete Response Letter.

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. In addition, raw materials and supplies include component parts used in the development of our CAG and raw materials and supplies used in manufacturing and product development activities for our novel ventilator circuit / patient interface connectors. The increase in raw materials and supplies in 2011 as compared to 2010 is primarily due to the manufacture of SURFAXIN batches needed to execute the comprehensive preclinical program that we conducted to respond to the 2009 Complete Response Letter.

Rents and utilities are associated with our leased manufacturing, laboratory and related facilities.

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 contract-management organization (CMO) with expertise in lyophilized formulations. The decrease in contract manufacturing costs in 2011 as compared to 2010 is due to a reduction in technology transfer activities associated with SURFAXIN LS while we focused our efforts on responding to the 2009 Complete Response Letter and securing marketing authorization for SURFAXIN.

Research and Development Projects

A substantial portion of our cumulative losses to date, including approximately $34.4 million in the two-year period ended December 31, 2011, relate to investments in our research and development projects. Due to the significant risks and uncertainties inherent in clinical development and the 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 affect 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 KL_4 surfactant drug product, SURFAXIN, was recently approved for marketing in the United States. In addition, we recently registered our initial AFECTAIR device in the United States and expect to complete the registration of that device in the European Union in 2012. Although we have two approved products at this time, neither are available for commercial sale. We currently plan to initiate the commercial introduction of SURFAXIN and AFECTAIR in late 2012, although there can be no assurance that we will be successful in commercializing these products or in realizing a profit in the foreseeable future.

Our other KL_4 surfactant drug development projects are initially focused on the management of RDS in premature infants and include 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. We plan in 2012 to seek regulatory and scientific guidance with respect to our planned development programs for SURFAXIN LS and AEROSURF; however, our ability to move forward with our planned clinical trials for both SURFAXIN LS and AEROSURF will depend upon the success of our efforts to complete our development activities and secure strategic alliances and/or necessary capital to support these activities. If we are successful within our target time frame, we believe that we could be in a position to initiate our clinical programs for SURFAXIN LS and AEROSURF in late 2013. However, there can be no assurance that we will be successful in securing such an alliance or capital, that our development plans for these products will be successful, if at all, and within our anticipated time frames. Accordingly, we are unable to reliably 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."

Our ability to generate sufficient capital to support our product development activities and, if approved, commercialization of SURFAXIN LS and AEROSURF in the European Union and other markets outside the U.S., depends upon many factors, including the success of our efforts (i) to commercialize SURFAXIN and AFECTAIR, (ii) to secure one or more strategic alliances or other collaboration arrangements to support the further development and, if approved, commercialization of SURFAXIN LS and AEROSURF in markets outside the United States, and/or (iii) to enter into alternative financial arrangements that would provide the required capital. We believe that our ability to successfully enter into meaningful strategic alliances has likely improved with receipt of marketing approval in the United States for SURFAXIN and our improved financial condition as a result of our March 2012 public offering (*see*, "– Liquidity and Capital Resources –Financings Pursuant to Common Stock Offerings – 2011 Universal Shelf"), and will further improve if we are able to advance our SURFAXIN LS and AEROSURF programs towards initiation of planned Phase 2 and Phase 3 clinical trials, respectively. There can be no assurance, however, that we will successfully commercialize SURFAXIN LS or AFECTAIR, 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. *See*, "– Liquidity and Capital Resources."

We believe that our KL4 surfactant technology has the potential to be developed into a broad product pipeline that could address a variety of debilitating respiratory conditions in patient populations ranging from premature infants to adults. At the present time, we plan to focus our resources on RDS programs and pace investments in potential non-RDS pipeline programs. *See*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine." However, we plan to consider opportunistically sponsoring and supporting third-party investigator-initiated preclinical and clinical programs directed at establishing proof-of-concept through Phase 2 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. *See*, "Item 1 – Business – Business Strategy," and "– Surfactant Replacement Therapy For Respiratory Medicine."

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, 2011 and 2010 were $7.9 million and $8.4 million, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.7 million and $1.1 million, respectively, for the years ended December 31, 2011 and 2010. In addition, general and administrative expenses include one-time charges of $0.4 million and $1.0 million for the years ended December 31, 2011 and 2010, respectively, associated with certain contractual cash severance obligations related to our former Executive Vice President and General Counsel in 2011 and for our former President and Chief Executive Officer in 2010. Excluding the charges related to our severance obligation and charges associated with stock-based compensation and depreciation, general and administrative expenses increased $0.5 million in 2011 as compared to 2010. The increase is primarily related to employee incentive payments and AFECTAIR market research activities.

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

With respect to our planned commercial introduction of SURFAXIN and AFECTAIR in late 2012, we expect to incur expenses at an annual rate of approximately $12-13 million, which primarily represents investment in marketing, field-based sales and medical affairs capabilities. We anticipate that our medical affairs personnel will provide medical education support for both SURFAXIN and AFECTAIR, as both products may be of interest to many of the same medical practitioners and involve many of the same medical congresses, many of the same medical journals and publications, and many of the same hospitals. We expect that this anticipated synergy will result in certain economies for each of these products.

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 Topic 815, either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued using the Black-Scholes or trinomial pricing models, depending on the applicable terms of the warrant agreement 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 registered warrants that we issued in our May 2009 and February 2010 public offerings generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, under generally accepted accounting principles, these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under the federal securities laws, it may not be within our absolute control to provide freely-tradable shares upon exercise of the warrants in all circumstances, and (ii) the warrant agreements do not expressly state that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that an event would result in a cash settlement. Accordingly, the May 2009 and February 2010 warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option-pricing model.

The registered five-year warrants that we issued in the February 2011 public offering (February 2011 five-year warrants) expressly provide that under no circumstances will we be required to effect a net cash settlement of these warrants. However, these warrants contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 five-year warrants. Due to the nature of the anti-dilution provisions, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

The change in fair value of common stock warrant liability for the years ended December 31, 2011 and 2010 resulted in income of $3.6 million and $6.4 million, respectively, due primarily to a decrease in our common stock share price during the periods.

Other Income / (Expense)

Other income / (expense), net, for the years ended December 31, 2011 and 2010, respectively, is as follows:

(Dollars in thousands)	Year Ended December 31, 2011	2010
Interest income	$ 13	$ 13
Interest expense	(20)	(357)
Other income / (expense)	(6)	275
Other income / (expense), net	$ (13)	$ (69)

Interest income consists of interest earned on our cash and cash equivalents. To ensure preservation of capital, we invest our cash in an interest-bearing operating cash account and a U.S. treasury-based money market fund.

Interest expense for the year ended December 31, 2011 consists of interest on our equipment financing facilities. Interest expense for the year ended December 31, 2010 consists of interest on our loan with PharmaBio, interest on our equipment financing facilities and amortization of deferred financing costs for a warrant issued to PharmaBio in October 2006 as consideration for restructuring our loan in 2006. The deferred financing costs were fully amortized as of April 2010. The decrease in interest expense in 2011 as compared to 2010 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 includes 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 a series of Committed Equity Financing Facilities (CEFFs), capital equipment and debt facilities, and strategic alliances. We expect to fund our business operations primarily through a combination, or all, of public offerings, including our CEFF and ATM Program (*see*, "– Committed Equity Financing Facility (CEFF)," and "– ATM Program"); anticipated revenue from the commercial introduction of SURFAXIN® and AFECTAIR®; strategic alliances; the exercise of outstanding warrants; and debt facilities.

Our future capital requirements depend upon many factors, primarily the success of our efforts (i) to execute the commercial introduction of SURFAXIN and AFECTAIR in the United States and other markets, as planned, (ii) to secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of SURFAXIN LS™ and AEROSURF® in the European Union and markets outside the U.S., (iii) to advance the SURFAXIN LS and AEROSURF development programs to be in a position to initiate planned Phase 3 and Phase 2 clinical trials, respectively, and (iv) to procure the additional capital necessary and desirable to support our activities until such time as the net revenues from our approved products, from potential strategic alliance and other collaboration arrangements and from other sources, such as future warrant exercises, are sufficient to offset cash flow requirements.

