2012 Annual Report

April 30, 2013

Dear Stockholders:

2012 was a pivotal year for Discovery Labs. The Food and Drug Administration (FDA) approved SURFAXIN® and we registered our AFECTAIR® device with the FDA. We also made significant progress in our development activities for AEROSURF® and remain on plan to initiate our phase 2 clinical program in the fourth quarter of 2013.

Despite our progress, we also faced many challenges in 2012 and, in the process, learned a lot about our vision, our Company and ourselves. Here are some of our key takeaways:

- **The RDS market remains underserved** – In a market that has remained relatively unchanged for the better part of two decades, neonatologists are seeking innovative alternatives for their fragile patients with or at risk for respiratory distress syndrome (RDS). SURFAXIN is now the first synthetic, peptide-containing surfactant to be approved by the FDA in the U.S. AEROSURF is our innovative drug/device combination product that has the potential to transform the treatment or prevention of RDS in premature infants. We have heard the neonatologists and are prepared to deliver the innovative products they are looking for.
- **Excellence must remain our first priority** – As part of an effort to consistently improve our quality assurance process, we identified an analytical method used to assess SURFAXIN that required improvement. We promptly notified the FDA and submitted updated product specifications. The result has been a delay in the launch of SURFAXIN, but notwithstanding, excellence must remain our first priority.
- **Persistence is a virtue** – In a year of much change and excitement, with many challenges, Discovery Labs – its management, employees and its Board, and its stakeholders – have remained positive and solutions-oriented, with an unwavering focus on achieving success. We are proud and appreciative of the persistence, encouragement and commitment exhibited at all levels and we are confident that, collectively, we have the ability to transform the treatment of RDS and set new standards for respiratory critical care.

OUR UNWAVERING COMMITMENT

As a specialty biotechnology company, we are committed to creating life-saving products for critical care patients with respiratory disease, beginning with products that 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 a prevalent respiratory disease in neonatal intensive care units (NICU). Our proprietary synthetic, peptide-containing (KL_4) surfactant is structurally similar to human pulmonary surfactant produced naturally in the lung, which is essential for survival. Additionally, our drug delivery technologies have the potential to enable the efficient delivery of our aerosolized KL_4 surfactant and other inhaled therapies, potentially without many of the risks normally associated with surfactant administration today.

We firmly believe in the breadth of our technologies, including AEROSURF, which has the potential to transform the treatment of RDS by providing a less invasive method to administer surfactant replacement therapy, making it potentially a viable treatment option for a significantly larger patient population. We are firmly committed to delivering these innovative products to address the persisting unmet medical needs of infants in NICUs and pediatric intensive care units (PICUs).

OUR PRODUCTS

In March 2012, the FDA granted us marketing approval for SURFAXIN for the prevention of RDS in premature infants at high risk of developing RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants, which are the standard of care in the U.S. today.

In February 2012, we registered our AFECTAIR aerosol-conducting airway connector with the FDA. AFECTAIR is designed to simplify the administration of aerosolized medication for infants in the NICU and PICU.

In 2012, we also advanced our AEROSURF development program. AEROSURF has the potential to provide practitioners with the ability to administer our aerosolized KL_4 surfactant using a less-invasive method. If approved, AEROSURF could enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but for whom the risks of administration outweigh the potential benefits. We expect to initiate our Phase 2 clinical program for AEROSURF in the fourth quarter of 2013.

These products represent innovation and potential future transformation in the management of neonates in critical care and are indicative of our commitment and perseverance.

OUR CHALLENGES

2012 was not without its challenges. In the third quarter, following a routine process review, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. As a result, the commercial introduction of SURFAXIN was delayed. Our

team quickly responded to the challenge, improved and revalidated the analytical chemistry method and submitted updated product specifications to the FDA. In April 2013, we received a further communication from the FDA requesting information and providing recommendations for the new product specifications. We are compiling the information, much of which is readily available, and will continue to communicate with the FDA to ensure our response meets its needs. We plan to submit our response by mid-June and, if the FDA agrees, we expect to manufacture SURFAXIN drug product for commercial use in the fourth quarter of 2013.

Our commitment to SURFAXIN remains unchanged and we firmly believe that it represents a significant step forward for the treatment of RDS and the first of many advancements Discovery Labs plans to bring to patients in need.

OUR UPDATED TEAM

To prepare and execute the commercial introduction of SURFAXIN and AFECTAIR in hospitals throughout the U.S., in addition to strengthening our capabilities throughout the Company, we also established our own specialty respiratory critical care commercial and medical affairs teams. We deployed these teams in the third quarter of 2012. Today they are doing the necessary work to ensure SURFAXIN meets the requirements to be included on the approved list of drugs that each hospital will purchase and to secure adoption of the AFECTAIR device for infants. They have made good progress and we continue to be impressed by the performance of these highly qualified teams.

We also have identified world class technical expertise to help us execute our product development strategy. In 2012, to prepare for AEROSURF clinical trials, we began collaborating with Battelle Memorial Institute (Battelle), the world's largest nonprofit research and development organization, with a particular expertise in developing and integrating aerosol devices using innovative and advanced technologies. Battelle is assisting us to further develop our capillary aerosol generator (CAG) for use in our planned AEROSURF clinical program. We also advanced manufacturing development of our lyophilized KL4 surfactant with a contract manufacturing organization (CMO) that has expertise in lyophilized products.

2012 also brought changes in our Board of Directors. Our newly-configured Board has significant commercial, operations, drug development and financial expertise to guide our Company through the milestones that lie ahead. Their talent and dedication is focused on a belief that our technology and products can truly represent a transformational improvement in the standard of care for infants with severe respiratory problems – and the lives of the families impacted by those problems. Our Board is fully engaged and we thank them for their willingness to invest a significant amount of their time and expertise and for their continuing support and belief in our technologies and our future.

OUR INVESTORS

We fully recognize that the creation of a significant pipeline of respiratory critical care products requires continued support from the investment community. We continue to be encouraged by the interest generated among investors in our technology and the promise of SURFAXIN, AFECTAIR and AEROSURF. In 2012, we continued to benefit from investor support and raised net proceeds of $50.3 million from a public offering in March, the exercise of warrants, and a financing under an at-the-market (ATM) program with Lazard Capital Markets, LLC. Recently, in February 2013, we established a new $25 million ATM program with Stifel Nicolaus & Company, Incorporated, and entered into a secured lending facility with Deerfield Management L.P. affiliates, a sophisticated and highly respected fund with a primary focus on healthcare, from which we could realize proceeds of up to $30 million.

OUR FUTURE

We believe Discovery Labs is poised for a bright future that will potentially deliver much needed advancements to manage premature infants at risk for RDS, as well as advancements in the broader field of respiratory critical care. Nobody said that bringing game-changing technologies to market would be easy and we are grateful to our employees and investors for not losing sight of the importance of these products or the patients they will treat. Today, we remain focused on the future and stand firm in our commitment to develop products that will revolutionize respiratory medicine. For our investors, our customers and more important, for the patients these products will treat, we will persevere.

We would like to give special thanks to our employees, many of whom have been stalwart supporters through challenging times. They have truly been outstanding and stand ready to move us into the future. We also thank our scientific and medical advisors for their continued support. Importantly, we would like to thank you, our stockholders, for your continued commitment, without which we could not proceed.

Thank you for your continued support of Discovery Labs,

John G. Cooper
President and Chief Executive Officer

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

FORM 10-K

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

None

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

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

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

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

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

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

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

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on The Nasdaq Capital Market under the symbol DSCO on June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $100 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 February 28, 2013 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of March 1, 2013, 43,660,244 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 2012 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. Forward-looking statements include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to commercialization of SURFAXIN®, the AFECTAIR®

device for infants and our products under development, if approved; our expectations, timing and outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning and development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant pipeline, our capillary aerosol generator (CAG) and aerosol-conducting airway connectors for delivery of aerosolized medications; plans for the manufacture of drug products and medical devices, including active pharmaceutical ingredients and materials thereof, 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 we will require, and be unable to raise, significant additional capital to continue our operations and our research and development activities, including our planned clinical programs. Moreover, to the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;

- the risk that we are unable for any reason to introduce, or if there is a significant delay beyond the second quarter of 2013 in the commercial introduction of, SURFAXIN and AFECTAIR in the United States (U.S.) and other markets as planned, or if we do not achieve the level of expected revenues that we have forecasted, we may be unable to secure additional capital when needed, from strategic alliances or other sources, to sustain our operations, which could have a material adverse effect on our ability to continue investments in our commercial and medical affairs activities, as well as our research and development programs and operations;

- the risk that, if we fail to successfully commercialize SURFAXIN and AFECTAIR, or if SURFAXIN and AFECTAIR do not gain market acceptance for any reason, our revenues would be limited, which ultimately could have a material adverse effect on our business, financial condition and results of 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 AEROSURF® (a drug/device combination product based on our aerosolized KL4 surfactant and our CAG technology), including the development of our lyophilized (freeze-dried) KL4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and to support the development of SURFAXIN LS™, our lyophilized dosage form of SURFAXIN, and to support the commercialization of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the United States Food and Drug Administration (FDA);

- risks relating to the ability of our sales and marketing organization to effectively market SURFAXIN and AFECTAIR in the U.S., 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 plans to secure marketing and distribution capabilities in certain markets 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 manage our growth effectively and timely modify our business strategy

as needed to respond to developments in our commercial operations and research and development activities, as well as our business, our industry and other factors;

- risks relating to our ability to manufacture our KL4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;

- the risk that we, our contract manufacturer organizations (CMOs) or any of our third-party suppliers, many of which are single-source providers, may encounter problems or delays in manufacturing our KL4 surfactant drug products, related substances used in the manufacture of our drug product, AFECTAIR aerosol-conducting airway connectors and related componentry, CAG devices and other materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants, as well as our research and development activities for our other product candidates;

- risks relating to the transfer of our manufacturing technology to CMOs and assemblers;

- 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 U.S. and elsewhere, for our drug product and medical device candidates, including AEROSURF, a drug-device combination product that we are developing to address RDS in premature infants and our KL4 lyophilized surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS; and AFECTAIR, our novel aerosol-conducting airway connectors;

- 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 among other things involve time-consuming and expensive preclinical studies and other efforts, and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds, or fail;

- risks relating to our ability to develop and manufacture drug-device combination products based on our KL4 surfactant and CAG technology for preclinical and clinical studies of our product candidates and, if approved, for commercialization;

- 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®, 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 ATM Program and Committed Equity Financing Facility (CEFF) 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 adjustments);

- risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;

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

- the risk that we will be unable to attract and retain key employees in a competitive market for skilled personnel, which could have a material adverse effect on our commercial, research and development activities and our operations;

- the risk that we or our strategic partners or collaborators will not be able to attract or retain qualified scientific, professional and other 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 device 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.

Trademark Notice
AEROSURF®, AFECTAIR®, DISCOVERYLABS®, INSPIRED INNOVATION®, SURFAXIN®, and **WARMING CRADLE®** are registered trademarks of Discovery Laboratories, Inc. (Warrington, PA).

DISCOVERY LABORATORIES, INC

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For the Fiscal Year Ended December 31, 2012

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 (KL4 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 KL4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of aerosolized drugs, including our aerosolized KL4 surfactant, and other inhaled therapies. 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.

Our initial strategy is to develop our KL4 surfactant and drug delivery technologies to improve the management of respiratory distress syndrome (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 have the potential to greatly improve the management of RDS and, collectively over time, to become a new standard of care for premature infants with RDS.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of 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. *See,* "–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 KL4 Surfactant Technology."

In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. We proactively communicated these findings to the FDA, improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. Although there can be no assurances, if we are able to successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline in the second quarter of 2013, we believe that we remain on track to manufacture SURFAXIN drug product for commercial use in the second quarter of 2013. This delay in availability of SURFAXIN drug product from the fourth quarter 2012 to the second quarter of 2013 is not expected to have a material adverse effect on our business or financial position, in part because our commercial launch plans for SURFAXIN during this period have always been to focus initially on hospital formulary acceptance.

AEROSURF® is a drug/device combination product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF for premature infants with or at risk for developing 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. Consequently, neonatologists generally will not treat infants who could benefit from surfactant therapy unless they determine that 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."

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and resuspended to liquid form prior to use 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 engaged in a technology transfer of our lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our preclinical and clinical development activities. Our development plan is intended initially to support the use of our lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the United States (U.S.) and potentially in other major markets.

AFECTAIR® devices are our novel disposable aerosol-conducting airway connectors that simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. Our initial device is AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units (NICUs and PICUs, respectively). We are initiating a user experience program that is being conducted in select U.S. critical care centers that represent approximately ten percent (10%) of our target institutions. This initial phase, which is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, is expected to be conducted in the first half of 2013. Following the initial phase, we expect to initiate a broader introduction of the AFECTAIR device for infants in a national phase. We believe that AFECTAIR aerosol-conducting airway connectors have the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to infants receiving aerosolized medication in the NICU and PICU. We believe that revenues from the AFECTAIR device for infants in the fourth full selling year could potentially be $10 million in the U.S. and $20 million globally.

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS and the AFECTAIR device for infants to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in PICUs and intensive care units (ICUs). However, we are delaying these development efforts in the near term in order to focus our resources and expertise on meeting our 2013 goals to advance our development program for AEROSURF to Phase 2 clinical trials and execute the commercial introduction of SURFAXIN and the AFECTAIR device for infants. If we are able to achieve our 2013 objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and aerosol-conductor airway connector technologies to address the critical care needs of patients in the PICU and ICU.

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in and will focus on neonatal indications. These organizations will be primarily responsible to effect the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations to effectively introduce the AFECTAIR device for infants in the U.S. We also expect that, in the future, these teams will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN and the AFECTAIR device for infants to efficiently support the introductions of AEROSURF and SURFAXIN LS, if approved.

An important priority is to secure strategic resources to support the continued development and commercial introduction of our RDS products. While we currently intend to retain all rights and commercialize our approved

products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our efforts, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the European Union (EU). In our discussions to date, the primary focus of our discussions has been on AEROSURF. We also would consider various financing alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 surfactant development programs. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA. There can be no assurance 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 and the AFECTAIR device for infants in the U.S. and advance development of our AEROSURF program, including development of our lyophilized KL4 surfactant and CAG. If we are able to secure the necessary additional capital, we also plan to implement a development program intended to gain marketing authorization for our lyophilized KL4 surfactant drug product, SURFAXIN LS, in the U.S. and potentially in other major markets. Key elements of our strategy to achieve these goals include:

- 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, AEROSURF and SURFAXIN LS, 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.

    - To advance our AEROSURF program, we continue our efforts to optimize the design of our CAG with our engineering staff and third-party medical device experts. In June 2012, we entered into an agreement with Battelle Memorial Institute (Battelle) under which Battelle has agreed to assist us in a multi-phase development program focused on design, testing, and manufacture of clinic-ready CAG devices for our planned AEROSURF Phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013. We have conducted preliminary meetings with the FDA regarding the development plan for AEROSURF and we have engaged regulatory consultants to assist us in implementing and, as needed, refining our development plan. We also plan to retain regulatory consultants to assist us in engaging international regulatory authorities regarding the AEROSURF development plan.

    - To support the planned Phase 2 clinical program for AEROSURF, we are developing clinical operations capabilities that will assume primary responsibility to administer the initial phase of our Phase 2 clinical trial. For subsequent phases of our clinical program, we expect to engage a contract research organization (CRO) with expertise in the management of clinical trials to assist us in the management of the trials.

    - We plan to develop our lyophilized KL4 surfactant drug product 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 2013, we plan to complete the ongoing technology transfer of our lyophilized KL4 surfactant manufacturing process to a CMO that has expertise in the manufacture of lyophilized dosage forms. Our current efforts are directed towards the manufacture of our lyophilized KL4 surfactant for use in our AEROSURF program. We have discussed with the FDA a proposed development program for SURFAXIN LS and expect to engage in further discussions with the FDA. Once we have secured the necessary capital, we plan to implement a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the

U.S., and thereafter potentially in other selected markets. We believe that SURFAXIN and, if approved, SURFAXIN LS collectively have the potential over time to displace animal-derived surfactants and take a substantial share of the markets in which they are available.