As of December 31, 2011, we had cash and cash equivalents of $10.2 million. From January 1, 2012 through March 21, 2012, (i) holders of 15-month warrants we issued in February 2011 have exercised warrants to purchase 2,233,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million; and (ii) holders of the five-year warrants we issued in February 2011 have exercised warrants to purchase 46,250 shares of our common stock at an exercise price of $3.20 per share, resulting in proceeds to us of $148,000. In addition, on March 7, 2012, we delivered a sales notice under our ATM Program to sell shares of common stock. We terminated the offering on March 8, 2012. As a result of that offering, we issued an aggregate 350,374 shares of common stock at an aggregate purchase price of approximately $1.56 million, resulting in net proceeds to us of approximately $1.52 million, after deducting commissions due to the sales agent. On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock for net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of common stock at a public offering price of $2.80 per share, with respect to which we potentially could realize additional net proceeds of $6.3 million.

As of December 31, 2011 and March 21, 2012, of the 100 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 56.5 million and 40.0 million shares of common stock, respectively.

To execute our business strategy over time, we anticipate potentially securing additional infusions of capital from a combination of some or all of the following sources:

Exercise of outstanding warrants:

- In connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (15-month warrants) of which 2,233,000 warrants have been exercised through March 21, 2012. If the market price of our common stock should exceed $2.94 at any time prior to May 2012 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the 15-month warrants and we have an effective registration statement covering the warrant shares, we potentially could raise up to an additional $8.1 million.

- Also in connection with the February 2011 public offering, we issued five-year warrants to purchase five million shares of our common stock at an exercise price of $3.20 per share (2011 five-year warrants). These warrants also contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price. As a result of the March 2012 public offering, the exercise price of these warrants has been adjusted downward to $2.80 per share. Thus, if the market price of our common stock should remain above $2.80 at any time prior February 2016 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the five-year warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants, we potentially could raise up to an additional $13.9 million.

Upfront and milestone payments and co-funding of development activities associated with potential strategic alliances or other similar transactions:

- We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the development of SURFAXIN LS and AEROSURF and, if approved, the introduction of these products in Europe and various markets outside the U.S.

Secured debt arrangements to fund working capital and/or investment in capital assets:

- In the future, if our efforts are successful, we believe that debt could potentially be a component of our capital structure and financing plans. We could potentially enter into capital equipment financing facilities, revolving working capital lines of credit, term loans and other similar transactions to satisfy our working capital requirements.

In appropriate circumstances, to secure additional capital and strengthen our financial condition, we will also consider equity public offerings and other financing transactions:

- We have a CEFF with Kingsbridge Capital Ltd. (Kingsbridge) that could allow us, at our discretion, to raise capital (subject to certain conditions, including volume limitations) at a time and in amounts we deem suitable to support our business plans. Based on the closing market price of our common stock on March 21, 2012 ($2.80) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.8 million.

- In December 2011, we established an "at-the-market" program (ATM Program), which allows us, at our discretion and at such times that we may choose, to sell up to a maximum of $15 million of shares of common stock. Based on the closing market price of our common stock on March 21, 2012 ($2.80), and assuming that the full amount available under the ATM Program ($13.4 million) is sold, we may issue up to approximately 4.8 million additional shares under the ATM Program. See, "– Financings Pursuant to Common Stock Offerings."

- We have agreed in connection with our March 2012 public offering that we will not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in June 2012. See, "- Financings Pursuant to Common Stock Offerings."

There can be no assurance that the market price of our common stock will remain at levels that make exercise of outstanding warrants likely or that holders of outstanding warrants will choose to exercise any or all of their warrants prior to the warrant expiration date; that we will be successful in concluding any strategic alliance, collaboration or other financing transaction; that the CEFF will be available at any time, or, even if available, that we will utilize the CEFF prior to its expiration in June 2013; that we will issue any shares pursuant to the ATM Program, or that the entire amount provided under the ATM Program will be realized prior the expiration or earlier termination of the ATM Program; or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

We believe, if we are successful in implementing our strategic business plan, that the anticipated net revenues from the sales of SURFAXIN and AFECTAIR, when combined with the other sources of anticipated capital outlined above, including from potential strategic alliances and collaboration arrangements to support the SURFAXIN LS and AEROSURF development programs, potentially could be sufficient to support our future operations. In that event, we would nevertheless continue to consider financings and similar transactions that would strengthen our financial condition and build value for our stockholders.

Although we currently believe that we will be successful in meeting our strategic planning goals within the time frame set forth above, there can be no assurance that we will successfully fund and build our own commercial organization to support the commercial introduction of SURFAXIN and AFECTAIR; that we will successfully execute the launch of SURFAXIN and AFECTAIR within the anticipated time frame; that the revenues we may realize from the sale of SURFAXIN and AFECTAIR will be in line with current expectations; that we will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of the SURFAXIN LS and AEROSURF product candidates; or that the revenues, if any, that we generate in the future will be sufficient at any time to fund the further development of our research and development programs and support our operations. If we are unable to identify and enter into strategic alliances for the development of SURFAXIN LS and AEROSURF, and if approved, commercialization of SURFAXIN LS and AEROSURF in the European Union and other markets outside the U.S., we may be unable to fund planned clinical trials, which would have a material adverse effect on our research and development programs.

Cash Flows

As of December 31, 2011 and 2010, we had cash and cash equivalents of $10.2 million. Cash outflows before financings for the year ended December 31, 2011 consist of $22.7 million used for ongoing operating activities and $0.1 million used for debt service. During 2011, we raised aggregate net proceeds of $22.9 million, including $21.6 million from a public offering in February 2011 and $1.3 million from financings under our CEFF.

Cash Flows Used In Operating Activities

Cash flows used in operating activities were $22.7 million and $24.3million for the years ended December 31, 2011 and 2010, respectively.

Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items associated with the change in fair value of common stock warrants ($3.6 million and $6.4 million for the years ended December 31, 2011 and 2010, respectively), stock-based compensation, 401(k) match and depreciation expense ($2.6 million and $3.2 for the years ended December 31, 2011 and 2010, respectively), and changes in working capital. Cash flows used in operating activities for the year ended December 31, 2010 included a one-time payment of $1.1 million to satisfy severance obligations to our former President and Chief Executive Officer.

Cash Flows Used In Investing Activities

Cash flows used in investing activities represent capital expenditures of $0.1 million for each of the years ended December 31, 2011 and 2010.

Cash Flows from Financing Activities

Cash flows from financing activities were $22.8 million and $18.8 million for the years ended December 31, 2011 and 2010, respectively, as summarized in the chart below:

(In millions)	Year Ended December 31, 2011	2010
Financings pursuant to common stock offerings	$ 21.6	$ 26.6
Financings under CEFFs	1.3	1.4
Debt service payments	(0.1)	(9.2)
Cash flows from financing activities, net	$ 22.8	$ 18.8

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

Committed Equity Financing Facility (CEFF)

Since 2004, we have maintained one or more 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 have allowed us, at our discretion, to raise capital, at the time and in amounts deemed suitable to us, to support our business plans. We are not obligated to utilize any of the funds available under any CEFF and our ability to access funds at any time is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2011, we had one CEFF dated June 11, 2010 (2010 CEFF). Two prior CEFF agreements, dated May 22, 2008 (May 2008 CEFF) and December 12, 2008 (December 2008 CEFF), expired in June 2011 and February 2011, respectively.

2010 CEFF

The 2010 CEFF related Stock Purchase Agreement originally provided for up to 2.1 million shares, up to a maximum of $35 million, and expires in June 2013. As of December 31, 2011, there were 1.1 million shares remaining under 2010 CEFF, up to a maximum of $32.3 million. The shares issuable under the 2010 CEFF were registered under a 2008 Universal Shelf.

Each draw down extends for an eight-day trading period. To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day must be at least equal to $0.20 per share. If on any trading day during the trading period, if the daily volume-weighted average price of our common stock (VWAP) is less than the Threshold Price (defined below), Kingsbridge has the right to purchase shares at the Threshold Price; otherwise 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. The 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. Unless Kingsbridge and we 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.

With respect to each draw down, Kingsbridge is obligated to purchase (“Obligated Amount”) the amount determined under one of two methodologies that we choose at our discretion, subject to a maximum 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 additional amount over the calculated 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 2010 CEFF is at a discount to the VWAP (as defined in the agreement) for each of the trading days in the draw down period as follows:

Daily VWAP	% of VWAP	Applicable Discount
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 2010 CEFF 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 2010 CEFF and prior CEFFs, we issued warrants to Kingsbridge. The following warrants are outstanding and are exercisable, in whole or in part, for cash, except in limited circumstances:

- 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.
- 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 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 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. This warrant expired unexercised 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. This warrant expired unexercised in January 2010.

CEFF Financings

Financings that we completed under the 2010 CEFF are as follows:

(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
October 10, 2011	35	69	1.97
October 24, 2011	37	63	1.71
November 8, 2011	129	218	1.69
	1,032	$ 2,746	

There were no financings under the May 2008 CEFF or December 2008 CEFF during 2010 and 2011.

ATM Program

On December 14, 2011, we entered into a Sales Agency Agreement (Agency Agreement) with Lazard Capital Markets LLC (Lazard), under which Lazard, as our exclusive agent, may, at our discretion and at such times that we may determine from time to time, sell over a two year period up to a maximum of $15,000,000 of shares of our common stock (Shares) through an “at-the-market” program (ATM Program). We are not required to sell any Shares at any time during the term of the ATM Program.

If we issue a sale notice to Lazard, we may designate the minimum price per share at which Shares may be sold and the maximum number of Shares that Lazard is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Lazard may sell the Shares by any method deemed to be an “at-the-market” equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers’ transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Lazard and us. Either party may suspend sales under Agency Agreement by notice to the other party.

The Agency Agreement will terminate upon the earliest of: (1) the sale of all Shares subject to Agency Agreement, (2) December 14, 2013 or (3) the earlier termination of Agency Agreement in accordance with its terms. Either party may terminate Agency Agreement at any time upon written notification to the other party. We have agreed to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales of Shares. We also agreed to reimburse Lazard for certain expenses incurred in connection with entering into Agency Agreement and have provided Lazard with customary representations and warranties, and indemnification rights.

The Shares to be issued under the ATM Program have been registered pursuant to a prospectus supplement dated December 14, 2011 to our 2011 Universal Shelf.

As of December 31, 2011, $15.0 million remained available under the ATM Program.

ATM Financings

On March 12, 2012, we completed an offering of 350,374 shares of our common stock for an aggregate purchase price of approximately $1.56 million, resulting in net proceeds to us of approximately $1.52 million, after deducting commissions due to Lazard under the Sales Agency Agreement.

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.

2011 Universal Shelf

In June 2011, we filed a universal shelf registration statement on Form S-3 (No. 333-174786) (2011 Universal Shelf) with the SEC for the proposed offering from time to time of up to $200 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. The 2011 Universal Shelf replaced the 2008 Universal Shelf, which simultaneously expired, and was declared effective by the SEC on June 21, 2011. As of December 31, 2011, $199.7 million remained unissued under the 2011 Universal Shelf.

On March 21, 2012, we completed a public offering of 16,071,429 shares of our common stock at a public offering price of $2.80 per share, resulting in gross proceeds of $45.0 million ($42.1 million net). In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of our common stock to cover over-allotments, if any.

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. Upon effectiveness of the 2011 Universal Shelf, the 2008 Universal Shelf was no longer available for proposed offerings. The following offerings were issued pursuant to the 2008 Universal Shelf.

On February 22, 2011, we completed a registered public offering of 10 million shares of our common stock, 15-month warrants to purchase five million shares of our common stock, and five-year warrants to purchase five million shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a 15-month warrant to purchase one half share of common stock, and a five-year 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 15-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 were initially exercisable at a price per share of $3.20. The exercise price of the five-year warrants is 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. In connection with the closing of our public offering on March 21, 2012, the exercise price of the five-year warrants has been adjusted downward to a price per share of $2.80.

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.

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.

Debt

Equipment Financing Facilities

Our equipment loan liabilities as of December 31, 2011 and 2010 are as follows:

(in thousands)	2011	2010
Pennsylvania Machinery and Equipment Loan		
Short-term	$ 66	$ 63
Long-term	224	296
Total	290	359
Capitalized Leases		
Short-term	2	22
Long-term	–	5
Total	2	27
GE Business Financial Services, Inc.		
Short-term	–	51
Long-term	–	–
Total	–	51
Total Short-term	68	136
Total Long-term	224	301
Total	$ 292	$ 437

For the years ended December 31, 2011 and 2010, we incurred interest expense associated with our equipment loans of $20,000 and $56,000, respectively.

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 Loan requires us to meet certain job retention and job creation goals in Pennsylvania within a three-year period (Jobs Covenant). If we fail to comply with the Jobs Covenant, the Department, in its discretion, may change the interest rate on the Promissory Note to a fixed rate equal to two percentage points above the current prime rate for the remaining term. As of September 30, 2011, the end of the three-year Jobs Covenant period, due to our efforts to conserve resources while we focused on securing the approval for SURFAXIN, we had not complied with the Jobs Covenant. In response to a request that we filed with the Department for a waiver, the Department granted us an extension through August 31, 2012 to achieve compliance with the Jobs Covenant and has waived any interest adjustment until that date.

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. (GE, formerly Merrill Lynch Business Financial Services Inc.), 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. As of December 31, 2011, all outstanding amounts under the Facility had been paid in full and all related security interests satisfied and released. Advances to finance the acquisition of property and equipment were amortized over a period of 36 months and all other equipment and related costs were 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 accrued at a fixed rate per annum equal to one-month LIBOR plus 6.25%, determined on the funding date of such advance.

Loan Payable – PharmaBio Development Inc.

On April 28, 2010, we restructured our $10.6 million loan with PharmaBio Development Inc (Pharma Bio), the former strategic investment subsidiary of Quintiles Transnational Corp. 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. All related security interests were satisfied and released. 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 year ended December 31, 2010, we incurred interest expense associated with the PharmaBio loan of $0.3 million. Interest expense for the year ended December 31, 2010 included $0.2 million of amortization of deferred financing costs for warrants issued to PharmaBio in 2006 in consideration for restructuring the loan.

Contractual Obligations and 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 that expires on December 3, 2012. *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.

Severance Arrangement

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement ("Separation Agreement") with our former, Executive Vice President, General Counsel and Corporate Secretary (Former Executive). Pursuant to the Separation Agreement, the Former Executive resigned his positions with us effective July 31, 2011, and was entitled to (i) payment of accrued vacation pay, (ii) the right to continue to hold a restricted stock award for 15,000 shares (RSA) without any continuing Service (as defined in the RSA) requirement, (iii) extended health benefits for up to 18 months, and, (iv) depending on the circumstances, certain outplacement services. In addition, we agreed to pay the Former Executive on February 1, 2012 severance in the amount of $400,000, which amount was reduced by any outstanding amount due under a promissory note that the Former Executive had issued to us in 2001. As of December 31, 2011, the outstanding aggregate principal amount of the Note was $169,958. The Separation Agreement also contains a general release of claims by the parties and a 12-month non-competition covenant by the Former Executive.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2011 or 2010, or during 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, 2011. 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, 2011.

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 on Form 10-K.

(c) Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter end December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2011 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 30, 2012

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 30, 2012
/s/ John G. Cooper	John G. Cooper President and Chief Financial Officer (Principal Financial Officer)	March 30, 2012
/s/ John Tattory	John Tattory Vice President, Finance and Controller (Principal Accounting Officer)	March 30, 2012
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	March 30, 2012
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 30, 2012
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 30, 2012
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 30, 2012

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 and October 3, 2011	Incorporated by reference to Exhibit 3.1 to Discovery's Form 8-K, as filed with the SEC on October 3, 2011.
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	Incorporated by reference to Exhibit 4.13 to Discovery's Annual Report on Form 10-KSB for the year ended December 31, 2010, as filed with the SEC on March 31, 2011.
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 (Commission File Number 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 Discovery 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.