- To prepare for the commercial introduction of SURFAXIN, we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in and will focus on neonatal indications, beginning with SURFAXIN. We have trained and deployed these teams in the field, with the primary immediate goal to engage with hospitals that have NICUs, determine and meet the requirements of each hospital to have SURFAXIN included on that hospital's formulary (the approved list of drugs and therapeutics that the hospital will purchase) and secure adoption of the AFECTAIR device for infants. Our sales and marketing strategy is focused primarily on hospitals with NICUs that we believe currently represent a significant portion of the surfactant market in the U.S. To execute this strategy, we expect to incur annual expenses of approximately $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.

- 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 development programs, and maximize stockholder value. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

    - We continue to focus in 2013 on securing a significant strategic alliance predominantly focused on the EU, potentially to provide development and commercial expertise and share research and development expenses for our AEROSURF development program and, if approved, to support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. We also are assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other selected markets and plan to seek a strategic alliance to support our efforts. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN NDA approved 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.

    - We have managed and plan in 2013 to continue closely managing our expenditures. We plan to focus our resources on the initiatives outlined above. To achieve our objectives, we will need access to additional capital. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources." On February 13, 2013, we entered into a Facility Agreement (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield agreed to loan us up to $30 million on a secured basis on the terms outlined in the Deerfield Facility. Deerfield advanced $10 million upon execution of the Deerfield Facility and agreed to advance an additional $20 million, subject to certain conditions, following the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources." We plan to use the proceeds of the loans to meet our working capital requirements, including to support our research and development programs. There can be no assurance that we will meet the conditions for the second $20 million disbursement.

    - Also, on February 11, 2013, we entered into an At-the-Market Equity Offering Sales Agreement (Stifel Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may

sell over a three-year period up to a maximum of $25,000,000 of shares of 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. We intend to use the net proceeds from the ATM Program, if any, to meet our working capital requirements to execute our business plans, including, without limitation, to support the commercialization in 2013 of SURFAXIN and the AFECTAIR device for infants. There can be no assurance that we will issue any Shares pursuant to the ATM Program. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

- We have invested, and will continue to invest, in maintaining and enforcing our potential competitive position by protecting our exclusive rights in and to our KL4 surfactant technology, pipeline products and our drug delivery technologies, including our CAG and aerosol-conducting airway 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 evaluated, 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 testing 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 KL4 surfactant product candidates. For AEROSURF, we plan to use our lyophilized KL4 surfactant drug product and are conducting a technology transfer of our lyophilized manufacturing process to a CMO that complies with the FDA's current good manufacturing processes (cGMP) and with expertise in lyophilization processes. To produce CAG devices, we have entered into an agreement with Battelle to manufacture clinic-ready CAG devices to be used in the first phase of our planned AEROSURF Phase 2 clinical trials. 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.

- While we are focused initially on advancing our lead KL4 surfactant and drug delivery technologies to treat critical care infants with or at risk for 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 will consider opportunities to conduct research and preclinical development activities potentially to address acute lung injury (ALI). We recently announced four collaborations with leading research institutions to conduct a series of preclinical studies funded through various U.S. Government-sponsored, Biodefense-related initiatives. *See,* "– Surfactant Replacement Therapy for Respiratory Medicine – Serious Respiratory Indications Associated with Inflammation of the Lungs – Acute Lung Injury (ALI)." In 2010, we supported 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). We may in the future consider supporting such independent initiatives that explore the utility of applying our KL4 surfactant to address CF and other respiratory diseases, such as COPD. *See,* "– Surfactant Replacement Therapy for Respiratory Medicine – Cystic Fibrosis (CF)," and "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – AEROSURF for RDS in Premature Infants."

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: 2010, *Pediatrics*, Martin et. al.; CDC National Vital Statistics, 2005; IMS Midas Data MAT, December 2011; 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 pharmacoeconomic 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 dosage form. 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 non-immunogenicity. 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. A number of preclinical studies assessing the potential advantages of our KL4 surfactant technology have been reported in professional journals and presented at major medical congresses, including the following:

- In September 2012, preclinical data from a study using a well-established preterm lamb model of RDS was published in *Pediatric Research*. The study found that the lungs of preterm lambs that were treated with

SURFAXIN were more homogenously expanded both within and between lung regions, a finding that is suggestive of more uniform distribution of surfactant throughout the lung, and the lungs of SURFAXIN treated lambs had less cellular debris and fewer inflammatory cells when compared with the lungs of non-treated lambs and the lambs treated with Curosurf® and Survanta®. The investigators also noted lower levels of inflammatory mediators following treatment with SURFAXIN compared with negative controls as well as both animal-derived surfactants. The study concluded that early intervention with SURFAXIN may mitigate progression of pulmonary pathophysiological consequences of RDS when compared with the animal-derived surfactants Curosurf and Survanta.

- In May 2012, preclinical data from a study comparing the effects of SURFAXIN LS and Curosurf on pulmonary function, as well as the physiologic reactions to surfactant administration in preterm lambs with RDS, was published in *Pediatric Research*. The study found that both surfactants significantly improved pulmonary function ($p < 0.05$). However, lambs treated with SURFAXIN LS required significantly lower mechanical ventilator pressures to maintain pulmonary function compared with Curosurf-treated lambs ($p < 0.05$). In contrast to lambs treated with SURFAXIN LS, lambs treated with Curosurf experienced significant reductions in heart rate and rapidly increased brain oxygenation during the peridosing period ($p < 0.05$). The investigators concluded that SURFAXIN LS may enable ventilation at lower mean airway pressures, thereby potentially reducing the incidence of bronchopulmonary dysplasia (BPD), and as such may be an effective substitute for the currently-marketed surfactant products.

- 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 ($p < 0.03$).

We believe that our KL4 surfactant has promising novel properties and attributes 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 KL4 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.

- In December 2012, the Journal of Pediatric Pharmacology and Therapeutics (Volume 17, Number 3, 2012*)* published a pharmacoeconomic analysis based on data from our pivotal SELECT and STAR Phase 3 clinical trials for SURFAXIN titled "A Pharmacoeconomic Analysis of In-Hospital Costs Resulting from Reintubation in Preterm Infants Treated with Lucinactant, Beractant, or Poractant Alfa." This study employed a pharmacoeconomic model that utilized observations from a *post hoc* analysis that examined the

consequences of reintubation and the potential effect of the choice of surfactant on reintubation rates (see below) to assess the potential cost benefits associated with the lower rate of reintubation observed with SURFAXIN when compared with reintubation rates of infants treated with the current global market leading surfactants, Curosurf and Survanta. The study concluded that the lower rate of reintubation, as observed in infants who received SURFAXIN, may result in significantly lower in-hospital costs primarily related to costs associated with mechanical ventilation.

- In December 2012 at the 2012 Hot Topics in Neonatology Annual Meeting, data was presented from a pharmacoeconomic analysis of data published in 2011 in the *Journal of Neonatal-Perinatal Medicine* (Volume 4, Number 2, 2011, discussed below). The analysis demonstrated that the previously-reported reduced rate of reintubation in preterm infants treated with SURFAXIN may also result in an average potential hospital cost savings of $389,247 per 100 treated infants by reducing the frequency of bronchopulmonary dysplasia (BPD) when compared with reintubation rates of infants treated with the current global market leading surfactants, Curosurf and Survanta. In addition, in May 2012, we announced the results of an earlier pharmacoeconomic analysis that demonstrated that the lower rate of reintubation observed in infants treated with SURFAXIN also resulted in a potential hospital cost savings of $160,000 to $252,000 per 100 infants.

- In 2011, the *Journal of Neonatal-Perinatal Medicine* (Volume 4, Number 2, 2011) published a post-hoc analysis of data from our 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). 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.

KL4 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. In addition to the liquid dosage form, we are developing our KL4 surfactant to potentially be available in aerosolized and lyophilized dosage forms.

We have also demonstrated through research and feasibility studies that we can aerosolize our KL4 surfactant and that our aerosolized KL4 surfactant has the following important characteristics:

- 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 KL4 surfactant technology also can be produced in a lyophilized (freeze-dried) dosage form that is resuspended to liquid form prior to administration. We plan to use our lyophilized KL4 surfactant in our AEROSURF development program. We have conducted several experiments that demonstrate that our lyophilized KL4 surfactant drug product (SURFAXIN LS) retains the key characteristics of our liquid KL4 surfactant (SURFAXIN) and may provide additional 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 KL4 surfactant throughout the lung and potentially reduce the frequency of transient peri-dosing events typically observed during administration of surfactants.

Our Aerosolization Delivery Technologies

Capillary Aerosol Generator Technology

We have worldwide exclusive rights to our CAG technology through exclusive license agreements with Philip Morris USA Inc. (PMUSA) in the U.S., and Philip Morris Products S.A. (PMPSA) in the territories outside of the U.S. 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 U.S. 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 KL4 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. 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.

Aerosol-Conducting Airway Connectors

We have also developed our AFECTAIR device, a novel aerosol-conducting airway connector. Our AFECTAIR aerosol-conducting airway connector simplifies the delivery of aerosolized medications and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. The initial AFECTAIR device for infants is being introduced in the U.S. in the first half of 2013. We are planning to develop a customized aerosol-conducting airway connector for use in our AEROSURF program for use with our CAG to address RDS in premature infants.

The AFECTAIR device has been registered in the U.S. as a Class I, exempt medical device. In the EU, we believe that this device will be classified as a Class IIa device, which must be cleared for marketing in the EU 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 EU by the fourth quarter of 2013.

With the information that we gain from the introduction of the AFECTAIR device for infants in the U.S., we expect to develop a plan for the introduction of the AFECTAIR device for infants in the EU and other major markets. We plan to support the launch of AFECTAIR in markets outside the U.S., including the EU, through arrangements with third-party distributors experienced in introducing respiratory medical products into hospitals. In addition, to benefit all critical care patients who require aerosolized medications or other inhaled therapies and who are receiving ventilatory support, we believe that our experience with the AFECTAIR device for infants will support efforts to develop one or more additional AFECTAIR devices, potentially for use in larger children and adults in PICUs and Intensive Care Units (ICUs). At the present time, however, we are focused on gaining information and learning from the introduction of the AFECTAIR device for infants in the U.S. Thereafter, we plan to implement a regulatory and manufacturing plan that, if successful, could result in the commercial introduction of a second AFECTAIR device. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to all critical care patients.

Several *in vitro* studies have been presented at medical meetings in the last few years that suggest that AFECTAIR improves the delivery of inhaled therapies to patients on ventilatory support, including:

- An *in vitro* study that compared the dose of aerosolized albuterol sulfate delivered to a lung simulator under various neonatal ventilator settings using the AFECTAIR device for infants 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;

- An *in vitro* study that compared the performance of the AFECTAIR device for infants 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 the AFECTAIR device 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 the AFECTAIR device in the delivery of other medical gases and with other ventilation methods;

- An *in vitro* study, the objective of which was to determine the particle size distribution (PSD) using the AFECTAIR device for infants 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 device spanned the entire respirable range, suggesting that the potential clinical use of the AFECTAIR device may result in increased delivery and retention of aerosolized medication in the lung;

- An *in vitro* study, the objective of which was to determine if the AFECTAIR device for infants 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; and

- A study that assessed the AFECTAIR device for infants and concluded that the 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 have and plan to continue to sponsor and support studies that explore the benefits of AFECTAIR devices. We have conducted 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 aerosolized medications and inhaled therapies to patients requiring ventilatory support.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

The only pulmonary surfactants commercially available today were introduced in the U.S. 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 U.S. and at risk for RDS (approximately 600,000 children inclusive of the U.S., major European medical markets and Japan). Of the U.S. 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 respiratory support therapy). 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 U.S. 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 and, if approved, SURFAXIN LS and AEROSURF have the potential over time to displace animal-derived products and take a substantial share of the markets in which they are available.

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 U.S., 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 as compared to Exosurf, the primary comparator. Although the reference arm using Survanta 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.

On March 6, 2012, the FDA granted marketing approval for SURFAXIN. In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. We improved and validated the analytical chemistry method and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. If we are able to successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline, we anticipate that SURFAXIN drug product will be commercially available in the second quarter of 2013.

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

AEROSURF for RDS in Premature Infants

AEROSURF is a drug-device combination product that produces our KL4 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 potentially 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 KL4 surfactant in neonatal respiratory medicine by potentially providing neonatologists with a means to administer KL4 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 announced the results of a pilot Phase 2 clinical trial using aerosolized KL4 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 aerosolized KL4 surfactant 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 KL4 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 KL4 surfactant drug product. *See,* "– Proprietary Platform – Surfactant and Aerosol Technologies – Our KL4 Surfactant Technology."

We are currently developing AEROSURF using our CAG technology. *See,* "– Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Delivery Technologies – Capillary Aerosol Generator Technology." In June 2012, we entered into a Research and Development Services Agreement with Battelle, which has a particular expertise in developing and integrating aerosol devices using innovative and advanced technologies. Battelle has agreed to provide technical support and expertise and assist our medical device engineering team in the development of CAG device components in phased programs focused on design, testing, and manufacture of clinic-ready CAG devices for our planned AEROSURF Phase 2 clinical trials. We have retained authority for all final decisions and all responsibility for the formulation, design, manufacture, assembly, packaging, marketing, distribution and sale of our products. For our AEROSURF development plan, we previously conducted preliminary meetings with the FDA. In addition to our internal resources, we have engaged regulatory consultants to assist us in implementing and, as needed, refining this development plan as we anticipate filing an Investigational New Drug (IND) application in advance of initiating the first part of our Phase 2 clinical program in the fourth quarter of 2013. We also plan to retain regulatory consultants to assist us in engaging international regulatory authorities regarding the AEROSURF development plan.

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 (SBIR) 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 of the SBIR Grant, which could provide up to an additional $1.88 million to support further AEROSURF 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,* "–Surfactant Replacement Therapy For Respiratory Medicine - Serious Respiratory Indications Associated with Inflammation of the Lungs – Acute Lung Injury (ALI)," and "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Philip Morris USA Inc. and Philip Morris Products S.A."

Lyophilized SURFAXIN for RDS in Premature Infants – SURFAXIN LS

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and resuspended to liquid form prior to use 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 engaged in a technology transfer of our lyophilized KL4 surfactant manufacturing process to a CMO that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our preclinical and clinical development activities. Our development plan is intended initially to support the use of our lyophilized KL4 surfactant in our AEROSURF development program. We have discussed with the FDA a proposed development program for SURFAXIN LS and expect to engage in further discussions with the FDA. We are assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other major markets.

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 KL4 surfactant technology may be used to address debilitating respiratory disorders such as ALI and, possibly in the future 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 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 U.S. for ALI annually and there are no currently approved therapies other than supportive respiratory care.

We believe that our aerosolized KL4 surfactant may potentially be effective as a preventive measure to treat patients at risk for ALI. We have conducted research and preclinical studies in collaboration with a prominent academic investigator to assess the use of our KL4 surfactant to potentially address ALI in an animal model. This prophylactic approach may reduce the number of patients requiring costly intensive care therapy, eliminate long periods of therapy and generate cost savings in the hospital setting.

In September 2012, we announced initiation of four research projects designed to explore the use of KL4 surfactants in the prevention and treatment of ALI. We believe that our KL4 surfactant may be an effective intervention for people at risk for, or with, ALI. We are collaborating with leading research institutions in a series of preclinical studies funded through various U.S. Government-sponsored, Biodefense-related initiatives. These studies include: a collaboration with the University of Pennsylvania funded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) to assess the ability of KL4 surfactant to mitigate effects of acute radiation exposure to the lung; a collaboration with the University of Rochester to evaluate the use of KL4 surfactant to protect the lung in a radiation-induced multi-organ dysfunction animal model; a collaboration with a facility of the U.S. Department of Defense through the NIH Office of the Director and the Countermeasures Against Chemical Threats (CounterACT) program assessing the utility of KL4 surfactant for the treatment of chemical-induced ALI; and a program funded by NIAID investigating the use of KL4 surfactant as a treatment for influenza-induced ALI.