Exhibit No.	Description	Method of Filing
10.5*	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.
10.6*	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.
10.7*	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.
10.8*	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.
10.8*	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.
10.10*	Form of 2011 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Appendix II to Discovery's Definitive Proxy Statement on Form DEF 14A, as filed with the SEC on August 15, 2011 (Commission File Number 000-26422).
10.11*	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.
10.12*	Employment Agreement dated as of October 18, 2010 between Discovery and W. Thomas Amick	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.
10.13*	Amendment dated August 11, 2011 to the Employment Agreement dated as of October 18, 2010 between Discovery and W. Thomas Amick	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, as filed with the SEC on August 15, 2011.
10.14*	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.
10.15*	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
10.16+	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.
10.17+	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.
10.18	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.
10.19	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.
10.20	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.
10.21	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.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	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.

Exhibit No.	Description	Method of Filing
10.27+	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.
10.28*	Separation of Employment Agreement and General Release between Discovery and David L. Lopez, Esq., C.P.A.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 18, 2011.
10.29	Sales Agency Agreement dated December 14, 2011, between Discovery and Lazard Capital Markets LLC	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 14, 2011.
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 and Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
101.1	The following consolidated financial statements from the Discovery Laboratories. Inc. Annual Report on Form 10-K for the year ended December 31, 2011, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2011 and December 31, 2010, (ii) Statements of Operations for the years ended December 31, 2011 and December 31, 2010, (iii) Statements of Changes in Equity for the years ended December 31, 2011 and December 31, 2010, (iv) Statements of Cash Flows for the years ended December 31, 2011 and December 31, 2010, and (v) Notes to consolidated financial statements	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

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

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

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Contents

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the "Company") as of December 31, 2011 and 2010, 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 evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. and subsidiary at December 31, 2011 and 2010, 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

Philadelphia, Pennsylvania
March 30, 2012

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,189	$ 10,211
Prepaid expenses and other current assets	442	285
Total current assets	10,631	10,496
Property and equipment, net	2,293	3,467
Restricted cash	400	400
Other assets	-	174
Total assets	$ 13,324	$ 14,537
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,111	$ 1,685
Accrued expenses	2,972	3,286
Common stock warrant liability	6,996	2,469
Equipment loans and capitalized leases, current portion	68	136
Total current liabilities	11,147	7,576
Equipment loans and capitalized leases, non-current portion	224	301
Other liabilities	689	634
Total liabilities	12,060	8,511
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 100,000 and 50,000 authorized; 24,603 and 13,822 shares issued, 24,582 and 13,801 shares outstanding	25	14
Additional paid-in capital	401,713	385,521
Accumulated deficit	(397,420)	(376,455)
Treasury stock (at cost); 21 shares	(3,054)	(3,054)
Total stockholders' equity	1,264	6,026
Total liabilities & stockholders' equity	$ 13,324	$ 14,537

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(In thousands, except per share data)

	Year Ended December 31, 2011	2010
Grant Revenue	$ 582	$ –
Expenses:		
Research & development	17,230	17,136
General & administrative	7,864	8,392
Total expenses	25,094	25,528
Operating loss	(24,512)	(25,528)
Change in fair value of common stock warrant liability	3,560	6,422
Other income / (expense):		
Interest and other income	13	288
Interest and other expense	(26)	(357)
Other income / (expense), net	(13)	(69)
Net loss	$ (20,965)	$ (19,175)
Net loss per common share - basic and diluted	$ (0.93)	$ (1.65)
Weighted average number of common shares outstanding - basic and diluted	22,660	11,602

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity
For Years Ended December 31, 2011 and 2010
(In thousands)

	Common Stock		Additional Paid-in	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Deficit	Shares	Amount	Total
Balance – January 1, 2010	**8,446**	**$ 8**	**$ 361,622**	**$ (357,280)**	**(21)**	**$ (3,054)**	**$ 1,296**
Comprehensive loss:							
Net loss	–	–	–	(19,175)	–	–	(19,175)
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**
Comprehensive loss:							
Net loss	–	–	–	(20,965)	–	–	(20,965)
Total comprehensive loss	–	–	–	–	–	–	(20,965)
Issuance of common stock, restricted stock awards	1	–	–	–	–	–	–
Issuance of common stock, 401(k) employer match	265	–	497	–	–	–	497
Issuance of common stock, February 2011 financing	10,000	10	13,513	–	–	–	13,523
Issuance of common stock, CEFF financings	515	1	1,315	–	–	–	1,316
Stock-based compensation expense	–	–	867	–	–	–	867
Balance – December 31, 2011	**24,603**	**$ 25**	**$ 401,713**	**$ (397,420)**	**(21)**	**$ (3,054)**	**$ 1,264**

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31, 2011	2010
Cash flow from operating activities:		
Net loss	$ (20,965)	$ (19,175)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,234	1,549
Stock–based compensation and 401(k) match	1,364	1,634
Fair value adjustment of common stock warrants	(3,560)	(6,422)
Loss / (gain) on sale of equipment	45	(16)
Changes in:		
Prepaid expenses and other current assets	(157)	(52)
Accounts payable	(574)	391
Accrued expenses	(314)	(166)
Other assets	174	4
Other liabilities and accrued interest on loan payable	55	(2,017)
Net cash used in operating activities	(22,698)	(24,270)
Cash flow from investing activities:		
Purchase of property and equipment	(106)	(101)
Net cash used in investing activities	(106)	(101)
Cash flow from financing activities:		
Proceeds from issuance of securities, net of expenses	22,927	27,977
Principal payments of loan payable	-	(8,500)
Principal payments under equipment loan and capital lease obligations	(145)	(636)
Net cash provided by financing activities	22,782	18,841
Net decrease in cash and cash equivalents	(22)	(5,530)
Cash and cash equivalents – beginning of year	10,211	15,741
Cash and cash equivalents – end of year	$ 10,189	$ 10,211
Supplementary disclosure of cash flows information:		
Interest paid	$ 20	$ 2,123
Non-cash transactions:		
Equipment acquired through capitalized lease	$ -	$ 48

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 specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug 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. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of inhaled therapies, including our aerosolized KL_4 surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We are implementing a plan that, if successful, is intended to result in the commercial introduction of SURFAXIN in the United States in the fourth quarter of 2012.

Our strategy is initially to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of RDS in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs, beginning with SURFAXIN and, if approved, SURFAXIN LS™ and AEROSURF®, have the potential to greatly improve the management of RDS and, collectively over time, to become the global standard of care for premature infants with RDS.

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing SURFAXIN LS with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States, the European Union and other major markets worldwide. AEROSURF is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG) and our novel AFECTAIR® ventilator circuit / patient interface connectors. We are developing AEROSURF for premature infants with or at risk of RDS. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. As a consequence, neonatologists will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. For this reason, we believe that AEROSURF, if approved, potentially may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but are currently not treated.

AFECTAIR, a series of disposable ventilator circuit / patient interface connectors, was initially developed for use in the NICU as part of our AEROSURF development program. AFECTAIR devices simplify the delivery of inhaled therapies (including our aerosolized KL_4 surfactant) to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. We initially developed a ventilator circuit / patient interface connector to be used with our CAG in the NICU. To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, we are developing AFECTAIR devices in different sizes for use in NICUs, pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. In February 2012, we successfully registered our initial AFECTAIR device, which is intended for use with jet nebulizers and other aerosol generators, in the United States as a Class I, exempt medical device. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients. We are implementing a regulatory and manufacturing plan that, if successful, is intended to result in the commercial introduction of the initial AFECTAIR device in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR DUO, in mid-2013.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

We are preparing for the commercial introductions, beginning in late 2012, of SURFAXIN in the United States, and AFECTAIR in the United States and the European Union and other markets worldwide thereafter. To accomplish our objectives, in the United States, we plan to build our own, in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN. We also expect that our commercial and medical affairs organization will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN to efficiently support the introductions of SURFAXIN LS and AEROSURF, if approved. We also expect that our in-house organization will also work in a coordinated manner with a network of third-party distributors to execute the commercial introduction of the AFECTAIR devices.

In major markets outside the United States, an important priority is to secure the strategic resources to support the continued development and commercial introduction of our RDS products. A key goal for us in 2012 is to secure one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF development programs, and, if approved, to support the commercial introduction of these products in Europe and elsewhere. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other similar transaction.

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 a series of Committed Equity Financing Facilities (CEFFs), capital equipment and debt facilities, and strategic alliances. We expect to fund our business operations primarily through a combination, or all, of public offerings, including our CEFF and At-the-Market (ATM) Program (*see*, Note 10); anticipated revenue from the commercial introduction of SURFAXIN® and AFECTAIR®; strategic alliances; the exercise of outstanding warrants; and debt facilities.