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 U.S., occurring in approximately one in every 3,500 Caucasian live births. CF affects approximately 30,000 patients in the U.S. 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 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 focused on developing our proprietary KL4 surfactant, CAG, and aerosol delivery technologies into a series of pipeline programs that potentially could support a significant respiratory critical care franchise. We are initially focused on RDS in premature infants. We continually evaluate our research and development priorities in light of a number of factors, including our cash flow requirements and financial liquidity, the potential for development partnerships and collaboration agreements, the results obtained in our research and development activities, advances in technology, and our ability to secure necessary capital. 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 have managed and in 2013 plan to continue closely managing our expenditures. We plan to focus our research and development resources on our RDS programs, primarily AEROSURF, and, if we secure the necessary capital, SURFAXIN LS. We expect to initiate a Phase 2 clinical program for AEROSURF in the fourth quarter of 2013. We also plan to conduct preclinical studies to assess the utility and potential benefits of the AFECTAIR device for infants. After we have completed the commercial introduction of the AFECTAIR device for infants in the U.S., we expect to implement a development plan that could result in a second AFECTAIR to address serious critical care respiratory conditions of larger children and adults in PICUs and ICUs. For our RDS programs, an important objective for us is to enter into a significant strategic alliance, predominantly focused on the European Union (EU). We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our efforts, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In our discussions to date, the primary focus of our discussions has been on AEROSURF. We also would consider various financing alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 surfactant development programs. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the United States (U.S.) and potentially other major markets. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN NDA approved by the FDA. 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. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

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. In anticipation of the AEROSURF Phase 2 clinical program, we plan to enhance these capabilities in 2013. For the initial phase of the AEROSURF program, we plan to analyze and report on our clinical trial data, supported by third-party technology systems and independent consultants, and will monitor all activities using our clinical operations capabilities. We rely on scientific advisory committees and other medical and consulting experts to assist in the design and monitoring of clinical trials. We also plan to rely on CROs to support operations of our planned multi-center trials, including for locations outside the U.S.;

- 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 are engaged in a development program with Battelle that provides consulting design engineers, medical device and planning experts and other resources to advance the development of our CAG device and manufacture of clinic-ready CAG devices for use in the first phase of our Phase 2 AEROSURF clinical trials;
- quality operations capabilities to assure compliance with applicable regulations;
- manufacturing capabilities to manufacture our liquid KL4 surfactant for use in preclinical studies. We also plan to rely on 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. 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, 2012, and 2011, our research and development expenses were $21.6 million, and $17.2 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, as applicable. SURFAXIN is a complex drug product 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 active pharmaceutical ingredients (APIs), such as KL4, which is provided by Bachem California, Inc., and other APIs, 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 APIs from single-source providers, although we plan to qualify secondary suppliers over the next 12 to 24 months. Our risk of losing a source of supply is somewhat mitigated by our strategy to maintain minimum inventories of all APIs. Suppliers of our primary packaging components and excipients used in our manufacturing process include West Pharmaceutical Services, Inc., Gerresheimer Glass Inc. and Spectrum Chemical Mfg. Corp. Our primary packaging components and excipients are generally readily available from multiple sources.

We have established arrangements with ASD Specialty Healthcare Inc. and Integrated Commercialization Solutions, Inc. (ICS), affiliates of AmerisourceBergen Specialty Group, for warehousing, distribution and related services. ICS is our third-party logistics provider and assists us with inventory tracking, customer service, order management, distribution, contract and accounts receivable management, certain financial management services and other similar services. We have also identified a provider of vial labeling and secondary packaging services for our SURFAXIN commercial drug product and have negotiated and are finalizing an agreement.

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 and approved to produce commercial SURFAXIN drug product. These operations also produce SURFAXIN for use in our research and development activities. Owning our manufacturing operations has provided us with direct operational control as we worked through manufacturing development activities and produced SURFAXIN drug product for preclinical activities supporting our efforts to gain regulatory marketing approval for SURFAXIN in the U.S. We also are conducting a technology transfer of the

SURFAXIN LS dosage form manufacturing process to a cGMP-compliant CMO with expertise in lyophilized formulations.

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. In March 2012, the FDA granted us marketing approval for SURFAXIN.

Our manufacturing operation also includes our analytical testing and quality system. We have consolidated all of our in-house analytical development and quality control activities in our analytical and technical support laboratory at our headquarters in Warrington, Pennsylvania. We conduct release testing of all APIs as well as release and stability testing of SURFAXIN clinical and commercial drug product supply. In the third quarter of 2012, during a review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess drug product conformance to specifications required improvement and that an update to product specifications will be necessary. We improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. Although there can be no assurance, if we successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline in the second quarter of 2013, we believe that we are on track to manufacture SURFAXIN drug product for commercial use in the second quarter of 2013.

We also perform research and development work at our Warrington analytical and technical support laboratory for our lyophilized and aerosolized KL4 surfactant dosage forms as well as other potential formulations of our KL4 surfactant, and in support of our efforts to identify and protect our intellectual property. In addition, we have a microbiology laboratory at our Totowa facility to support the manufacture of our drug product candidates. We also maintain a medical device development laboratory with resources and capabilities that our internal development engineering team uses for ongoing preclinical development activities for AEROSURF and our aerosol delivery technologies, 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 control 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 expect over the next 12-24 months to implement 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 combines our KL4 surfactant technology with our CAG and aerosol delivery technologies. 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 believe that our aerosolized KL4 surfactant may be used to address a broad range of serious respiratory conditions.

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. AEROSURF includes components that 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."

In June 2012, we entered into an agreement with Battelle under which Battelle has agreed to assist us in a multi-phase development program focused on design, testing, and manufacture of clinic-ready CAG devices for our planned AEROSURF Phase 2 clinical trials, which we expect to initiate in fourth quarter of 2013. Under our

agreement with Battelle, Battelle will manufacture CAG devices for the initial phase of the AEROSURF Phase 2 clinical program. In the future, we expect to rely on third-party CMOs to manufacture and assemble the CAG device and related components to support our development activities, planned clinical studies and, if approved, potential commercialization of AEROSURF.

AFECTAIR Aerosol-Conducting Airway Connectors

In February 2012, we entered into a supply agreement (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. In addition to providing manufacturing support, Lacey will label, package, and prepare AFECTAIR devices for shipment. Lacey will ship the finished product to ICS who has agreed to warehouse and provide third-party logistic services for us. *See,* "– KL4 Surfactant." ASD has agreed to act as distributor for AFECTAIR devices.

The initial term of our Agreement with Lacey is four years. 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 more 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. (ASD) to act as our distributor for SURFAXIN, WARMING CRADLE dry-block heaters and AFECTAIR devices in the U.S. This arrangement was originally put in place in 2006. We have amended and updated this agreement to provide for distribution and related services. We also expect that ASD may 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,* "– 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 devices in the EU and elsewhere, we will consider different opportunities, including potentially a network of distributors, or one or more strategic alliances (either as separate collaborations or integrated with broader alliances for the development of our RDS portfolio of KL4 surfactant drug candidates, including AEROSURF). We expect that any distributor network would involve regional distributors that have a focus and expertise in distributing hospital-based medical device products in their respective territories.

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 and corporate and healthcare compliance 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. Antonio Esteve, Ph.D., a member of our Board of Directors from May 2002 until his resignation in January 2013, is a principal of Esteve. Under the alliance, 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 that included Esteve returning certain rights to us in certain territories (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 the 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. While we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our efforts, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the EU. In our discussions to date, the primary focus of our discussions has been on AEROSURF. We also would consider various financing alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 surfactant development programs. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA. 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 aerosol-conducting airway 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 J&J. 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 $950,000 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 ten years beginning on the date of the first commercial sale of the first licensed product in such country and thereafter until the expiration of the last licensed patent containing a valid claim covering the licensed product in such country; or for countries in the EU 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 U.S. and Western Europe territories (as defined in the agreement), on a country-by-country basis, on six months' prior written notice; and as to the entire agreement, on 60 days' prior written notice.

Patents covering our proprietary precision-engineered surfactant technology that have been issued worldwide include composition of matter, formulation, and uses and include the following issued United States patents: U.S. Patent No. 5,407,914; U.S. Patent No. 5,952,303; U.S. Patent No. 6,013,619; and U.S. Patent No. 6, 613,764 (along with certain corresponding issued 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 the U.S. and foreign patents 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; U.S. Patent No. 6,492,490; and U.S. Patent No. 8,217,142 (along with certain corresponding issued foreign counterparts).

The patent term of U.S. Patent No. 5,407,914 has been extended until November 17, 2013 with further extensions potentially available until November 17, 2014. 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 and U.S. Patent No. 8,217,142 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. Some of these patent applications have issued and some are still pending in the U.S. 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 synthetic peptide containing pulmonary surfactants and methods of manufacture.

In December 2005, we filed U.S. and International patent applications (US 11/316,308 which is now U.S. Patent No. 8,337,815 issued on December 25, 2012 and PCT US/2005/046862, now entered national phase), directed to synthetic peptide containing 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 U.S. (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 U.S. (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 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 AEROSURF 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 U.S. 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 2031, 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 valid patent claim in such country; the date a generic form of the product is introduced in such country; or the tenth anniversary of the first commercial sale of such licensed product.

Aerosol-Conducting Airway Connector Technology Patents and Patent Rights

In March 2009, we filed International patent application (PCT US/2009/037409) directed to aerosol-conducting airway connectors that we plan to market under the trademark AFECTAIR and improvements of an aerosol delivery system using AFECTAIR. The International patent application is an interim phase in the prosecution of patents and is now concluded. 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 (an aerosol-conducting airway connector) 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. In November 2012, we filed and International patent application (PCT/US12/63038) directed to further improvements of an aerosol delivery system and ventilation circuit adaptors. *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, DISCOVERYLABS®, 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 may provide extended marketing exclusivity of five years. However, the FDA has not made its final determination as to the length of the exclusivity period for SURFAXIN.

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 U.S. 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 were advised in 2012 that the FDA had denied our request. If we develop AEROSURF or SURFAXIN LS for the treatment of RDS, this orphan drug designation may 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 KL4 surfactant for the treatment of ARDS in adults, and (iii) our KL4 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 KL4 surfactant for the treatment of ALI in adults (which in this circumstance encompasses ARDS), and (iii) our KL4 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 KL4 surfactant for the treatment of ARDS.

COMPETITION

We are engaged in the 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 conventional pharmaceutical companies, among others. 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 U.S. by Cornerstone Therapeutics Inc. In addition, Chiesi has published the results of a preclinical study indicating that it is engaged in an early-stage effort to develop a synthetic surfactant (Sato A, Ikegami M (2012) SP-B and SP-C Containing New Synthetic Surfactant for Treatment of Extremely Immature Lamb Lung. PLoS ONE 7(7): e39392.doi:10.1371/journal.pone.0039392). Survanta historically has been marketed by Abbott Nutritionals, Inc. (Abbott). On December 10, 2012, a wholly-owned subsidiary of Abbott, AbbVie Inc. (AbbVie) filed with the SEC a Form S-1 Registration Statement, which was declared effective by the SEC on December 31, 2012, in connection with a distribution by Abbott to its shareholders of 100% of the outstanding shares of AbbVie. The registration statement indicates that the distribution is intended to effect the separation of Abbott's research-based pharmaceuticals business from the remainder of its businesses. We understand that Survanta is among the assets

transferred to AbbVie. ONY, Inc. markets Infasurf®, a surfactant derived from calf lung surfactant lavage in the U.S.

With respect to our drug delivery technologies, efforts to aerosolize animal-derived surfactants have not been very successful. Recent studies suggest that to aerosolize a surfactant for delivery to premature infants, it is necessary to optimize the aerosol to a particular particle size range, use an aerosol generator with characteristics that are compatible with the patient's breathing, and employ a delivery system that delivers sufficient drug product to the patient (Mazela, et. al., Aerosolized Surfactants, Current Opinion in Pediatrics 2007, 19:155–162; Finer, et. al., An Open Label, Pilot Study of AEROSURF Combined with nCPAP to Prevent RDS in Preterm Neonate, Journal of Aerosol, Medicine and Pulmonary Drug Delivery, Volume 23, Number 5, 2010). There are a number of device manufacturers with aerosolization expertise, including Pari and Aerogen. These companies manufacture aerosol devices such as nebulizers, aerosol masks, and compressors. Pari, for example, has provided nebulizers for use in clinical research and in commercial product for several companies. Aerogen manufactures a number of aerosolization devices, including a disposable, single patient nebulizer and a reusable, multi-patient nebulizer. Our AFECTAIR devices are novel aerosol-conducting airway connectors that are intended to replace standard connectors in the ventilatory circuit. We currently are not aware of any efforts on the part of any of these or other companies to develop an alternative to AFECTAIR.

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 U.S., 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 CMOs 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 are 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 programs for AEROSURF and SURFAXIN LS 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 U.S. 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. The FDA may not accept an NDA and may deliver what is referred to as a Complete Response Letter that describes the shortcomings of the application, including whether the applicant should consider additional clinical trials, which could have the effect of terminating a development program.

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 FDA 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, New Jersey manufacturing operations and our analytical and testing laboratory in Warrington, Pennsylvania, 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 manufacturing operations for the manufacture of SURFAXIN. The FDA may determine to conduct such inspections at any time and for any reason, including in connection with our recent notification that one of our analytical chemistry methods used to assess drug product conformance to specifications required improvement and our submission of updated product specifications for SURFAXIN. *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 product 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 U.S., we also expect to apply for such approval with other international regulators. Regulatory requirements and approval processes are similar in approach to that of the U.S. but are not fully harmonized. 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 (off-label) use, 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. Regulation and enforcement of advertising and promotion by institutions other than FDA are discussed below.

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 aerosolized KL4 surfactant drug products are similarly subject to extensive regulation by federal, state and local governmental authorities in the U.S. 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 U.S., our aerosolized KL4 surfactant combination drug-device product will be reviewed by the Center for Drug Evaluation and Research (CDER) of the FDA, with input from the Center for Devices and Radiological Health (CDRH). 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 U.S., 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. As noted below, we have determined that our AFECTAIR device qualities as a Class I medical device. We have not determined at this time under which classification our CAG device and related componentry will fall. A brief summary overview of the three classifications is set forth below.

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. After consulting with our regulatory experts, in February 2012, we registered our AFECTAIR device as an exempt Class I medical device. We will be required to update and renew our registration annually.

510(k) Clearance Process: A Class II medical device requires FDA clearance in the U.S. pursuant to the 510(k) clearance process. The 510(k) clearance process is available to medical device developers that can demonstrate that their device is substantially equivalent to a legally marketed medical device. In this process, the developer would be required to submit data that supports the equivalence claim and wait for an order from the FDA finding substantial equivalence to another legally marketed medical device before distributing the device for commercial sale. 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 the developer to independently demonstrate that a medical device is safe and effective. This is done by presenting 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.

European Compliance (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 our AFECTAIR device qualifies as a Class IIa device, which requires 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 ISO13485 quality management system certification audit to ensure that our manufacturers and we are in compliance with the standard. If the audit is successful, the Notified Body will grant ISO13485 certification, which is a requisite to pursue CE marking for our AFECTAIR device. We obtained ISO13485 certification in early 2013, and we are currently working 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;

- 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.

Anti-Kickback, False Claims Act, and Other Laws Regarding Advertising and Promotion

In addition to FDA's ongoing post-approval regulation of drugs, devices, and combination products discussed above, several other types of laws and regulations, subject to differing enforcement regimes, govern advertising and promotion. In recent years promotional activities of FDA-regulated products have come under intense scrutiny and have been the subject of enforcement action brought by the Department of Justice (DOJ), state authorities, and even private individuals.

The federal Anti-Kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical or device manufacturers, on the one hand, and prescribers, purchasers, and formulary managers on the other. Violations are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Any sales or marketing practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny under the Anti-Kickback statute. Many states have likewise adopted state anti-kickback statutes, and enforcement has been significant.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act to impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. If certain conditions are met, the False Claims Act allows a private individual called a "whistleblower" to bring a civil action on behalf of the federal government and to share in any monetary recovery. In recent years, the number or suits brought by private individuals has increased dramatically. In addition, many states have enacted false claim laws similar to the federal False Claims Act.

A host of other laws and regulations govern the advertising and promotion of drugs and devices. The federal Sunshine Law, which is part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010, imposes federal "sunshine" provisions, requiring annual reporting of various types of payments to physicians and teaching hospitals. Although implementation of the sunshine provisions was initially delayed by the U.S. Centers for Medicare and Medicaid Services (CMS), a final rule was released in February 2013. Under the rule, applicable manufacturers must begin tracking relevant transfer-

of-value data in August 2013, and must report data collected between August 1 and the end of 2013 to CMS by March 31, 2014. CMS will publish the data on a public website by September 30, 2014. Inaccurate or incomplete reports may be subject to enforcement. Like the federal Sunshine Law, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state. Additionally, other laws such as the federal Lanham Act and similar state laws allow competitors and others to initiate litigation relating to advertising claims. Additionally, the U.S. Foreign Corrupt Practices Act and local laws of other countries potentially implicate the sale and marketing of drugs and devices internationally. This complex patchwork of laws can change rapidly with relatively short notice.