Our future capital requirements depend upon many factors, primarily the success of our efforts (i) to execute the commercial introduction of SURFAXIN and AFECTAIR in the United States and other markets, as planned, (ii) to secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of SURFAXIN LS™ and AEROSURF® in the European Union and markets outside the U.S., (iii) to advance the SURFAXIN LS and AEROSURF development programs to be in a position to initiate planned Phase 3 and Phase 2 clinical trials, respectively, and (iv) to procure the additional capital necessary and desirable to support our activities until such time as the net revenues from our approved products, from potential strategic alliance and other collaboration arrangements and from other sources, such as future warrant exercises, are sufficient to offset cash flow requirements.

As of December 31, 2011, we had cash and cash equivalents of $10.2 million. From January 1, 2012 through March 21, 2012, (i) holders of 15-month warrants we issued in February 2011 have exercised warrants to purchase 2,233,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million; and (ii) holders of the five-year warrants we issued in February 2011 have exercised warrants to purchase 46,250 shares of our common stock at an exercise price of $3.20 per share, resulting in proceeds to us of $148,000. In addition, on March 7, 2012, we delivered a sales notice under our ATM Program to sell shares of common stock. We terminated the offering on March 8, 2012. As a result of that offering, we issued an aggregate 350,374 shares of common stock at an aggregate purchase price of approximately $1.56 million, resulting in net proceeds to us of approximately $1.52 million, after deducting commissions due to the sales agent. On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock for net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of common stock at a public offering price of $2.80 per share, with respect to which we potentially could realize additional net proceeds to us of $6.3 million.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

As of December 31, 2011 and March 21, 2012, of the 100 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 56.5 million and 40.0 million shares of common stock, respectively.

To execute our business strategy over time, we anticipate potentially securing additional infusions of capital from a combination of some or all of the following sources:

Exercise of outstanding warrants:

- In connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (15-month warrants) of which 2,233,000 warrants have been exercised through March 21, 2012. If the market price of our common stock should exceed $2.94 at any time prior to May 2012 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the 15-month warrants and we have an effective registration statement covering the warrant shares, we potentially could raise up to an additional $8.1 million.

- Also in connection with the February 2011 public offering, we issued five-year warrants to purchase five million shares of our common stock at an exercise price of $3.20 per share (2011 five-year warrants). These warrants also contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price. As a result of the March 2012 public offering, the exercise price of these warrants has been adjusted downward to $2.80 per share. Thus, if the market price of our common stock should remain above $2.80 at any time prior February 2016 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the five-year warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants, we potentially could raise up to an additional $13.9 million.

Upfront and milestone payments and co-funding of development activities associated with potential strategic alliances or other similar transactions:

- We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the development of SURFAXIN LS and AEROSURF and, if approved, the introduction of these products in Europe and various markets outside the U.S.

Secured debt arrangements to fund working capital and/or investment in capital assets:

- In the future, if our efforts are successful, we believe that debt could potentially be a component of our capital structure and financing plans. We could potentially enter into capital equipment financing facilities, revolving working capital lines of credit, term loans and other similar transactions to satisfy our working capital requirements.

In appropriate circumstances, to secure additional capital and strengthen our financial condition, we will also consider equity public offerings and other financing transactions:

- We have a CEFF with Kingsbridge Capital Ltd. (Kingsbridge) that could allow us, at our discretion, to raise capital (subject to certain conditions, including volume limitations) at a time and in amounts we deem suitable to support our business plans. Based on the closing market price of our common stock on March 21, 2012 ($2.80) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.8 million. *See*, Note 10.

- In December 2011, we established an “at-the-market” program (ATM Program), which allows us, at our discretion and at such times that we may choose, to sell up to a maximum of $15 million of shares of common stock. Based on the closing market price of our common stock on March 21, 2012 ($2.80), and assuming that the full amount available under the ATM Program ($13.4 million) is sold, we may issue up to approximately 4.8 million additional shares under the ATM Program. See, “– Financings Pursuant to Common Stock Offerings.”

- We have agreed in connection with our March 2012 public offering that we will not issue or sell (with certain limited exceptions) securities for a period of 90 days ending in June 2012. See, "- Financings Pursuant to Common Stock Offerings."

There can be no assurance that the market price of our common stock will remain at levels that make exercise of outstanding warrants likely or that holders of outstanding warrants will choose to exercise any or all of their warrants prior to the warrant expiration date; that we will be successful in concluding any strategic alliance, collaboration or other financing transaction; that the CEFF will be available at any time, or, even if available, that we will utilize the CEFF prior to its expiration in June 2013; that we will issue any shares pursuant to the ATM Program, or that the entire amount provided under the ATM Program will be realized prior the expiration or earlier termination of the ATM Program; or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

We believe, if we are successful in implementing our strategic business plan, that the anticipated net revenues from the sale of SURFAXIN and AFECTAIR, when combined with the other sources of anticipated capital outlined above, including from potential strategic alliances and collaboration arrangements to support the SURFAXIN LS and AEROSURF development programs, potentially could be sufficient to support our future operations. In that event, we would nevertheless continue to consider financings and similar transactions that would strengthen our financial condition and build value for our stockholders.

Although we currently believe that we will be successful in meeting our strategic planning goals within the time frame set forth above, there can be no assurance that we will successfully fund and build our own commercial organization to support the commercial introduction of SURFAXIN and AFECTAIR; that we will successfully execute the launch of SURFAXIN and AFECTAIR within the anticipated time frame; that the revenues we may realize from the sale of SURFAXIN and AFECTAIR will be in line with current expectations; that we will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of the SURFAXIN LS and AEROSURF product candidates; or that the revenues, if any, that we generate in the future will be sufficient at any time to fund the further development of our research and development programs and support our operations. If we are unable to identify and enter into strategic alliances for the development of SURFAXIN LS and AEROSURF, and if approved, commercialization of SURFAXIN LS and AEROSURF in the European Union and other markets outside the U.S., we may be unable to fund planned clinical trials, which would have a material adverse effect on our research and development programs.

Note 3 – Accounting Policies and Recent Accounting Pronouncements

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

Consolidation

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

Use of estimates

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

Cash and cash equivalents

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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents and restricted cash. The fair values of our cash equivalents are based on quoted market prices. The carrying amount of cash equivalents is equal to their respective fair values at December 31, 2011 and December 31, 2010. 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, 2011 and 2010, as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Grant Revenue

We recognize grant revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured. For the year ended December 31, 2011, grant revenue represents funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL_4 surfactant for RDS. The amount of the award was approximately $582,000 and the grant revenue was recognized in the period in which the related expenditures were incurred. For the year ended December 31, 2010, we received grant proceeds, recorded as other income, of $244,480 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.

Research and development

Research and development costs consist primarily of expenses associated with our personnel, facilities, manufacturing operations, pharmaceutical and device 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 Topic 718 *"Stock Compensation"* (ASC Topic 718). *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 Accounting Standards Codification Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. We classify 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 or trinomial pricing models, depending on the applicable terms of the warrant agreement, to value the derivative warrant liabilities. 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." *See*, Note 8 – Common Stock Warrant Liability, for a detailed description of our accounting for derivative warrant liabilities.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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. Because we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

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, 2011 and 2010, 15.4 million and 5.3 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.

Concentration of Suppliers

We currently obtain the active ingredients of our KL4 surfactant drug products from single-source suppliers. The loss of one or more of these suppliers could have a material adverse effect upon our operations.

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 May 2011, the FASB amended the accounting guidance for fair value to develop common requirements between U.S. Generally Accepted Accounting Principles and International Financial Reporting Standards. The amendments, which are effective for interim and annual periods beginning after December 15, 2011, require entities to (i) provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements, and (ii) provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In June 2011, the FASB issued accounting guidance related to the presentation of comprehensive income. The guidance, which is effective for interim and annual periods beginning after December 15, 2011, require entities to present all components of comprehensive income in either (i) a single continuous statement of comprehensive income or (ii) in a statement of net income and statement of other comprehensive income. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

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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 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, 2011 and 2010:

(in thousands)	Fair Value December 31, 2011	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money markets	$ 9,377	$ 9,377	$ –	$ –
Certificate of deposit	400	400	–	–
Total Assets	$ 9,777	$ 9,777	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 6,996	$ $ –	$ –	$ 6,996

(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

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

The following table summarizes the activity of Level 3 inputs measured on a recurring basis for the year ended December 31, 2011:
(in thousands)

	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2010	$ 2,469
Issuance of common stock warrants	8,087
Change in fair value of common stock warrant liability	(3,560)
Balance at December 31, 2011	$ 6,996

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 13 – Commitments, for further discussion on our leases). Under terms of the lease agreement the required restricted cash balance as of December 31, 2011 and 2010 was $400,000, 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, 2011 and 2010 was comprised of the following:

(in thousands)	December 31, 2011	2010
Equipment	$ 7,428	$ 7,418
Furniture	815	801
Leasehold improvements	2,875	2,838
Subtotal	11,118	11,057
Accumulated depreciation and amortization	(8,825)	(7,590)
Property and equipment, net	$ 2,293	$ 3,467

Equipment primarily consists of: (i) manufacturing equipment to produce our KL4 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 commercial drug product supply. We also perform development work with respect to our aerosolized and lyophilized dosage forms of our KL4 surfactant. 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, 2011 and 2010 was $1.3 million and $1.4 million, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 7 – Accrued Expenses

Accrued expenses as of December 31, 2011 and 2010 were comprised of the following:

(in thousands)	December 31, 2011	December 31, 2010
Accrued compensation [1]	$ 957	$ 760
Accrued manufacturing	917	796
Accrued research and development	461	689
Accrued accounting and legal fees	315	395
All other accrued expenses	322	646
Total accrued expenses	$ 2,972	$ 3,286

(1) Accrued compensation primarily consists of employee incentive arrangements (pursuant to plans approved by our Board) and employees' unused earned vacation. As of December 31, 2011, accrued compensation also included contractual severance arrangements for our former Executive Vice President and General Counsel (*See*, Note 13 – Commitments).

Note 8 – Common Stock Warrant Liability

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

The registered warrants that we issued in our May 2009 and February 2010 public offerings generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, under generally accepted accounting principles, these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under the federal securities laws, it may not be within our absolute control to provide freely-tradable shares upon exercise of the warrants in all circumstances, and (ii) the warrant agreements do not expressly state that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that an event would result in a cash settlement. Accordingly, the May 2009 and February 2010 warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option pricing model.

The registered five-year warrants that we issued in the February 2011 public offering (February 2011 five-year warrants) expressly provide that under no circumstances will we be required to effect a net cash settlement of these warrants. However, these warrants contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 five-year warrants. Due to the nature of the anti-dilution provisions, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Selected terms and estimated fair value of warrants accounted for as derivative liabilities at December 31, 2011 and 2010 are as follows:

Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands) Value at Issuance Date	December 31, 2011	December 31, 2010
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ 82	$ 782
2/23/2010	916,669	12.75	2/23/2015	5,701	554	1,687
2/22/2011	5,000,000	3.20	2/22/2016	8,087	6,360	
					$ 6,996	$ 2,469

Changes in the estimated fair value of warrants classified as derivative liabilities are reported in the accompanying Consolidated Statement of Operations as the "Change in fair value of common stock warrants."

Note 9 – Debt

Equipment Loans

Our equipment loan liabilities as of December 31, 2011 and 2010 are as follows:

(in thousands)	**2011**	**2010**
Pennsylvania Machinery and Equipment Loan		
Short-term	$ 66	$ 63
Long-term	224	296
Total	290	359
Capitalized Leases		
Short-term	2	22
Long-term	–	5
Total	2	27
GE Business Financial Services, Inc.		
Short-term	–	51
Long-term	–	–
Total	–	51
Total Short-term	68	136
Total Long-term	224	301
Total	$ 292	$ 437

For the years ended December 31, 2011 and 2010, we incurred interest expense associated with our equipment loans of $20,000 and $56,000, respectively.

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 Loan requires us to meet certain job retention and job creation goals in Pennsylvania within a three-year period (Jobs Covenant). If we fail to comply with the Jobs Covenant, the Department, in its discretion, may change the interest rate on the Promissory Note to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term. As of September 30, 2011, the end of the three-year Jobs Covenant period, due to our efforts to conserve resources while we focused on securing approval for SURFAXIN®, we had not complied with the Jobs Covenant. In response to a request that we filed with the Department for a waiver, the Department granted us an extension through August 31, 2012 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

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. (GE, formerly Merrill Lynch Business Financial Services Inc), 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. As of December 31, 2011, all outstanding amounts under the Facility were paid in full and all related security interests satisfied and released. Advances to finance the acquisition of property and equipment were amortized over a period of 36 months and all other equipment and related costs were 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 accrued at a fixed rate per annum equal to one-month LIBOR plus 6.25%, determined on the funding date of such advance.

Loan Payable – PharmaBio Development Inc.

On April 28, 2010, we restructured our $10.6 million loan with PharmaBio Development Inc (Pharma Bio), the former strategic investment subsidiary of Quintiles Transnational Corp. 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. All related security interests satisfied and released. 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 year ended December 31, 2010, we incurred interest expense associated with the PharmaBio loan of $0.3 million. Interest expense for the year ended December 31, 2010 included $0.2 million, of amortization of deferred financing costs for warrants issued to PharmaBio in 2006 in consideration for restructuring the loan.

Note 10 – Stockholders' Equity

Registered Public Offerings and Private Placements

On February 22, 2011, we completed a registered public offering of 10 million shares of our common stock, 15-month warrants to purchase five million shares of our common stock, and five-year warrants to purchase five million shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a 15-month warrant to purchase one half share of common stock, and a five-year 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 15-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 were initially exercisable at a price per share of $3.20. The exercise price of the five-year warrants is 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. In connection with the closing of our public offering on March 21, 2012, the exercise price of the five-year warrants has been adjusted downward to a price per share of $2.80. *See*, Note 17 – Subsequent Events.

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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.

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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Committed Equity Financing Facility (CEFF)

Since 2004, we have maintained one or more 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 have allowed us, at our discretion, to raise capital, at the time and in amounts deemed suitable to us, to support our business plans. We are not obligated to utilize any of the funds available under any CEFF and our ability to access funds at any time is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2011, we had one CEFF dated June 11, 2010 (2010 CEFF). Two prior CEFF agreements, dated May 22, 2008 (May 2008 CEFF) and December 12, 2008 (December 2008 CEFF), expired in June 2011 and February 2011, respectively.

2010 CEFF

The 2010 CEFF related Stock Purchase Agreement originally provided for up to 2.1 million shares, up to a maximum of $35 million, and expires in June 2013. As of December 31, 2011, there were 1.1 million shares remaining under 2010 CEFF, up to a maximum of $32.3 million. The shares issuable under the 2010 CEFF are registered under the 2011 Universal Shelf. *See*, this Note – Universal Shelf Registration Statements.

Each draw down extends for an eight-day trading period. To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day must be at least equal to $0.20 per share. If on any trading day during the trading period, if the daily volume-weighted average price of our common stock (VWAP) is less than the Threshold Price (defined below), Kingsbridge has the right to purchase shares at the Threshold Price; otherwise 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. The 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. Unless Kingsbridge and we 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.

With respect to each draw down, Kingsbridge is obligated to purchase ("Obligated Amount") the amount determined under one of two methodologies that we choose at our discretion, subject to a maximum 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.

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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 additional amount over the calculated 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 2010 CEFF is at a discount to the VWAP (as defined in the agreement) for each of the trading days in the draw down period as follows:

Daily VWAP	% of VWAP	Applicable Discount
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 2010 CEFF 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 2010 CEFF 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 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 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 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 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. This warrant expired unexercised 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. This warrant expired unexercised in January 2010.

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CEFF Financings

Financings that we completed under the 2010 CEFF are as follows:

(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
October 10, 2011	35	69	1.97
October 24, 2011	37	63	1.71
November 8, 2011	129	218	1.69
	1,032	$ 2,746	

There were no financings under the May 2008 CEFF or December 2008 CEFF during 2010 and 2011.