SURFAXIN is our first approved drug product in the U.S. and AFECTAIR is our first registered medical device in the U.S. None of our other products under development has been approved for marketing in the U.S. 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 KL4 surfactant technology, our novel CAG technology, and our novel aerosol-conducting airway connectors;" "– Our research and development programs for AEROSURF and SURFAXIN LS 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", "– We may fail in the development and commercialization of our products," "– 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," and "– Even if we succeed in gaining 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 U.S. and provides certain advantages to the Orphan Drugs sponsors, including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drugs. *See,* "Item 1A – Risk Factors – Even though some of our product candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other product candidates that do not qualify for expedited review," and "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Other Regulatory Designations."

EMPLOYEES

As of March 1, 2013, we have 121 employees, 105 of which are full-time, two 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, 2013. All are employed in the U.S. *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 will require significant additional capital to continue our operations and continue our planned research and development activities. Moreover, such additional financing 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 need substantial additional funding to support our commercial operations and our ongoing research and development activities and our operations. As of December 31, 2012, we have an accumulated deficit of approximately $434.7 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, 2012, we had cash and cash equivalents of approximately $26.9 million. In February 2013, we entered into an agreement (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield advanced $10 million to us and has agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. While we believe that we remain on track to effect the first commercial sale of SURFAXIN in the second quarter of 2013, if for any reason we fail to meet the condition for disbursement of the second Deerfield advance, we would forego access to those funds.

Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement (Stifel Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25,000,000 of shares (Shares) of our common stock. During the term of the ATM Program, we are not required to sell any Shares at any time. We intend to use the net proceeds from the ATM Program, if any, to meet our working capital requirements to execute our business plans, including, without limitation, to support the commercialization in 2013 of SURFAXIN and the AFECTAIR device for infants. There can be no assurance that we will issue any Shares pursuant to the ATM Program.

In addition to potential funding that may be available under the Deerfield Facility, the ATM Program, and our Committed Equity Financing Facility (CEFF) (which is subject to certain conditions and expires on June 11, 2013), we will require significant infusions of capital to fund the anticipated increase in our cash outflows as we continue to invest in our commercial and medical affairs organization and execute the commercial introduction of our approved products, as well as our research and development programs. The process of achieving hospital formulary acceptance and securing adoption of our approved products is expensive and can be time consuming. As a result, our investments in commercial and medical affairs activities are expected to outpace the rate at which we generate revenues until such time as our revenues have achieved the anticipated rate over time. We will require infusions of capital until such time as our revenues from SURFAXIN and AFECTAIR are sufficient to fund our ongoing activities.

If for any reason, we experience a longer delay in the commercial introduction of SURFAXIN than currently anticipated, depending upon the length of delay and the underlying cause, we believe that such events could have a material adverse impact on our ability to raise additional capital, whether through use of our ATM Program or otherwise. We anticipate that, in a moderate delay, we would likely assess our level of investment in ongoing programs and pace our expenditures to manage and extend the availability of our existing cash resources. Such reductions in investment could cause us to experience delays in the progress of some of our programs and affect the valuations of our business. However, if the delay were not of a long duration, we believe that our fundamental strategy could remain intact and we would continue to manage our cash resources closely until such time as we have resolved our issues and reinitiated our efforts to effect the commercial introduction of SURFAXIN. If any delay were extended for longer periods of time and we are unable to raise additional capital for any reason, we would have to reassess our business strategy and the level of our investments in all categories and would have to consider fundamental changes to our business plans. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and/or strategic and collaborative arrangements with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations as presently contemplated. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as outsourcing certain of our activities and licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop or commercialize ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

Even if we are successful in generating revenues from the sale of approved products in the future, we will likely not have sufficient cash flow and liquidity to fund our research and development programs and will require additional capital to support these efforts. We would prefer to accomplish these objectives through strategic alliances and collaboration arrangements. We are seeking strategic alliances to support the development of AEROSURF® and, if approved, to commercialize these product candidates in the European Union (EU) and other markets outside the United States (U.S.). We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other major markets. 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 and may be forced to further limit investments in our development programs, which could have a material adverse effect on our business. 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. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Moreover, 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 the potential second disbursement of funds under our Deerfield Facility, our ATM Program and our CEFF, which has available approximately 1.1 million shares and expires in June 2013, 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.

Our near-term prospects are highly dependent on the success of SURFAXIN and AFECTAIR. To the extent we fail to successfully commercialize SURFAXIN and AFECTAIR, or if our efforts to commercialize SURFAXIN and AFECTAIR are significantly delayed, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.

In March 2012, the FDA approved SURFAXIN (lucinactant) for the prevention of RDS in premature infants at high risk for RDS. In February 2012, we successfully registered our AFECTAIR device in the United States. The initial AFECTAIR device has been developed for use with infants in the Neonatal Intensive Care Unit (NICU) and smaller

infants in the Pediatric Intensive Care Unit (PICU) receiving ventilatory support. We believe that SURFAXIN and AFECTAIR product sales may constitute all or most of our total revenue over the next several years.

In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. We proactively communicated these findings to the FDA, improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. Although there can be no assurances, if we are able to successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline in the second quarter of 2013, we believe that we remain on track to manufacture SURFAXIN drug product for commercial use in the second quarter of 2013. This delay in availability of SURFAXIN drug product from the fourth quarter 2012 to the second quarter of 2013 is not expected to have a material adverse effect on our business or financial position, in part because our commercial launch plans for SURFAXIN during this period have always been to focus initially on hospital formulary acceptance. However, if the delay is extended for any reason, failure to timely initiate the commercial introduction of SURFAXIN could have a material adverse effect on our operations, including our research and development programs, and our financial condition.

We currently believe that we will successfully execute the commercial introduction of SURFAXIN within our anticipated timeframe. However, our efforts are subject to a variety of risks and uncertainties that could cause actual results to be materially different. The FDA may not accept our submission or may require that we develop and submit additional data or other information. Moreover, although the guidelines set forth in the Prescription Drug User Fee Act (PDUFA) indicate that the FDA will endeavor to respond within four months after the date of our submission, the FDA may not respond within that timeframe, or may require additional information that would require additional time and extend the FDA's review. Ultimately, the FDA may deny our request to consider updated product specifications. In addition, the FDA may determine to initiate a facility inspection to review our manufacturing, quality control and assurance activities and verify the thoroughness of our investigation into the issues identified in our review of the analytical method. Any failure to satisfy any issues raised by the FDA, in our submission or in connection with a facilities inspection, could significantly delay, or preclude outright, our gaining FDA confirmation of the updated product specifications, or, ultimately, could result in an action by the FDA to restrict our ability to commercialize some or all of our products, which could potentially delay or prevent the commercial availability of SURFAXIN drug product.

In addition, if we successfully make our products commercially available, the commercial success of SURFAXIN and AFECTAIR and our ability to generate and increase revenues will depend on a number of factors, including the following:

- the number of hospitals and critical care centers that agree to place SURFAXIN drug product on their formulary lists and the length of time required to achieve broad formulary acceptance;
- the willingness of the target hospitals to accept and employ WARMING CRADLE® dry-block heater;
- the number of hospitals and critical care centers that agree to include AFECTAIR devices on their approved materials list and the degree of use of AFECTAIR devices for critical care patients;
- the effectiveness of our marketing, sales and medical affairs organizations and their ability to (a) accurately describe SURFAXIN consistent with its approved labeling, (b) educate and provide critical care providers and hospitals with medical and scientific education and information concerning our products, and (c) educate critical care providers and hospitals regarding the potential utility of AFECTAIR devices;
- our ability to gain access to the entire market with our commercial organizations and, if we so determine, through any third-party distributor arrangements;
- the safety and efficacy of SURFAXIN, our ability to provide hospitals acceptable evidence of the safety and efficacy of SURFAXIN, and the perceived advantages of SURFAXIN and AFECTAIR over alternative treatment methods;
- the pharmacoeconomic benefits (which are determined by comparing, among other things, the cost and

effects of a product when compared to different treatment options) and cost-effectiveness of our products;

- the budget impact of adding our products and devices to relevant formulary and medical device hospital lists and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs and other competitive products;
- the availability of different size drug vials and medical devices to meet the specific needs of healthcare practitioners;
- the claims, limitations, warnings and other information that appear in the package insert and labeling of SURFAXIN drug product;
- the willingness of third-party payers, including government payers, to provide coverage and reimbursements to patients, physicians and other providers who wish to prescribe and use our products;
- our ability to secure and maintain regulatory marketing approvals from the U.S. and foreign regulatory authorities;
- the rate of preterm births;
- the number of infants who are diagnosed with respiratory distress syndrome (RDS) and the number treated with SURFAXIN;
- our ability to finalize development of a second AFECTAIR device for use with children and adults;
- the growth of commercial sales;
- our ability to meet commercial demand for SURFAXIN and AFECTAIR, including through maintenance of commercial supplies of our active drug substances and other excipients, and manufacturing capabilities, by ourselves and through third-party manufacturers; and commercial inventory supplies of our medical device products; and
- the sufficiency of coverage or reimbursement by third parties.

Our efforts to achieve formulary acceptance of SURFAXIN and adoption of AFECTAIR, and to educate the medical community and third-party payers regarding the benefits of SURFAXIN and AFECTAIR will require significant, focused and competent resources and we may not be successful in achieving our objectives. SURFAXIN is approved for marketing only in the U.S. While we plan to register AFECTAIR in markets outside the U.S., beginning with the EU, we cannot predict the extent to which AFECTAIR will be utilized in the rest of the world. We cannot predict whether physicians, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize SURFAXIN, AFECTAIR and our other products and devices, if approved. If we are not successful in our efforts to gain broad acceptance of SURFAXIN and AFECTAIR in our target hospitals, the revenues we generate from sales will be limited and our business may not be profitable.

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

Even if we are successful in achieving our goals for formulary acceptance of SURFAXIN and adoption of AFECTAIR devices, if we do not achieve broad market acceptance of our products by physicians, patients, healthcare payers and others in the medical community, we may not generate sufficient revenues to support continued commercialization of these and our other products, if approved for commercial sale. The degree of market acceptance of SURFAXIN and AFECTAIR and our product candidates, if approved, will depend on a number of factors, including:

- the willingness of physicians to utilize our products;
- the degree of acceptance of AFECTAIR devices as the standard of care for delivery of inhaled therapies for patients requiring ventilatory support;
- the safety and efficacy of our products as perceived by the medical community, regulatory agencies and insurers and other payers, on both a short and long-term basis;

- the potential advantages over alternative treatments;
- the relative convenience and ease of administration;
- the prevalence and severity of any adverse events, including any unexpected adverse events of which we become aware; and
- the degree to which the market believes that we are able to manufacture our products and produce supply sufficient to meet market demand.

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 in the second quarter of 2013. We are initiating a user experience program with our AFECTAIR aerosol-conducting airway connector for infants in the first half of 2013, to be followed by a national program. We are also conducting further development activities to introduce a second vial size of SURFAXIN and, after we have completed introduction of our AFECTAIR device for infants, had planned to complete development a second AFECTAIR device for use with children and adults. However, we have decided to delay these development efforts in the near term so that we can focus our resources and expertise on meeting our 2013 goals to advance our development program for AEROSURF to address RDS. We have and will continue to conduct and sponsor studies evaluating the potential utility of AFECTAIR in delivering aerosolized medications and other inhaled therapies, as compared to current standard of care. We are also 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 U.S. and other markets as planned, or we may not succeed with our development efforts to manufacture a second vial size of SURFAXIN or a second AFECTAIR device. We may not successfully develop and market our other KL_4 surfactant and drug/device combination and aerosol delivery products. Our long-term viability will be impaired if we experience a significant delay or fail 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.

Generally, before we can attempt to sell products in a hospital, drug products must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's pharmacy and therapeutics (P&T) committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including the review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at hospitals varies considerably, and P&T committees often require additional information to aid in their decision-making process. Therefore, we may experience substantial delays in obtaining formulary approvals. In addition, our AFECTAIR devices must be approved for use by hospitals' materials management. There can be no assurance that we will successfully gain the required hospital approvals for our products. Additionally, hospitals may be concerned that the cost of acquiring our products for use in their institutions will adversely impact their overall budgets, which could cause resistance to efforts to add our drugs to the formulary and products to the materials list, or to implement restrictions on the usage of our drugs and products in order to control costs. We cannot guarantee that we will be successful in obtaining the approvals we need from enough hospitals quickly enough to optimize hospital sales of SURFAXIN, AFECTAIR or our other products, if approved.

In order to facilitate proper preparation and administration of SURFAXIN, we plan to make available to hospitals WARMING CRADLE dry-block heating devices that are designed to warm drug vials at the same temperature and for the time period that is designated in the SURFAXIN prescribing information. We will need to arrange with each hospital to include WARMING CRADLE dry-block heating devices on the hospital's list of approved laboratory equipment. There can be no assurance that we will be successful in gaining such approvals.

We may commit substantial efforts, funds and other resources to developing commercially successful products. A high rate of failure, or costly delay, is inherent in the development of new medical products. Currently, we are in the process of developing a second vial size for SURFAXIN as well as additional designs of AFECTAIR devices. There can be no assurance that our efforts to develop these products will be successful or that these products will be commercially viable. Failure can occur at any point in the development process, including after significant funds have been invested.

Promising new product candidates may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, failure to achieve market adoption, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or the infringement of intellectual property rights of others. Even if we successfully develop new products or enhancements or new generations of our existing products, they may be quickly rendered obsolete by newer products, changing customer preferences or changing industry standards. Innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license or otherwise acquire products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete.

To support the commercialization of SURFAXIN in markets outside the U.S., we plan to rely on one or more strategic alliances to support the development and, if approved, distribution and commercialization of our KL4 surfactant products and AFECTAIR devices. We may enter into distributor arrangements to manage the commercial introduction of AFECTAIR devices in markets outside the U.S. 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 U.S., we plan to rely on our own commercial and medical affairs organization. However, in markets outside the U.S., we plan to seek one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our KL4 surfactant development programs, and, if approved, to support the commercial introduction of these products in the Europe Union and elsewhere. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS, in countries where regulatory marketing authorization is facilitated by the recent approval of SURFAXIN by the FDA.

If we succeed in entering into one or more strategic alliances, our ability to execute our 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 U.S. 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.

Our plan to use strategic alliances and collaboration arrangements to leverage our capabilities may not be successful if we are unable to integrate our partners' capabilities with our operations or if our partners' capabilities do not meet our expectations.

As part of our strategy, we intend to continue to evaluate strategic partnership opportunities and collaboration arrangements. In order for these efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. Technologies to which we gain access may prove ineffective or unsafe. Ownership of these technologies may be disputed. The agreements that grant us access to such technologies may expire and may not be renewable or could be terminated if our partners or we do not meet our respective obligations. In addition, our partners may provide certain services for us, such as product development support or distribution services. These agreements may be subject to differing interpretations and we and our partners may not agree on the appropriate interpretation or specific requirements. Among other things, our partners may prove difficult to work with, less effective than we originally expected or unable to satisfy their financial and other commitments to us. Failure of our partners to perform as needed could place us at a competitive disadvantage.

If one of our strategic partners or collaborators pursues a product that competes with our products, there could be a conflict of interest and we may not receive expected revenues or milestone or royalty payments.

Certain of our potential strategic partners and collaborators may be developing or marketing a variety of products, some with other partners. Partners or collaborators with whom we enter into distribution agreements may sell and market products that compete with ours, or they may seek to develop, market or sell existing or alternative products or technologies or products targeted at the same diseases or conditions as the products that are the subject of an arrangement with us. Our strategic partners and collaborators may also develop products that are similar to or compete with products they are developing in collaboration with us. If these entities pursue other products instead of our products, we may not receive the anticipated revenues or milestone or royalty payments, or our efforts to distribute our products may be adversely affected.

We currently have limited experience in marketing or selling pharmaceutical products and limited marketing capabilities, which may restrict our success in commercializing our product candidates. We have developed our own commercial and medical affairs organizations to launch our drug products in the U.S. While we believe that this strategy greatly improves our ability to introduce our products in the U.S., it may also increase the cost to commercialize our products. We also plan to use our marketing, sales and medical affairs organizations to executive the commercial introduction of our AFECTAIR device for infants. We plan to consider strategic alliances and third-party distribution arrangements to support the commercialization of AFECTAIR in markets outside the U.S., which could require us to give up rights to our products.

We have limited experience in marketing or selling pharmaceutical products, although we have endeavored to hire individuals that individually have significant experience in neonatal indications and/or hospital-based products. We plan primarily to rely on our own specialty respiratory critical care commercial and medical affairs organizations to market and support SURFAXIN, and, if approved, AEROSURF and SURFAXIN LS in the U.S. We expect that our commercial organization will also support the commercial introduction of our AFECTAIR device. Commercializing our drug product candidates in the U.S. 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 and thereby potentially increase the revenue opportunity. Building our own 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, motivate and retain our commercial and medical affairs organizations 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.

We also plan to rely on our own commercial and medical affairs organizations to introduce the AFECTAIR device for infants in the U.S. We believe that this AFECTAIR device will be of interest to many of the same hospitals, neonatologists and neonatal intensive care units that purchase SURFAXIN. We plan to review and re-assess this strategy at the time that we introduce additional AFECTAIR devices in the future.

Even with our own commercial and medical affairs organizations to support the launch of SURFAXIN and the AFECTAIR device for infants in the U.S., we may also need to enter into co-marketing arrangements with third parties where our own personnel are neither well situated nor numerous 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 and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the FDA. We also plan to consider strategic alliances and/or collaboration arrangements, including third-party distributors or marketing alliances to sell, our AFECTAIR devices in international markets. We may not be successful in entering into any such arrangements, and the terms of any such arrangements may not be favorable to us. In addition, if we enter into co-marketing arrangements to market and sell additional products directly, we may need to further expand our commercial staff and incur additional expense.

We may not be successful in identifying strategic alliances and/or collaboration arrangements, third-party distributorships or marketing alliances 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 products on a timely basis. If we are not successful in finalizing such arrangements, we may not have sufficient funds to successfully commercialize SURFAXIN and AFECTAIR or any other potential product, in the U.S. or elsewhere. If we enter into alliances and distribution arrangements to commercialize our products, 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 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 maintain our 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.

We may have difficulty managing our growth.

We have experienced significant growth in the scope of our operations as we prepare for the anticipated launch of our products in the U.S., and thereafter, through strategic partnerships or distributorships, in the EU and in selected markets outside the U.S. As this potential growth occurs, it has and will continue to place additional significant demands on our management and our financial and operational resources, and will require that we continue to develop and improve our operational, financial and other internal controls. We also are engaged in discussions with potential strategic partners, which, if successful, will require additional management resources and controls to implement and potentially add a layer of complexity to our operations. We plan at various stages of development to distribute our products in the U.S. and potentially the EU and other major markets, through potential strategic alliances and collaboration arrangements. This expansion could further increase the challenges involved in implementing appropriate operational and financial systems, expanding manufacturing and production capacity, expanding our marketing and sales infrastructure and capabilities, and providing adequate training and supervision to maintain high quality standards. We believe that the significant challenges associated with our potential growth will include our ability to recruit, train and integrate skilled marketing, sales, medical affairs, supply chain, administrative and management personnel; to establish strategic partnerships and collaboration arrangements to support our development and commercialization activities; and to provide for manufacturing, including analytical testing and distribution capabilities, for our products, and clinical capabilities for our products under development. Our inability to grow our business appropriately or otherwise adapt to growth would cause our business, financial condition and results of operations to suffer.

We are continually evaluating our business strategy and may modify this strategy in light of developments in our business and other factors.

As we proceed with our plans to commercialize SURFAXIN and AFECTAIR in markets both inside and outside the U.S., we will continually evaluate our commercial strategy and will modify our plans as necessary to achieve our objectives. The activities associated with introduction of a new product are complex, involve many persons and entities, including third parties that we may not be able to control, and require the coordination of a number of elements, any one of which could involve unforeseen events or circumstances that require adjustment or the development of alternative strategies. If we encounter such events or circumstances, we will change our strategy and plans if we believe that such a change will be in our best interest. For example, if we experience any significant delay in our efforts to commercialize our products, we may adjust our approach to take into account any potential impact such a delay may have on our ability to fund our activities, or, if we were to determine that an alternative approach or structure would allow us to maintain control of our products or improve the profitability of our products in one or more markets, we will consider adopting such other approaches. Similarly, if a potential partner were to make observations or recommendations concerning the focus, sequence or approach of any or all of our research and development programs, we may consider taking such observations or recommendations into account in our planning process and activities. There can be no assurance, whether or not we alter our strategy or plans for any reason, that we will be successful, or that our product launches will be effectively executed on time, if at all, in all markets that we may identify.

Our ability to discover and develop new products depends on our internal research capabilities and our ability to acquire products. Although we continue to conduct research and development activities on products and have increased our activities in this area, our limited resources may not be sufficient to discover and develop new product candidates. To assist us with the development of our products and, if approved, commercialization of our products in markets outside the U.S., we continue to evaluate potential strategic partnership and collaboration arrangements. However, there can be no assurance that our efforts will be successful or that, even if we identify and enter into any such strategic partnership or collaboration arrangement, that such transactions will be successfully implemented within our expected time frames.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. With respect to our research and development activities, to respond to changing circumstances, we may, from time to time, refocus our product development efforts on different products or may pace, delay or halt the development of various products. As a result of changes in our strategy, we may also change or refocus our existing drug discovery, development, commercialization and manufacturing activities. This could require changes in our facilities and personnel and restructuring various financial arrangements. There can be no assurances that any product

development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives.

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 engage in business development activities intended to develop strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar 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 existing and future debt obligations could impair our liquidity and financial condition, and in the event we are unable to meet our debt obligations, the lenders could foreclose on our assets.

In connection with a Facility Agreement entered into on February 13, 2013, Deerfield has agreed to advance to us, subject to certain conditions, up to $30,000,000 principal amount of long-term debt. Our debt obligations:

- could impair our liquidity;
- could make it more difficult for us to satisfy our other obligations;
- require us to dedicate cash flow to payments on our debt obligations, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- impose restrictions on our ability to incur other indebtedness, grant liens on our assets, other than permitted indebtedness and permitted liens, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes;
- impose restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;
- could adversely affect our ability to enter into strategic transactions and similar agreements, or require us to obtain the consent of our lenders;
- make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets; and
- could place us at a competitive disadvantage when compared to our competitors who are not similarly restricted.

We have pledged substantially all of our assets to secure our obligations under the Facility Agreement. In the event that we were to fail in the future to make any required payment under the Facility Agreement or fail to comply with the covenants contained in the Facility Agreement and other related agreements, we would be in default regarding that indebtedness. A debt default would enable the lenders to foreclose on the assets securing such debt and could significantly diminish the market value and marketability of our common stock and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.

Even after completing our Deerfield Facility, we will need to obtain additional capital to successfully commercialize our approved products and develop our products under development, including AEROSURF and SURFAXIN LS, and continue our other research and development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to execute our business plans, including to effect the commercial introduction of SURFAXIN and AFECTAIR, execute our development plans for AEROSURF and our lyophilized KL4 surfactant (SURFAXIN LS), including our planned clinical trials, and continue our research and development programs to advance our product pipeline in the future. At the present time, we believe that our existing cash and cash equivalents, including net proceeds from the initial disbursement under the Deerfield Facility, will be sufficient to fund our operations through the third quarter of 2013. We will need to raise additional funds to continue our operations. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of our products or our research and development programs. We also could be required to:

- seek collaborators for one or more of our development programs for territories that we had planned to retain or on terms that are less favorable than might otherwise be available; or

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

We plan to seek additional sources of non-dilutive financing, including potentially a capital financing facility, to fund a portion of our expenses. However, such facilities may not be available, if at all, on terms that are favorable or acceptable to us. If we are unable to secure such financing, we may seek additional capital from the public markets, which could have a dilutive impact on our stockholders and the issuance, or even potential issuance, of shares could have a negative effect on the market price of our common stock.

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 manufacturing organizations (CMOs) or our materials and drug substances suppliers may experience manufacturing or quality control and assurance problems that could result in a failure to maintain compliance with cGMP and Quality requirements, or those of foreign regulators, which is necessary to continue manufacturing of 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;

- difficulties with production and yields, including manufacturing and completing all required release testing on a timely basis to meet demand;

- quality control and assurance problems related to, among other things, the release and stability testing of our drug product, or materials and drug substances;

- 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.

We have recently executed a plan to upgrade and validate one of our analytical chemistry methods used to assess drug product conformance to specifications of SURFAXIN drug product and to update related product specifications and have submitted updated product specifications to the FDA. As a result of this effort, the commercial introduction of SURFAXIN has been delayed until the second quarter of 2013. Manufacturing or quality control problems have occurred in the past and may again occur at our manufacturing and quality facilities or at the facilities of a CMO of our drug substances and materials suppliers. Such problems may in the particular circumstance 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, New Jersey, could result in a shortage of our commercial drug supply of SURFAXIN and could affect our commercial supply and potentially 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 manufacture and market our approved products and execute our development plans for our pipeline products. Such delays could adversely impact our operations and financial performance.

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, for our approved products, commercial sales. Our ability to manufacture depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. The supply of any of our manufacturing materials may be interrupted because of supply shortages, poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in lost sales and increased expenses.

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 provider 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. The process of changing a supplier could have an adverse impact on future growth opportunities during the transition period if supplies of drug substances, materials or excipients on hand are insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business.

A catastrophic event at our Warrington, Pennsylvania or Totowa, New Jersey facilities or any of the facilities used by our third party-manufacturers would prevent us from producing many of our drug products candidates and/or medical devices.

Our facilities consist of our headquarters in Warrington, Pennsylvania and our manufacturing facility in Totowa, New Jersey. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. Our facility in New Jersey is specifically designed for the aseptic manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only drug manufacturing facility. While we manufacture our SURFAXIN liquid instillate at our facilities in Totowa, we depend upon third-party manufacturers to manufacture WARMING CRADLE dry-block heaters, our lyophilized KL4 surfactant, our AFECTAIR devices and our CAG. All of these products are or will be manufactured at a single facility. If a catastrophic event occurred at any our facilities or the facilities of any of our third-party manufacturers, such as a fire, flood or tornado, many of those products could not be produced until the manufacturing portion of such facility was restored and cleared by the FDA. With respect to our Totowa facility, we maintain a disaster plan to minimize the effects of such a catastrophe, and we have obtained insurance to protect against certain business interruption losses. However, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

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, New Jersey, we plan to depend upon third-party manufacturers to manufacture our lyophilized dosage form of our KL4 surfactant, AFECTAIR devices and our CAG. Our planned 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 as well as a potentially lengthy qualification process. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval;
- 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, or we may have difficulty scheduling the production of product batches in a timely manner to meet our timing requirements;
- CMOs 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;
- CMOs 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; or
- 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.

For the development and, if approved, commercialization of AEROSURF, we will depend in large measure upon the manufacturers and assemblers of our CAG devices. If we are unable to identify qualified manufacturers and assemblers, the timeline of our plans for the development and, if approved, commercialization of AEROSURF and any 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 AEROSURF, which is a drug/device combination product that produces our aerosolized KL4 surfactant, we plan to rely on CMOs to manufacture and assemble the subcomponents of our CAG technology to support our preclinical experiments, planned clinical studies and, if approved, commercial device. Certain of these components must be manufactured in an environmentally-controlled area and, when assembled, the critical drug product-contact components must be packaged and sterilized. Each of the aerosolization system devices must pass quality control testing 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 working with Battelle to develop an optimized CAG device to meet regulatory and ease-of-use design requirements for AEROSURF and prepare a clinic-ready device for our planned Phase 2 clinical trials. As with many device development initiatives, there is a risk that, even if we are able to finalize specifications for the CAG, 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 in the manufacture of our AFECTAIR device for infants. 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 regulations of the FDA and foreign regulators. In the event of any release of defective product, Lacey is obligated to cooperate with us, including for those defects that result in product recalls or other similar events. If Lacey is unable to manufacture to our specifications, or if Lacey fails to comply with the regulations 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 system, including an objective and systematic process for monitoring and the evaluation of key process 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 device 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.

Marketing authorization to promote, manufacture and/or sell AFECTAIR will be limited and subject to continuing review. Similar risks arise with our SURFAXIN drug product.

We have successfully registered our AFECTAIR device in the U.S. We also expect to register this device in the EU. These registrations do not include substantial claims with respect to potential use or efficacy. Even if regulatory clearance of this product is granted in the EU, such clearance will be subject to limitations on the uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue

from the product. Similarly, although our label for SURFAXIN contains more information, including data from our pivotal Phase 3 clinical trial, there are limitations that affect the manner in which we may market and sell our SURFAXIN drug 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 were to determine that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could direct us to cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities could 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 marketing and sales efforts will have to focus on the general technical attributes and benefits of AFECTAIR and any FDA-cleared indications for use. We have conducted a series of studies, and plan to conduct further 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. For SURFAXIN, our marketing and sales efforts will have to be based on our label, although there is other data and information available that speaks to the benefits of our KL4 surfactants.

In addition, for both our AFECTAIR device and SURFAXIN, we will have to comply with reporting requirements applicable to medical devices and drug products, including the reporting of adverse events and device malfunctions related to our products. Later discovery of previously unknown problems, 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.

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 U.S. 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 post-marketing reporting, 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 and implementing any 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.

With the commercial launch of SURFAXIN and AFECTAIR, we will be required to comply with not only the requirements of the FDA and international regulators, but will also become subject to various federal, state and international laws regulating the sales, marketing, and distribution of healthcare-related products. These laws govern such activities as our relationships with healthcare providers, the promotion of our products, and pricing of prescription drug products and medical devices. 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, and 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.

Of particular importance, federal and state anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. These laws can be complicated, are subject to frequent change and may be violated unknowingly. In addition, the absence of guidance for some of these laws and the very few court decisions addressing industry practices increase the likelihood that our practices could be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to the government (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. Many pharmaceutical, device, and other health care companies have been investigated and prosecuted for alleged violations of these laws. Sanctions under these laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi-million dollar fines to the government and agreed to abide by corporate integrity agreements, which often include significant and costly burdens. Under the federal False Claims Act and related state laws, private individuals may bring similar actions. In addition, an increasing number of state laws require manufacturers to report to the state certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

We are refining our comprehensive compliance program, including policies, training and various forms of monitoring, designed to address the sales-and-marketing-related risks set forth above. However, no compliance program can mitigate risk in its entirety. 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 European Medicines Agency (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 Market Authorization Application (MAA) filed for a drug product on a timely basis or at all. *See,* "Item 1 – Business – Government Regulation" in this 2012 Form 10-K.

We are currently planning to initiate a Phase 2 clinical program for AEROSURF in the fourth quarter of 2013. We believe that our success in gaining approval for SURFAXIN in the U.S. may facilitate our efforts to gain regulatory approval for AEROSURF and SURFAXIN LS in the U.S. and potentially other major markets. However, there can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical programs will be concluded successfully. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF or SURFAXIN LS, if at all, within our expected time frame.

We plan to pursue clinical development in the U.S. and potentially in the EU and other markets, and, if approved, market and sell our products in the U.S. and potentially in the EU and other major markets. To accomplish this objective, we must obtain and maintain regulatory approvals and comply with regulatory requirements in each jurisdiction. To avoid the significant expense and lengthy time required to complete multiple clinical programs, we expect to meet with the FDA and other regulatory authorities to potentially address the requirements of the various regulatory authorities through a single, global clinical program. There can be no assurance that our efforts will be

successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our products in all of our selected markets.

The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the U.S. 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 EU, 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 U.S. or the EU, we could be adversely affected.

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.

Even if we succeed in gaining 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 U.S. Our development programs for AEROSURF and SURFAXIN LS are in the preclinical stage, with Phase 2 clinical trials for AEROSURF anticipated in the fourth quarter of 2013. Foreign regulators have not yet approved SURFAXIN or any of our products under development. 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.