ATM Program

On December 14, 2011, we entered into a Sales Agency Agreement (Agency Agreement) with Lazard Capital Markets LLC (Lazard), under which Lazard, as our exclusive agent, may, at our discretion and at such times that we may determine from time to time, sell over a two year period up to a maximum of $15,000,000 of shares of our common stock (Shares) through an “at-the-market” program (ATM Program). We are not required to sell any Shares at any time during the term of the ATM Program.

If we issue a sale notice to Lazard, we may designate the minimum price per share at which Shares may be sold and the maximum number of Shares that Lazard is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Lazard may sell the Shares by any method deemed to be an “at-the-market” equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers’ transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Lazard and us. Either party may suspend sales under Agency Agreement by notice to the other party.

The Agency Agreement will terminate upon the earliest of: (1) the sale of all Shares subject to Agency Agreement, (2) December 14, 2013 or (3) the earlier termination of Agency Agreement in accordance with its terms. Either party may terminate Agency Agreement at any time upon written notification to the other party. We have agreed to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales of Shares. We also agreed to reimburse Lazard for certain expenses incurred in connection with entering into Agency Agreement and have provided Lazard with customary representations and warranties, and indemnification rights.

The Shares to be issued under the ATM Program have been registered pursuant to a prospectus supplement dated December 14, 2011 to our 2011 Universal Shelf. *See*, Note 17 – Subsequent Events.

As of December 31, 2011, $15.0 million remained available under the ATM Program.

ATM Financings

On March 12, 2012, we completed an offering of 350,374 shares of our common stock for an aggregate purchase price of approximately $1.56 million, resulting in net proceeds to us of approximately $1.52 million, after deducting commissions due to Lazard under the Sales Agency Agreement.

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401(k) Employer Match

We have a voluntary 401(k) savings plan covering eligible employees that allows for periodic discretionary company matches equal to a percentage of each participant's contributions (up to the maximum deduction allowed, excluding "catch up" amounts). We provide for the company match in the form of newly-issued shares of common stock, which are registered pursuant to a registration statement filed with the U.S. Securities and Exchange Commission (SEC) on Form S-8. For the years ended December 31, 2011 and 2010, the match resulted in the issuance of 265,185 and 61,158, 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, 2011	December 31, 2010	Exercise Price	Expiration Date
Former Employee Warrant	30	-	$ 3.20	3/18/2016
Investor Warrants – February 2011 Financing	5,000	-	$ 3.20	2/22/2016
Investor Warrants – February 2011 Financing	5,000	-	$ 2.94	5/22/2012
PharmaBio – October 2010 Financing	79	79	$ 4.10	10/13/2015
Investor Warrants – June 2010 Financing	1,190	1,190	$ 4.20	6/22/2015
Investor Warrants – June 2010 Financing	-	1,190	$ 6.00	3/22/2011
Kingsbridge – 2010 CEFF	83	83	$ 6.69	12/11/2015
PharmaBio – April 2010 Financing	135	135	$ 10.59	4/30/2015
Investor Warrants – February 2010 Financing	917	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	$ 47.70	11/22/2011
Class C Investor Warrants – 2006 CEFF	-	33	$ 84.29	10/17/2011
Total	13,001	4,348		

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

In October 2011, our stockholders approved the adoption of the 2011 Equity Incentive Plan (the 2011 Plan). The 2011 Plan provides for the grant of long-term equity and cash incentive compensation awards and replaces the 2007 Long-Term Incentive Plan (the 2007 Plan). The 2011 Plan continues many of the features of the 2007 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 2007 and 1998 Plan will continue to be governed by the terms of the respective plans and the agreements under which they were granted, although any shares returnable to the 2007 Plan as a result of cancellations, expirations and forfeitures will be returned to, and become available for issuance under, the 2011 Plan.

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Stock options and awards outstanding and available for future issuance as of December 31, 2011 and 2010 are as follows:

(in thousands)	As of December 31, 2011	2010
2011 Plan[1]		
Outstanding	1,709	–
Available for Future Grants	2,106	–
Total	3,815	–
2007 Plan		
Outstanding	297	564
Available for Future Grants	–	3
Total	297	567
1998 Plan		
Outstanding	432	533
Available for Future Grants	–	–
Total	432	533
Total Outstanding	2,438	1,097
Total Available for Future Grants	2,106	3
Total	4,544	1,100

(1) See, Note 11 – Stock Options and Stock-based Employee Compensation – Long-Term Incentive Plans.

Universal Shelf Registration Statements

2011 Universal Shelf

In June 2011, we filed a universal shelf registration statement on Form S-3 (No. 333-174786) (2011 Universal Shelf) with the SEC for the proposed offering from time to time of up to $200 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. The 2011 Universal Shelf was declared effective by the SEC on June 21, 2011. As of December 31, 2011, $199.7 million remained unissued under the 2011 Universal Shelf.

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. Upon effectiveness of the 2011 Universal Shelf, the 2008 Universal Shelf expired. *See*, in this note – Registered Public Offering and Private Placements, for offerings made pursuant to the 2008 Universal Shelf.

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Common shares reserved for potential future issuance under CEFF arrangements

Common shares reserved for potential future financings under our CEFF arrangements are as follows:

(in thousands)		Potential future issuance as of December 31,	
	Expiration	**2011**	**2010**
2010 CEFF	June 11, 2013	1,074	1,589
May 2008 CEFF	June 18, 2011	-	851
December 2008 CEFF	February 6, 2011	-	475

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

As of December 31, 2011 and 2010, we had 342,833 and 58,018 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 October 2011, our stockholders approved the 2011 Plan, which replaced the 2007 Plan. *See*, Note 10 – Common shares reserved for potential future issuance upon exercise of stock options or granting of additional equity incentive awards. The purpose of the 2011 Plan is 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. The 2011 Plan continues many of the features of the 2007 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 2007 Plan and 1998 Plan continue to be governed by the terms of that plan and the applicable award agreements.

Under the 2011 Plan, we may grant awards for up to 3.7 million shares of our common stock. Additionally, any shares returnable to the 2007 Plan as a result of cancellations, expirations and forfeitures will become available for issuance under the 2011 Plan. As of December 31, 2011, under the 2011 Plan, awards with respect to 1,709,000 shares are outstanding, 114,721 shares have been made available for issuance from the 2007 Plan and 2,105,721 shares are available for grant. An administrative committee (the Committee – currently the Compensation Committee of the Board of Directors) or Committee delegates may determine the types, the number of shares covered by, and the terms and conditions of, such awards. Eligible participants may include any of our employees, directors, advisors or consultants.

Awards under the 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, awards under the 2011 Plan must comply with the provisions of Section 162(m) of the Internal Revenue Code.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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.

Dividend Equivalents

The Committee may grant dividend equivalent awards that entitle the participant receiving such award the right to receive payments equivalent to dividends or interest with respect to the number of shares and on the terms as determined by the Committee. The Committee may provide that the amounts (if any) of such awards will be deemed to have been reinvested in additional shares or otherwise reinvested.

No SARs, Performance Awards or Dividend Equivalents have been granted under any 2011 Plan. During 2010, there were 154,333 RSAs granted under the 2007 Plan. The RSA's granted to non-officer employees vested on the first anniversary of the grant date. The RSA's granted to officers provided for vesting on the earliest of (i) the second anniversary of the grant date; (ii) FDA marketing approval for SURFAXIN®; or (iii) the effective date of a strategic alliance or collaboration agreement as determined by the Board of Directors. These RSAs vested on March 6, 2012 upon the issuance of FDA marketing approval for SURFAXIN. As of December 31, 2011 and 2010, there were 128,334 and 154,333 unvested restricted stock awards outstanding, respectively.