Our research and development programs for AEROSURF and SURFAXIN LS 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 CMOs, 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 CMOs, to produce sufficient drug product, including for KL4 surfactant-related studies, AEROSURF and SURFAXIN LS development activities, and CAG devices and related materials to meet our preclinical and clinical development requirements; and
- 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 completed our pivotal Phase 3 clinical trials for SURFAXIN for the prevention of RDS in premature infants at high risk for RDS and have conducted certain Phase 2 trials for other drug product candidates for other indications. If we successfully advance our KL4 surfactant RDS development programs through the initial preclinical phase of development, we plan to conduct Phase 2 clinical trials for AEROSURF, potentially beginning in the fourth quarter of 2013. We also are assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other selected markets and plan to seek a strategic alliance to support our efforts. Before we will initiate a clinical program, it will be important to secure adequate capital to support that activity. Such clinical programs 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, or we may be unable to reach agreement on a single trial design that would permit us to conduct a single clinical program. 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. For example, we may not be successful in achieving a trial design that is acceptable to the FDA and regulators in other countries, which would cause us to greatly increase our investment or limit the scope of our activities. 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 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 AEROSURF and SURFAXIN LS, 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.

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 or our other aerosolized KL4 surfactant products, and our business strategy.

We are currently working to develop 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 are currently working with Battelle, which has expertise in medical device development and medical device design and a successful track record in developing aerosolization systems for the medical and pharmaceutical industries. If for any reason we are unable to retain our own engineering capabilities, the agreement with Battelle is terminated, and 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 have a material adverse effect on our business strategy and 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 and commercialization 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 KL4 surfactant products.

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

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. In selecting the appropriate software packages and systems to manage and support our activities, we will consider both in-house development and specialty software and system packages offered by third party vendors, service providers and consultants. The systems we select may not be adequate to meet our needs or may fail to perform to the specified requirements. We may be required to seek other sources of system support, which would increase our costs and potentially delay our implementation of necessary activities. There can be no assurance that the systems that we select or choose to develop will be adequate to our needs, that they will perform to our requirements or that we will be successful in integrating them into our operations.

In addition, 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, or if the systems we implement do not meet our expectations, 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.

Our business planning requires us to forecast demand and revenues despite numerous uncertainties. Actual results of operations may deviate materially from projected results. 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 EU 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 and to Deerfield in connection with the Deerfield Facility 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 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 1, 2012, we had 43,660,244 shares of common stock issued and outstanding. In addition, as of December 31, 2012, approximately (i) 8.0 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 4.0 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 26,290 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 U.S. or foreign regulatory policy during the period of product development;
- changes in the U.S. 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, 2012, the price of our common stock ranged between $1.67 and $5.39. 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, 2012, the average daily trading volume in our common stock was approximately 875,035 shares, and the average number of transactions per day was approximately 2,208. 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 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. Any failure at any time to meet the continuing The Nasdaq Capital Market listing requirements could have an adverse impact on the value of and trading activity in our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the U.S. 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 U.S. 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 EU. In the U.S., 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 U.S. 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 includes provisions, typically referred to as the federal Physician Payments Sunshine Act, that establish new reporting and disclosure requirements for pharmaceutical and medical device manufacturers. Under the law, pharmaceutical and device manufacturers are required to annually report various types of payments and other transfers of value to physicians and teaching hospitals. Although implementation of the sunshine provisions was initially delayed by the U.S. Centers for Medicare and Medicaid Services (CMS), a final rule was released in February 2013. Under the rule, applicable manufacturers must being tracking relevant payment data in August 2013, and must report data collected between August 1 and the end of 2013 to CMS by March 31, 2014. CMS will publish the data on a public website by September 30, 2014. Inaccurate or incomplete reports may be subject to enforcement. Like the federal Sunshine Law, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state, or even go so far as to 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. In others, it is possible that we will be subject 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 U.S.

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.

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 The Nasdaq Capital Market, 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 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, 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 The Nasdaq Capital Market, regardless of the outcome, are likely to 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 continue to implement our plan to hire additional qualified personnel to support (i) the commercialization of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and SURFAXIN LS development programs. In particular, we have established our field-based sales and marketing and medical affairs organizations,

and expect to hire for our regulatory affairs, quality control and assurance and administrative functions. 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.

We have entered into employment agreements with five executive officers, including the President and Chief Executive Officer and Chief Financial Officer; the Senior Vice President and Chief Operating Officer; the Senior Vice President, General Counsel and Corporate Secretary; the Senior Vice President, Human Resources; and the Senior Vice President, Research and Development. These agreements expire on May 3, 2013, subject to automatic renewal for an additional one year period, unless a party provides notice of non-renewal at least 90 days in advance. The Compensation Committee of our Board of Directors (Committee) directed that notices of non-renewal be issued to all executive officers to provide an opportunity to replace the form of agreement. In addition, with five other officers we have entered into retention agreements that also expire on May 3, 2013. We expect that, after the Committee completes its review of current market information and other data, the Committee will approve new forms of agreements for all executives. 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 need to attract and retain highly-qualified personnel 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. Moreover, the equity incentives in the form of options 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.

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 in many ways. We need to successfully introduce new products to achieve our strategic business objectives. The development and acquisition of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

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;
- 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. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our products in such markets. As 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 available at this time, 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, protect our trade secrets, and otherwise prevent others from infringing our proprietary rights.

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 U.S. 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 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 KL4 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 KL4 surfactant products. These patents, which include important KL4 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 2013, with further extensions possible into 2014. For our aerosolized KL4 surfactant, we hold worldwide exclusive licenses from PMUSA and PMPSA to the CAG technology for use with pulmonary surfactants together or in combination with other products for all respiratory diseases. Our exclusive license in the U.S. 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 2031, 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 U.S. 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 KL4 surfactant technology, our novel CAG technology, and our novel aerosol-conducting airway connectors.

Our technology platform is based on the scientific rationale of using our KL4 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 U.S. 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, PMPSA and The Scripps Institute. 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 all employees enter into agreements with us that include non-compete covenants, and our five senior executive officers have agreements that include broader non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, such non-compete 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 infringement 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 unquantifiable 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 U.S. 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 or our device-related patent applications 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.

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.

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 consist of 39,594 square feet of space that we lease. On January 3, 2013, we entered into a Second Amendment to the lease agreement (Amendment) to extend the lease for an additional five years until February 2018. In addition the Amendment provides for a reduction to the base rent effective as of October 1, 2012; a reduction in the security deposit over a two year period beginning in 2013, from $400,000 to $225,000; the elimination of our obligation to remove certain improvements and restore the premises; and an adjustment of our option to extend the lease to an additional period of five years through February 2023. The total aggregate base rental payments under the Lease prior to the extension were approximately $7.2 million and the total aggregate base rental payments under the extended portion of the Lease are approximately $4.9 million. We do not own any real property.

We also maintain at our principal executive office an analytical and technical support laboratory that is predominantly involved in release testing of all APIs as well as release and stability testing of SURFAXIN® clinical and commercial drug product supply. We also perform at this location research and development work for our lyophilized and aerosolized KL4 surfactant dosage forms as well as other potential formulations of our KL4 surfactant, and in support of our efforts to identify and protect our intellectual property. We also maintain a medical device development laboratory with resources and capabilities that our internal development engineering team uses for ongoing preclinical development activities for AEROSURF® and our aerosol delivery technologies, while at the same time controlling the related expense and conserving our financial resources. The facility includes a controlled environment with two class 10,000 hoods (for activities requiring clean room procedures).

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. We currently are assessing our available alternatives for dealing with the expiration of this lease and are considering a long-term manufacturing strategy that could include (i) subject to the landlord's agreement, potentially

renegotiating or extending our current lease for a period of time, (ii) building or acquiring additional manufacturing capabilities to support product development and commercial production of our KL4 surfactant product candidates, and (iii) potentially using CMOs. We are currently in discussion with the landlord and with a third party CMO to assure the continued availability of SURFAXIN commercial drug product into 2015.

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 1, 2013, we had 129 stockholders of record of shares of our common stock. We also have been advised by Broadridge Financial Solutions, Inc. that, as of March 1, 2013, there are approximately 20,735 beneficial owners of our common stock whose positions are held in street name. As of March 1, 2013, there were 43,660,244 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 The Nasdaq Capital Market.

	2012		2011	
	High	Low	High	Low
Period:				
First Quarter	$5.39	$1.67	$4.18	$1.71
Second Quarter	$3.15	$2.12	$2.95	$1.79
Third Quarter	$3.51	$2.30	$2.70	$1.93
Fourth Quarter	$3.29	$1.71	$2.01	$1.44

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

Sales of Unregistered Securities

During the year ended December 31, 2012, we issued 40,000 unregistered shares of common stock to an unaffiliated consultant as compensation for management consulting services rendered during 2012. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

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, 2012, we did not conduct any stock repurchases.

ITEM 6. SELECTED FINANCIAL DATA.

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

	For the year ended December 31,				
	2012	**2011**	**2010**	**2009**	**2008**
Revenues from grants	$ 195	$ 582	$ -	$ -	$ -
Revenues from collaborative agreements	-	-	-	-	4,600
Operating Expenses:					
Research and development	21,570	17,230	17,136	19,077	26,566
Selling, general and administrative	16,444	7,864	8,392	10,120	16,428
Total expenses[(1)]	38,014	25,094	25,528	29,197	42,994
Operating loss	(37,819)	(24,512)	(25,528)	(29,197)	(38,394)
Change in fair value of common stock warrant liability	555	3,560	6,422	369	-
Other (expense) / income	(51)	(13)	(69)	(1,043)	(712)
Net loss	$ (37,315)	$ (20,965)	$ (19,175)	$ (29,871)	$ (39,106)
Net loss per common share - basic and diluted	$ (0.95)	$ (0.93)	$ (1.65)	$ (3.89)	$ (5.98)
Weighted average number of common shares outstanding	39,396	22,660	11,602	7,680	6,541

[(1)] Included in the net loss for 2012, 2011, 2010, 2009, and 2008 were non-cash charges for stock-based compensation and depreciation of $3.3 million, $2.2 million, $2.8 million, $4.3 million and $6.3 million, respectively.

Consolidated Balance Sheet Data:
(in thousands)

	December 31,				
	2012	**2011**	**2010**	**2009**	**2008**
Cash and investments	$ 26,892	$ 10,189	$ 10,211	$ 15,741	$ 24,792
Working capital	16,107	(516)	2,920	176	15,551
Total assets	29,943	13,324	14,537	21,403	32,889
Long-term obligations, less current potion	591	913	935	1,118	12,090
Total stockholder's equity	$ 17,653	$ 1,264	$ 6,026	$ 1,296	$ 10,933

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, 2012, 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 (KL4 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 KL4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of aerosolized drugs, including our aerosolized KL4 surfactant, and other inhaled therapies. 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.

Our initial strategy is to develop our KL4 surfactant and drug delivery technologies to improve the management of respiratory distress syndrome (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 have the potential to greatly improve the management of RDS and, collectively over time, to become a new standard of care for premature infants with RDS.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of 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. *See,* "–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 KL4 Surfactant Technology."

In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. We proactively communicated these findings to the FDA, improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. Although there can be no assurances, if we are able to successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline in the second quarter of 2013, we believe that we remain on track to manufacture SURFAXIN drug product for commercial use in the second quarter of 2013. This delay in availability of SURFAXIN drug product from the fourth quarter 2012 to the second quarter of 2013 is not expected to have a material adverse effect on our business or financial position, in part because our commercial launch plans for SURFAXIN during this period have always been to focus initially on hospital formulary acceptance.

AEROSURF® is a drug/device combination product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF for premature infants with or at risk for developing 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. Consequently, neonatologists generally will not treat infants who could benefit from surfactant therapy unless they determine that 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."

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and resuspended to liquid form prior to use 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 engaged in a technology transfer of our lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our preclinical and clinical development activities. Our development plan is intended initially to support the use of our lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the United States (U.S.) and potentially other major markets.

AFECTAIR® devices are our novel disposable aerosol-conducting airway connectors that simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. Our initial device is AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units (NICUs and PICUs, respectively). We are initiating a user experience program that is being conducted in select U.S. critical care centers that represent approximately ten percent (10%) of our target institutions. This initial phase, which is

intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, is expected to be conducted in the first half of 2013. Following the initial phase, we expect to initiate a broader introduction of the AFECTAIR device for infants in a national phase. We believe that AFECTAIR aerosol-conducting airway connectors have the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to infants receiving aerosolized medication in the NICU and PICU. We believe that revenues from the AFECTAIR device for infants in the fourth full selling year could potentially be $10 million in the U.S. and $20 million globally.

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS and the AFECTAIR device for infants to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in PICUs and intensive care units (ICUs). However, we are delaying these development efforts in the near term in order to focus our resources and expertise on meeting our 2013 goals to advance our development program for AEROSURF to Phase 2 clinical trials and execute the commercial introduction of SURFAXIN and the AFECTAIR device for infants. If we are able to achieve our 2013 objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and aerosol-conductor airway connector technologies to address the critical care needs of patients in the PICU and ICU.

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in and will focus on neonatal indications. These organizations will be primarily responsible to effect the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations to effectively introduce the AFECTAIR device for infants in the U.S. We also expect that, in the future, these teams will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN and the AFECTAIR device for infants to efficiently support the introductions of AEROSURF and SURFAXIN LS, if approved.

An important priority is to secure strategic resources to support the continued development and commercial introduction of our RDS products. While we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our efforts, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the EU. In our discussions to date, the primary focus of our discussions has been on AEROSURF. We also would consider various financing alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 surfactant development programs. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA. There can be no assurance 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 U.S., 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, 2012, 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 (ASC) Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity,"* 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 terms of a 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.

Inventory

Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. In connection with the FDA's approval of SURFAXIN and the registration of our initial AFECTAIR device in the U.S., we assessed the potential capitalization of inventory and the timing of when the related costs are expected to be recoverable through the commercialization of our products. Costs incurred prior to receipt of marketing authorization have been recorded in our statement of operations as research and development expense. As a result, inventory balances and cost of revenue may reflect a lower average per-unit cost of materials for several quarters after we launch our products. As of December 31, 2012, inventories were valued at $0.2 million and consisted of raw materials used in the production of SURFAXIN.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the years ended December 31, 2012, 2011 and 2010 was $37.3 million (or $0.95 per share), $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 $0.6 million, $3.6 million and $6.4 million for 2012, 2011 and 2010, respectively.

The operating loss for the years ended December 31, 2012, 2011 and 2010 was $37.8 million, $24.5 million and $25.5 million, respectively. The operating loss includes $3.3 million, $2.2 million and $2.8 million for non-cash items related to depreciation and stock-based compensation for 2012, 2011 and 2010, respectively. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was $34.5 million, $22.4 million and $22.7 million for 2012, 2011 and 2010, respectively.

The increase in operating loss from 2011 to 2012 is primarily due to investments that we have made (i) to establish our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in and will focus on neonatal indications, beginning with SURFAXIN and the AFECTAIR device for infants. With the information gained and relationships developed during the SURFAXIN introduction, we anticipate that these teams may be able to efficiently effect the commercial introduction of AEROSURF and SURFAXIN LS, if approved; and (ii) to advance the development of our CAG for potential use in our planned AEROSURF Phase 2 clinical program in the fourth quarter of 2013.

Grant Revenue

For the year ended December 31, 2012, we recognized $0.2 million of grant revenue for funds received and expended under a Small Business Innovation Research (SBIR) Phase I award from National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) Center for Medical Counter Measures Against Radiation and Nuclear Threats to assess the ability of KL4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury. We believe that our aerosolized KL4 surfactant may be an effective intervention for people at risk for, or with, Acute Lung Injury (ALI), and that our development work with AEROSURF for RDS may form the basis for a pipeline of products to address ALI. We are collaborating with leading research institutions in a series of preclinical studies funded through various U.S. Government-sponsored, Biodefense-related initiatives, including NIAID. The total amount of the award is $600,000 and the remainder of the award is expected to be received and expended in 2013.

For the year ended December 31, 2011, we recognized $0.6 million of revenue for funds received and expended under a Fast Track SBIR from NIH to support the development of aerosolized KL4 surfactant for RDS.

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 KL4 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 by category are as follows:

	Years Ended December 31,		
	2012	2011[1]	2010[1]
		(in thousands)	
Product development and manufacturing	$ 15,788	$ 12,359	$ 11,739
Medical and regulatory operations	4,818	3,452	3,337
Direct preclinical and clinical programs	964	1,419	2,060
Total Research and Development Expenses	$ 21,570	$ 17,230	$ 17,136

[1] Certain prior year expenses have been reclassified to conform to 2012 presentation.

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.3 million, $1.4 million and $1.7 million for 2012, 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.

Product Development and Manufacturing

Product development and manufacturing includes (i) the cost of our manufacturing operations and technical transfer of our lyophilized manufacturing process to a CMO, validation activities and 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 primarily for use in our anticipated AEROSURF clinical program and, if approved, commercial use; (iii) design and development activities related to our AFECTAIR aerosol-conducting airway connectors, 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.

Product development and manufacturing expenses increased $3.4 million from 2011 to 2012 primarily due to (i) investments in manufacturing and quality activities as we prepare for commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) costs associated with our efforts to optimize the design of our CAG with our engineering staff and third-party medical device experts, including work that we began in June 2012 with Battelle Memorial Institute (Battelle), which is assisting us in a multi-phase development program focused on design, testing, and manufacturing of clinic-ready CAG devices for our planned AEROSURF Phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013, and (iii) costs associated with employee incentive compensation plans.

Product development and manufacturing expenses increased $0.6 million from 2010 to 2011 primarily due to costs associated with the manufacture of SURFAXIN drug product for preclinical studies to support our response to a complete response letter that we received from the FDA in 2009 (2009 Complete Response Letter), partially offset by a reduction in costs associated with a slow-down and pacing of the technology transfer of our lyophilized KL4 manufacturing process to a CMO as we focused on securing marketing approval for SURFAXIN. The SURFAXIN batches were needed to execute certain preclinical and analytical studies associated with our efforts to, among other things, optimize and revalidate our fetal rabbit biological activity test (BAT, a quality control and stability release test for SURFAXIN and our other KL4 pipeline products).

Product development and manufacturing expenses include non-cash charges associated with stock-based compensation and depreciation of $1.0 million, $1.2 million and $1.4 million, for the years ended December 31, 2012, 2011 and 2010, respectively.

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) beginning in 2012, medical affairs activities to provide scientific and medical education support related to both SURFAXIN and AFECTAIR as well as our other KL4 surfactant and aerosol delivery products under development. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Medical and regulatory operations expenses increased $1.4 million from 2011 to 2012 primarily due to (i) investment in our medical affairs organization in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants, and (ii) costs associated with employee incentive compensation plans.

Medical and regulatory operations expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million, $0.2 million and $0.3 million for the years ended December 31, 2012, 2011 and 2010, respectively.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an initial annual rate of approximately $13 million. Of this amount, the portion attributed to medical affairs, anticipated to be approximately $3 million, will be charged to medical and regulatory operations expenses. *See also,* "– Selling, General and Administrative Expenses."

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) activities related to responding to the 2009 Complete Response Letter; (ii) development activities, including preparatory activities for the anticipated clinical program for AEROSURF for RDS in premature infants and, potentially, SURFAXIN LS, 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, if any, associated with conducting 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 completing a Phase 2 clinical trial evaluating the use of SURFAXIN in children up to two years of age suffering with Acute Respiratory Failure (ARF).

Direct preclinical and clinical programs expenses decreased $0.5 million from 2011 to 2012 primarily due to a decrease in costs associated with activities completed in 2011 to respond to the 2009 Complete Response Letter, offset by a $0.5 million charge related to a milestone payment that became payable to J&J upon FDA approval of SURFAXIN in March 2012.

Direct preclinical and clinical programs expenses decreased $0.6 million from 2010 to 2011 primarily due to the completion of the Phase 2 ARF clinical trial in 2010.

We plan to continue to focus our drug research and development activities on the management of RDS in premature infants, specifically our AEROSURF and lyophilized KL4 surfactant development programs. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other major markets. To prepare for initiation of our AEROSURF clinical program, we have conducted preliminary meetings with the FDA and we have engaged regulatory consultants to assist us in implementing and, as needed, refining our development plan. We also plan to retain regulatory consultants to assist us in engaging international regulatory authorities regarding the AEROSURF development plan. We expect that we will use our lyophilized KL4 surfactant for AEROSURF. We have discussed with the FDA a proposed development program for SURFAXIN LS and expect to engage in further discussions with the FDA. Once we have secured the necessary capital, we plan to implement a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the U.S., and thereafter potentially in other selected markets. We plan to initiate the first phase of the AEROSURF Phase 2 clinical program in the fourth quarter of 2013. As resources permit, we plan to leverage the development investments to date in our aerosol technology programs (AEROSURF and AFECTAIR) to address respiratory critical care conditions in larger children and adults, including potentially ALI.

Research and Development Expense by Major Expense Category

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

(in thousands)	Years Ended December 31,		
	2012	**2011**	**2010**
Salaries & Benefits	$ 9,986	$ 8,231	$ 6,858
Contracted Services	6,332	3,317	4,395
Raw Materials & Supplies	1,652	1,871	1,009
Rents & Utilities	1,366	1,531	1,442
Depreciation	841	1,141	1,207
Contract Manufacturing	15	143	990
Travel	316	188	202
Stock-Based Compensation	488	289	479
All Other	574	519	554
Total	$ 21,570	$ 17,230	$ 17,136

The increase in salaries and benefits from 2011 to 2012 is primarily due to the establishment of our medical affairs organization to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants, increased benefit costs and employee incentive payments. The increase in salaries and benefits in from 2010 to 2011 was 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, including our BAT, consulting services, aerosol device design and engineering services, etc. The increase from 2011 to 2012 is primarily due to costs associated with work that we began in June 2012 with Battelle to optimize design, test, and manufacture clinic-ready CAG devices to be used in the first phase of our planned AEROSURF Phase 2 clinical trial in the fourth quarter of 2013, and investments in our manufacturing and quality activities as we prepare for the commercial introduction of SURFAXIN and the AFECTAIR device for infants. The decrease from 2010 to 2011 is primarily due to the completion of the Phase 2 ARF clinical trial in 2010 and a decrease in 2011 in outside laboratory testing related to activities as we completed work to respond to the 2009 Complete Response Letter.

Raw materials and supplies consist of purchases of our active pharmaceutical ingredients (APIs) for the manufacture of our KL4 surfactant product candidates and supplies to support our manufacturing and analytical testing and development laboratories 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 AFECTAIR aerosol-conducting airway connectors. The decrease in raw materials and supplies from 2011 to 2012 is primarily due to a decrease in raw material purchases following submission in 2011 of our response to the 2009 Complete Response Letter**.** The increase in raw materials and supplies from 2010 to 2011 was primarily due to the manufacture of SURFAXIN drug product for preclinical studies to support our response to the 2009 Complete Response Letter.

Rents and utilities are costs related to our leased manufacturing, laboratory and related facilities. The decrease from 2011 to 2012 is primarily due to decreased utility costs at our manufacturing facility associated with a decrease in the number of batches of SURFAXIN drug product manufactured.

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. The decrease from 2011 to 2012 is primarily due to capitalized assets becoming fully depreciated during 2012.

Contract manufacturing represents costs related to the technology transfer of our lyophilized KL4 manufacturing process to a cGMP-compliant CMO with expertise in manufacturing lyophilized drug products. The decrease in contract manufacturing costs over the three year period is due to pacing of our technology transfer activities while we focused our efforts on responding to the 2009 Complete Response Letter and securing marketing authorization for SURFAXIN. Contract manufacturing costs are expected to increase in 2013 since we have restarted our technology transfer activities.

The category "All Other" consists primarily of ongoing research and development costs such as insurance, taxes, education and training and software licenses.

Research and Development Projects

A substantial portion of our cumulative losses to date, of which $55.9 million is associated with the three-year period ended December 31, 2012, 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 initial KL4 surfactant drug product, SURFAXIN, was approved for marketing in the U.S. in March 2012. Also in 2012, we registered our AFECTAIR device in the U.S. and expect to complete the registration of the AFECTAIR device in the EU in 2013. Although we have two commercial products at this time, neither is broadly available for commercial sale. There can be no assurance that we will be successful in commercializing these products or in realizing a profit in the foreseeable future.

Our lead KL4 surfactant drug development programs, AEROSURF and SURFAXIN LS, are focused on the management of RDS in premature infants. We believe that these programs have the potential to greatly improve the management of RDS and expand the current RDS market in our target markets. We plan in 2013 to seek regulatory and scientific guidance with respect to our planned development programs for AEROSURF and initiate the Phase 2 clinical program for AEROSURF. We also are assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other selected markets and plan to seek a strategic alliance to support our efforts. However, our ability to move forward with our planned clinical programs will depend upon the success of our efforts to complete our development activities, secure strategic alliances and/or necessary capital to support these activities. If we are successful within our target time frame, we expect to initiate our Phase 2 clinical programs for AEROSURF in the fourth quarter of 2013. However, there can be no assurance that we will be successful in completing our development activities and securing a strategic alliance or capital, 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."

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. However, we also 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 ALI. 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 U.S. 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.

Selling, General and Administrative Expenses

(in thousands)	Years Ended December 31,		
	2012	2011	2010
Selling, General and Administrative Expenses	$ 16,444	$ 7,864	$ 8,392

Selling, general and administrative expenses consist primarily of the costs of executive management, marketing and field-based sales, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

Selling, general and administrative expenses increased $8.6 million from 2011 to 2012 primarily due to (i) investments in our marketing and field-based sales force in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) marketing related activities for both SURFAXIN and the AFECTAIR device for infants; (iii) a one-time charge associated with certain contractual cash severance obligations and stock-based compensation charges related to the resignation of our former Chief Executive Officer; and (iv) costs associated with employee incentive compensation plans.

Selling, general and administrative expenses decreased $0.5 million from 2010 to 2011 due primarily to a one-time charge in 2010 associated with certain contractual cash severance obligations related to the 2009 resignation of Robert J. Capetola, Ph.D., our former Chief Executive Officer, offset by employee incentive payments and AFECTAIR market research activities in 2011.

Selling, general and administrative expenses include non-cash charges associated with stock-based compensation and depreciation of $2.0 million, $0.7 million and $1.1 million, for the years ended December 31, 2012, 2011 and 2010, respectively. The 2012 amount includes $0.8 million of stock-based compensation charges resulting from the resignation of W. Thomas Amick, our former Chief Executive Officer.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an initial annual rate of approximately $13 million. Of this amount, the portion attributed to marketing and field-based sales, anticipated to be approximately $10 million, will be charged to selling, general and administrative expenses. *See also,* "– Medical and Regulatory Operations."

In addition to developing our commercial marketing and sales organization, we have made and may make additional investments to enhance certain of our general and administrative resources, including legal and compliance, finance and accounting, and information technologies, to support our commercial activities. With these investments, we believe that our general and administrative resources will be sufficient to support our business operations.

We plan to continue our investments in prosecuting and maintaining our existing patent portfolio and trademarks, and in protecting our trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities. We also plan, when appropriate, to invest in potential 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

(in thousands)	Years Ended December 31,		
	2012	2011	2010
Change in fair value of common stock warrant liability	$ 555	$ 3,560	$ 6,422

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 at the date of initial issuance and as of each subsequent balance sheet date using the Black-Scholes or trinomial pricing models, depending on the terms of the applicable warrant agreement. 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, generally accepted accounting principles (GAAP) provide that these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under federal securities laws, providing freely-tradable shares upon exercise of the warrants may not be within our control in all circumstances, and (ii) the warrant agreements do not expressly provide that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The accounting guidance expressly precludes an evaluation of the likelihood that cash settlement could occur. 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 form of warrant agreement for the registered five-year warrants that we issued in the February 2011 public offering (February 2011 five-year warrants) expressly provides 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.

Changes in our common stock warrant liability are primarily related to changes in our common stock share price during the periods.

Other Income / (Expense)

(in thousands)	Years Ended December 31,		
Other Income / (Expense):	**2012**	**2011**	**2010**
Interest income	$ 3	$ 13	$ 13
Interest expense	(13)	(20)	(357)
Other income / (expense)	(41)	(6)	275
Other income / (expense), net	$ (51)	$ (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 2012 and 2011 consists of interest on our equipment financing facilities. Interest expense for 2010 consists of interest on our equipment financing facilities, interest on our loan with PharmaBio 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 from 2010 to 2011 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 of $244,479 received under the Patient Protection and Affordable Care Act of 2010 to reimburse costs incurred in 2009 to advance our aerosolized KL4 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) and a previous at-the-market Program that we entered in December 2011 with Lazard Capital Markets (Lazard ATM Program), capital equipment and debt facilities, and strategic alliances.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. Before additional financing activities, including the second disbursement under the Deerfield Facility and under the ATM Program, as discussed below, we anticipate that we have sufficient cash available to support our operations and debt service obligations through the third quarter of 2013. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and/or strategic and collaborative arrangements with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our December 31, 2012 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

To execute our business strategy and fund our operations over time, we will require additional infusions of capital until such time as the net revenues from SURFAXIN and AFECTAIR, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset cash flow requirements. Given the time required to secure formulary acceptance at our target hospitals and acceptance of a new product, we expect our revenues from SURFAXIN and AFECTAIR will not increase immediately but rather slowly over a period of years. As a result, our investments in our operations are expected to outpace the rate at which we generate revenues in the near term. Even if we are successful in executing the commercial introduction of these products within our planned timeframe, we will require significant additional capital to support our operations. We expect that we may potentially secure additional capital under our Deerfield Facility (discussed below) as well as equity public offerings and other financing transactions, including but not limited to our June 2010 CEFF with Kingsbridge Capital Ltd. (Kingsbridge), pursuant to which, through June 11, 2013, we may sell to Kingsbridge up to approximately 1.1 million shares of our common stock. Based on the closing market price of our common stock on March 1, 2013 ($2.44) we could realize proceeds from the sale of shares under our CEFF of approximately $2.5 million. *See,* "Committed Equity Financing Facility." In addition, under our February 2013 ATM Program with Stifel (discussed below), we have the ability to sell up to $25,000,000 of common stock over a period of three years, at such times and in such amounts that we deem appropriate. However, the ATM Program can be cancelled at any time by either us or Stifel. *See,* Note 17 – Subsequent Events, to our Consolidated Financial Statements. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. To fund our long-term development programs, we would prefer to enter into strategic alliances or collaboration agreements that 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) and, if approved, the introduction of our approved products in various markets outside the U.S.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S. as planned; (ii) advance the AEROSURF development program to initiation of the planned Phase 2 clinical program in the fourth quarter of 2012, and the SURFAXIN LS development program towards potential clinical trials; and (iii) secure one or more strategic alliances or other collaboration arrangements to (a) support the further development and, if approved, commercialization of AEROSURF, and (b) to support the commercial introduction of SURFAXIN and AFECTAIR and , if approved, AEROSURF and SURFAXIN LS, in markets outside the U.S. We believe that our ability to successfully enter into meaningful strategic alliances has likely improved with receipt of marketing approval in the U.S. for SURFAXIN and will further improve if we are able to initiate our AEROSURF Phase 2 clinical program in the fourth quarter of 2013 and advance our SURFAXIN LS program towards initiation of clinical trials. There can be no assurance, however, that our efforts 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.

During the year ended December 31, 2012, we completed the following financing transactions:

- On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock, resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million.
- In March 2012, we initiated an offering under our Lazard ATM Program and issued 350,374 shares of our common stock at an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to the sales agent.
- Holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012.
- Holders of the five-year warrants that we issued in February 2011 (February 2011 five-year warrants) exercised warrants to purchase 51,250 shares of our common stock at an exercise price ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000.

As of December 31, 2012, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 40.3 million shares of common stock were available for issuance and not otherwise reserved.