A summary of stock option activity under our long-term incentive plans during the periods ended December 31, 2011 and 2010, respectively, is presented below:

(in thousands, except for weighted-average data)

Stock Options	Price Per Share (range)	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
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	
Granted	$ 1.58 – $3.41	1,771	$ 1.84	
Exercised	–	–	–	
Forfeited or expired	$ 1.83 – $137.55	(276)	$ 44.95	
Outstanding at December 31, 2011	$ 1.58 – $156.45	2,438	$ 17.97	8.1
Exercisable at December 31, 2011	$ 2.55 – $156.45	667	$ 60.73	4.2

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, 2011 and 2010 was $1.45 and $2.48, respectively. There were no options exercised during the years ended December 31, 2011 and 2010, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2011 is $1,155, $0 and $0, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

A summary of nonvested shares issuable upon exercise of outstanding options and changes during 2011 is presented below:

(shares in thousands)	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2010	64	$ 10.05
Granted	1,771	1.84
Vested	(59)	10.86
Forfeited	(5)	7.43
Non-vested at December 31, 2011	1,771	$ 1.85

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2011:

(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
$ 1.58 - $3.60	1,783	$ 1.85	9.58 Years	13	$ 3.08	8.84 Years
$ 3.61 – $10.95	12	$ 9.69	6.66 Years	12	$ 9.73	7.85 Years
$ 10.96 – $156.45	643	$ 62.78	4.05 Years	642	$ 62.87	4.21 Years
	2,438			667		

Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2011 and 2010, of $0.9 million and $1.4 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2011	2010
Research and development	$ 289	$ 479
General and administrative	578	931
Total	$ 867	$ 1,410

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.

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	December 31, 2011	2010
Weighted average expected volatility	113%	112%
Weighted average expected term	4.8 years	4.9 years
Weighted average risk-free interest rate	1.08%	1.47%
Expected dividends	–	–

The total fair value of the underlying shares of the options vested during 2011 and 2010, equals $0.6 million and $1.5 million, respectively. As of December 31, 2011, there was $2.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.7 years.

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 KL4 surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Esteve will pay us a transfer price on sales of our KL4 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, in consideration of Esteve returning commercialization rights in portions of the territory originally licensed to Esteve, including key European markets and Latin America (Former Esteve Territories), we agreed to pay to Esteve 10% of any cash up front and milestone fees (up to a maximum of $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 KL4 surfactant products 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 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 (J&J) and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, are parties to a license agreement granting to us an exclusive worldwide license to the proprietary KL4 surfactant technology, including SURFAXIN®. Under the license agreement, we are obligated to pay 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 in the range of 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.

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Note 13 – Commitments

Future payments due under contractual obligations at December 31, 2011 are as follows:

(in thousands)	2012	2013	2014	2015	2016	There-after	Total
Equipment loan obligations [1]	$ 80	$ 85	$ 85	$ 71	$ –	–	$ 321
Operating lease obligations	1,166	320	150	–	–	–	1,636
Former Exec. VP Severance Commitment	435	–	–	–	–	–	435
Total	$ 1,681	$ 405	$ 235	$ 71	$ –	$ –	$ 2,392

[1] *See*, Note 9 – Debt.

Operating Leases

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 operations in Totowa, New Jersey, at an annual rent of $150,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. This lease expires in December 2014, subject to the landlord's right, in certain circumstances and upon two years' prior notice, to terminate the lease early. In addition, depending upon the timing of the notice, if we satisfy certain financial conditions at the time, 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 that expires on December 3, 2012. 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, 2011 and 2010 was $1.0 million and $1.0 million, respectively.

Severance Arrangement

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement ("Separation Agreement") with our former, Executive Vice President, General Counsel and Corporate Secretary (Former Executive). Pursuant to the Separation Agreement, the Former Executive resigned his positions with us effective July 31, 2011, and was entitled to (i) payment of accrued vacation pay, (ii) the right to continue to hold a restricted stock award for 15,000 shares (RSA) without any continuing Service (as defined in the RSA) requirement, (iii) extended health benefits for up to 18 months, and, (iv) depending on the circumstances, certain outplacement services. In addition, we agreed to pay the Former Executive on February 1, 2012 severance in the amount of $400,000, which amount was reduced by any outstanding amount due under a promissory note that the Former Executive had issued to us in 2001. As of December 31, 2011, the outstanding aggregate principal amount of the Note was $169,958. The Separation Agreement also contains a general release of claims by the parties and a 12-month non-competition covenant by the Former Executive.

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Note 14 – Litigation

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

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

Note 15 – Income Taxes

Since our inception, we have never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to our recorded tax benefit for the years ended December 31, 2011 and 2010 is as follows:

(in thousands)	December 31, 2011	December 31, 2010
Income tax benefit, statutory rates	$ 7,128	$ 6,519
State taxes on income, net of Federal benefit	1,633	1,206
Research and development tax credit	662	656
Employee Related	(1,758)	(4,746)
Warrant Valuation Related	1,210	2,184
Other	–	18
Income tax benefit	8,875	5,837
Valuation allowance	(8,875)	(5,837)
Income tax benefit	$ –	$ –

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The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2011 and 2010, are as follows:

(in thousands)	December 31, 2011	December 31, 2010
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 147,045	$ 132,994
Research and development tax credits	9,080	8,447
Compensation expense on stock	3,535	5,126
Charitable contribution carryforward	7	7
Other accrued	608	607
Depreciation	2,682	2,493
Capitalized research and development	1,740	1,932
Total long-term deferred tax assets	164,697	151,606
Long-term deferred tax liabilities	–	–
Net deferred tax assets	164,697	151,606
Less: valuation allowance	(164,697)	(151,606)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2011 and 2010 before the consideration of a valuation allowance. Because we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

At December 31, 2011 and 2010, we had available carryforward net operating losses for Federal tax purposes of $363.3 million and $329.7 million, respectively, and a research and development tax credit carryforward of $9.1 million and $8.4 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2031. Approximately $3.1 million of the $363.3 million net operating loss carryforwards expire prior to 2013.

At December 31, 2011, 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, 2011 and 2010, we had available carryforward losses of approximately $360.1 million and $319.9 million, respectively, for state tax purposes. Of the $360.1 million state tax carryforward losses, $325.6 million is associated with the state of Pennsylvania, with the remainder associated with New Jersey and California.

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.

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Note 16 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2011 and 2010. The operating results for any quarter are not necessarily indicative of results for any future period.

2011 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Grant Revenues	$ 381	$ 201	$ –	$ –	$ 582
Expenses:					
Research and development	4,620	4,615	3,981	4,014	17,230
General and administrative	1,820	1,966	2,189	1,889	7,864
Total expenses	6,440	6,581	6,170	5,903	25,094
Operating loss	(6,059)	(6,380)	(6,170)	(5,903)	(24,512)
Change in fair value of common stock warrant liability	2,228	(1,693)	1,422	1,603	3,560
Other expense, net	(6)	(3)	(3)	(1)	(13)
Net loss	$ (3,837)	$ (8,076)	$ (4,751)	$ (4,301)	$ (20,965)
Net loss per common share - basic and diluted	$ (0.21)	$ (0.34)	$ (0.20)	$ (0.18)	$ (0.93)
Weighted average number of common shares outstanding	18,114	24,027	24,106	24,309	22,660

2010 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Grant 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

Note 17 – Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2011 up through the date we issued these financial statements. During this period we did not have any material recognized subsequent events, however, there were four nonrecognized subsequent events described below:

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From January 1, 2012 through March 21, 2012, (i) holders of 15-month warrants we issued in February 2011 have exercised warrants to purchase 2,233,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million; and (ii) holders of the five-year warrants we issued in February 2011 have exercised warrants to purchase 46,250 shares of our common stock at an exercise price of $3.20 per share, resulting in proceeds to us of $148,000.

On March 12, 2012, we completed an offering under out ATM Program of 350,374 shares of our common stock for an aggregate purchase price of approximately $1.56 million, resulting in net proceeds to us of approximately $1.52 million, after deducting commissions due to Lazard under the Sales Agency Agreement.

On March 21, 2012, we completed a registered public offering of 16,071,429 shares of our common stock, at a price of $2.80 per share resulting in gross proceeds of $45.0 million ($42.1 million net). In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of common stock at a public offering price of $2.80 per share, with respect to which we potentially could realize additional net proceeds to us of $6.3 million.

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. 333-156237, and Form S-3 No. 333-174786) 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, Form S-8 No. 333-169662, and Form S-8 No. 333-173259) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our report dated March 30, 2012, 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, 2011.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 30, 2012

Exhibit 31.1

CERTIFICATIONS

I, W. Thomas Amick, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2012

/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 30, 2012

/s/ John G. Cooper
John G. Cooper
President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 (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 30, 2012

/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.