As of December 31, 2012, we had cash and cash equivalents of $26.9 million. In February 2013, we entered into a Facility Agreement (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield agreed to loan to us up to $30 million on a secured basis. Deerfield advanced $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, following the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. At the time of each disbursement, we agreed to pay Deerfield a transaction fee equal to 1.5% of the amount disbursed. Interest will accrue on the outstanding principal amount of the loan at a rate of 8.75% per annum, payable quarterly in cash. We have the right to prepay the loan at any time without penalty. *See,* "Item 1A – Risk Factors – Our existing and future debt obligations could impair our liquidity and financial condition, and in the event we are unable to meet our debt obligations, the lenders could foreclose on our assets," and "– Even after completing our Deerfield Facility, we will need to obtain additional capital to successfully commercialize our approved products and develop our products under development, including AEROSURF and SURFAXIN LS, and continue our other research and development programs." In connection with the first disbursement, we issued to Deerfield a warrant to purchase approximately 2.3 million shares at an exercise price of $2.81, and in connection with the second disbursement, we have agreed to issue to Deerfield a warrant to purchase approximately 4.7 million shares at an exercise price of $2.81 (individually and collectively, the Deerfield Warrants). Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement (Stifel Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25,000,000 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. We will pay Stifel a commission for each transaction equal to 3% of the gross proceeds.

In addition, as of December 31, 2012, we had outstanding warrants to purchase approximately 8.0 million shares of our common stock at various prices, exercisable on different dates into 2016. Of these warrants, approximately

4.9 million are February 2011 five-year warrants that were issued at an exercise price of $3.20 per share. These warrants contain anti-dilution 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 warrants. Accordingly, the exercise price of these warrants was adjusted downward to $2.80 per share following a public offering in March 2012 that we conducted at an offering price of $2.80 per share. As of December 31, 2012, 4,948,750 of the February 2011 five-year warrants were outstanding. If the market price of our common stock should exceed $2.80 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these 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. The holders of the Deerfield Warrants may exercise the warrants either for cash or on a cashless basis. In addition, in lieu of paying cash, the holders may elect to reduce the principal amount of the related loan to satisfy the exercise price of the warrants upon exercise. If we issue the second Deerfield warrant and if the holders determine in their discretion to exercise the Deerfield Warrants in a cash exercise instead of a cashless exercise, we potentially could raise up to an additional $19.7 million. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, there can be no assurance that the market price of our common stock will equal or exceed price 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. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Although we currently believe that we will be able to meet our strategic planning goals, there can be no assurance that we will be successful. We require additional capital, either through strategic alliances or other financing transactions, to satisfy debt obligations and sustain operations, and to complete the development and support the commercial introduction of our products, including SURFAXIN, AFECTAIR, and, if approved, AEROSURF and potentially SURFAXIN LS. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

Cash Flows

As of December 31, 2012, 2011 and 2010, we had cash and cash equivalents of $26.9 million, $10.2 million and $10.2 million. Cash outflows before financings for 2012 consisted of $32.9 million used for ongoing operating activities, $0.6 million for purchases of property and equipment, and $75,000 used for debt service. During 2012, we raised aggregate net proceeds of $50.3 million, including $42.1 million from the March 2012 registered public offering, $6.7 million from warrant exercises, and $1.5 million from a financing under the Lazard ATM program that we entered in December 2011 with Lazard Capital Markets, LLC.

Operating Activities

Net cash used in operating activities was $32.9 million, $22.7 million and $24.3 million for the years ended December 31, 2012, 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 ($0.6 million, $3.6 million and $6.4 million for 2012, 2011 and 2010, respectively), stock-based compensation, employer match under our 401(k) Plan and depreciation expense ($4.4 million, $2.6 million and $3.2 for 2012, 2011 and 2010, respectively) and changes in working capital.

The increase in net cash used in operating activities from 2011 to 2012 is primarily due to (i) investments in marketing, field-based sales and medical affairs capabilities, and manufacturing and quality activities in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) costs associated with our efforts to optimize the design of our CAG with our engineering staff and third-party medical device experts, including work that we began in June 2012 with Battelle to optimize design, test, and manufacture clinic-ready CAG devices to be used in the first phase of our planned AEROSURF Phase 2 clinical trial in the fourth quarter of 2013; and (iii) costs associated with one-time cash severance obligations related to the resignation of W. Thomas Amick in December 2012, our former Chief Executive Officer.

Investing Activities

Net cash used in investing activities represents capital expenditures of $0.6 million, $0.1 million and $0.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Financing Activities

Net cash flows from financing activities are summarized in the chart below:

(in millions)	Years Ended December 31,		
	2012	**2011**	**2010**
Financings pursuant to common stock offerings	$ 42.1	$ 21.6	$ 26.6
Financings under the 2010 CEFF	-	1.3	1.4
Exercise of warrants	6.7	-	-
Financings under the Lazard ATM Program	1.5	-	-
Debt service payments	(0.1)	(0.1)	(9.2)
Cash flows from financing activities, net	$ 50.2	$ 22.8	$ 18.8

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

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, 2012, $71.0 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, which expired unexercised in April 2012.

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. The following offerings were issued pursuant to the 2008 Universal Shelf.

On February 22, 2011, we completed a registered public offering of 10,000,000 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 expired in May 2012 and were 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 unexercised 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.

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, 2012, 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 Stock Purchase Agreement originally provided for the lesser of up to 2.1 million shares or a maximum of $35 million, and expires in June 2013. As of December 31, 2012, there were 1.1 million shares remaining under 2010 CEFF, subject to a maximum of $32.3 million. The remaining shares issuable under the 2010 CEFF will be issued pursuant to the 2011 Universal Shelf. See, "– Financings Pursuant to Common Stock Offerings – 2011 Universal Shelf." For a description of our 2010 CEFF, *see,* "Item 8 – Notes to consolidated financial statements – Note 10, Committed Equity Financing Facility (CEFF) – 2010 CEFF."

CEFF Financings

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

(in thousands, except per share data)			Discounted Average Price
Completion Date	**Shares Issued**	**Gross Proceeds**	**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 2012, 2011 and 2010.

Warrants

During the year ended December 31, 2012, holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012. In addition, holders of the five-year warrants that we issued in February 2011 (February 2011 five-year warrants) exercised warrants to purchase 51,250 shares of our common stock at an exercise price ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000. For a listing of

outstanding warrants, *see,* "Item 8 – Notes to consolidated financial statements – Note 10, Common Shares Reserved for Future Issuance – Common shares reserved for potential future issuance upon exercise of warrants."

Lazard 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, could, at our discretion and at such times that we 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 (Lazard ATM Program).

We 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 provided Lazard with customary representations and warranties, and indemnification rights.

The Shares issuable under the ATM Program were registered pursuant to a prospectus supplement dated December 14, 2011 to our 2011 Universal Shelf. *See,* "– Financings Pursuant to Common Stock Offerings – 2011 Universal Shelf."

We understand that under the U.S. securities regulations, analysts affiliated with brokers and dealers are not permitted to initiate coverage of an issuer's securities while a securities offering is underway. Also under the securities laws, ATM Programs are deemed to be continuous securities offerings at all times, including when no sales are taking place. As a result, an analyst affiliated with Lazard would be prohibited from initiating coverage of our stock so long as we maintain the Lazard ATM Program. Therefore, in connection with initiation of coverage of our stock by an analyst affiliated with Lazard, we agreed with Lazard to terminate the Lazard ATM Program effective August 6, 2012. This decision was based on a number of factors, including, among others, that we did not intend the Lazard ATM Program to be the primary source of the capital that we will need to execute our business plan, and that we believe that coverage of our stock by well-regarded stock analysts may enhance our market exposure and may improve the trading support that our stock receives in the future. We also were not precluded from initiating another at-the-market program with another institution.

Lazard 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 $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to Lazard under the Sales Agency Agreement.

Debt

Debt is comprised of the following:

(in thousands)	December 31, 2012	2011
Pennsylvania Machinery and Equipment Loan		
Short-term	$ 69	$ 66
Long-term	148	224
Total	217	290
Capitalized Leases		
Short-term	–	2
Long-term	–	–
Total	–	2
Total Short-term	69	68
Total Long-term	148	224
Total	$ 217	$ 292

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 October 31, 2013 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

Contractual Obligations and Commitments

Operating Lease Agreements

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 January 2013, the landlord under the lease and we agreed to extend the term of the lease by an additional five years from February 2013 to February 2018. The total aggregate base rental payments under the Lease prior to the extension were approximately $7.2 million and the total aggregate base rental payments under the extended portion of the Lease are approximately $4.9 million.

We lease approximately 21,000 square feet of space for our manufacturing facility in Totowa, New Jersey, at an annual rent of $150,000. The lease expires in December 2014. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. 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, 2013. *See,* "Item 1 – Business – Business Operations – Manufacturing and Distribution," and "Item 2 – Properties."

Rent expense under the foregoing leases was $1.0 million for each the years ended December 31, 2012, 2011 and 2010, respectively.

Severance Arrangements

On December 31, 2012, we entered into a Separation of Employment Agreement and Plenary Release Agreement (CEO Separation Agreement) with Mr. W. Thomas Amick, our former Chief Executive Officer and Chairman of the Board of Directors. Pursuant to the CEO Agreement, Mr. Amick resigned his positions with us effective December 31, 2012, and was entitled to (i) on December 31, 2012, a cash payment equal to the sum of (a) all unpaid compensation accrued through December 31, 2012, less any applicable withholding, any unreimbursed employee business expenses (subject to submission of appropriate documentation), and a severance payment in the amount of $1,250,000, less any applicable withholding; (ii) the accelerated vesting of all outstanding stock options which shall remain exercisable to the end of their respective stated terms; and (iii) through July 31, 2013, reimbursement of $2,000 per month, plus a tax-gross up adjustment, for temporary living expenses related to an apartment leased by Mr. Amick. We also agreed to pay Mr. Amick's attorneys' fees incurred in connection with negotiating the CEO Agreement.

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement (EVP Separation Agreement) with a former executive who served as Executive Vice President, General Counsel and Corporate Secretary. Pursuant to the EVP 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, in accordance with terms of the EVP Separation Agreement, we paid the former executive, in 2012, severance in the amount of $400,000, which amount was reduced by any outstanding amount due under a promissory note that the former execute had issued to us in 2001. The EVP 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, 2012, 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 President and Chief Executive Officer and Chief Financial Officer (principal executive officer and 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 President and Chief Executive Officer and Chief Financial Officer has 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 President and Chief Executive Officer and 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 President and Chief Executive Officer and 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 President and 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, 2012. 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, 2012.

Our independent registered public accounting firm has audited management's assessment of our internal control over financial reporting, and issued an unqualified opinion dated March 15, 2013 on such assessment and on our internal control over financial reporting, which opinion is included herein.

(c) Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited Discovery Laboratories, Inc. and subsidiary's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Discovery Laboratories, Inc. and subsidiary's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on our Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Discovery Laboratories, Inc. and subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the three years in the period ended December 31, 2012 and our report dated March 15, 2013 expressed an unqualified opinion thereon, that included an explanatory paragraph regarding Discovery Laboratories, Inc. and subsidiary's ability to continue as a going concern.

/s/ Ernst & Young

Philadelphia, Pennsylvania
March15, 2013

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 2012 fiscal year.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

We have adopted a Code of Business Conduct and 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 Business Conduct and Ethics on our Internet website at "http://www.DiscoveryLabs.com" under the "Company" tab in the Corporate Governance 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 Business Conduct and 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 15, 2013

By: /s/ John G. Cooper
John G. Cooper, Chief Executive Officer and President

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/ John G. Cooper	John G. Cooper Director, President and Chief Executive Officer and Chief Financial Officer (Principal Executive and Principal Financial Officer)	March 15, 2013
/s/ John Tattory	John Tattory Vice President, Finance and Controller (Principal Accounting Officer)	March 15, 2013
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	March 15, 2013
/s/ Joseph M. Mahady	Joseph M. Mahady Director	March 15, 2013
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 15, 2013
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 15, 2013

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 by a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on December 27, 2010, as further amended by a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on October 3, 2011	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report for the quarter ended September 30, 2011, as filed with the SEC on November 14, 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	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.
4.3	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.
4.4	Form of Warrant to Purchase Common Stock 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.
4.5	Form of Warrant to Purchase Common Stock 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.
4.6	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.
4.7	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.

Exhibit No.	Description	Method of Filing
4.8	Form of Series I Warrant to Purchase Common Stock issued on June 22, 2010(Five-Year Warrant)	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.
4.9	Form of Series II Warrant to Purchase Common Stock 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.
4.10	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.
4.11	Form of Series I Warrant to Purchase Common Stock issued on February 22, 2011 (Five-Year Warrant)	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.
4.12	Form of Series II Warrant to Purchase Common Stock 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.
4.13+	Form of Warrant issued to Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
4.14	Form of Notes evidencing loan from Deerfield	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
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 +	Amended and Restated 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.
10.3 +	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.
10.4+	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.

Exhibit No.	Description	Method of Filing
10.5+	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.
10.6*	Form of Notice of Grant of Stock Option under the 1998 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-QSB for the quarter ended September 30, 1999, as filed with the SEC on November 15, 1999.
10.7*	Discovery's 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.
10.8*	Form of 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.
10.9*	Discovery's 2011 Long-Term Incentive Plan Stock	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)
10.10*	Form of Employee Option Agreement under Discovery's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012.
10.11*	Form on Non-Employee Director Agreement under Discovery's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012.
10.12*	Employment Agreement dated as of May 4, 2012 between Discovery and W. Thomas Amick	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012.
10.13*	Employment Agreement dated as of May 4, 2012 between Discovery and John G. Cooper	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012.
10.14*	Employment Agreement dated as of May 4, 2012 between Discovery and Thomas F. Miller	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012 as amended by Exhibit 10.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on May 11, 2012.
10.15*	Employment Agreement dated as of May 4, 2012 between Discovery and Russell G. Clayton	Filed herewith.

Exhibit No.	Description	Method of Filing
10.16*	Employment Agreement dated as of May 4, 2012 between Discovery and Mary B. Templeton	Filed herewith.
10.17*	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. 18*	Separation Agreement of Employment and Plenary Release dated as of December 23, 2012 between Discovery and W. Thomas Amick	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 4, 2013.
10.19	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.
10.20	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	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.
10.21	Second Amendment to Lease Agreement, dated January 3, 2013 by and between TR Stone Manor Corp. and Discovery	Incorporated by reference to Exhibits 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 8, 2013.
10.22	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.
10.23	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.
10.24	Common Stock Purchase Agreement dated as of June 11, 2010, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
10.25+	Supply Agreement dated as of December 22, 2010 between by and between Corden Pharma (formerly Genzyme Pharmaceuticals LLC, now known as Corden Pharma) 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.
10.26+	Product Development and Supply Agreement between Discovery and Lacey Manufacturing Company, a Division of Precision Engineered Products, LLC	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012.
10.27+	Research and Development Services Agreement between Discovery and Battelle Memorial Institute, dated June 22, 2012	Incorporated by reference to Exhibit 10.4 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on August 14, 2012.

Exhibit No.	Description	Method of Filing
10.28+	Facility Agreement dated as of February 13, 2013, between Discovery and Deerfield	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.29	Registration Rights Agreement dated as of February 13, 2013, between Discovery and Deerfield	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.30	Security Agreement dated as of February 13, 2013, between Discovery and Deerfield	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.31	At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Discovery and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 13, 2013.
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 Chief Financial 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, 2012, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2012, December 31, 2011 and December 31, 2010, (ii) Statements of Operations for the years ended December 31, 2012, December 31, 2011 and December 31, 2010, (iii) Statements of Changes in Equity for the years ended December 31, 2012, December 31, 2011 and December 31, 2010, (iv) Statements of Cash Flows for the years ended December 31, 2012, December 31, 2011 and December 31, 2010, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith

Exhibit No.	Description	Method of Filing
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.

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DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Contents

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 as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. and subsidiary at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Discovery Laboratories Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ Ernst and Young LLP

Philadelphia, Pennsylvania
March 15, 2013

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,892	$ 10,189
Inventory	195	-
Prepaid expenses and other current assets	719	442
Total current assets	27,806	10,631
Property and equipment, net	1,737	2,293
Restricted cash	400	400
Total assets	29,943	13,324
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,166	$ 1,111
Accrued expenses	4,159	2,972
Common stock warrant liability	6,305	6,996
Equipment loans and capitalized leases, current portion	69	68
Total current liabilities	11,699	11,147
Equipment loans and capitalized leases, non-current portion	148	224
Other liabilities	443	689
Total liabilities	$ 12,290	$ 12,060
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 100,000,000 authorized; 43,673,636 and 24,602,706 issued, 43,652,744 and 24,581,814 shares outstanding	44	25
Additional paid-in capital	455,398	401,713
Accumulated deficit	(434,735)	(397,420)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' equity	$ 17,653	$ 1,264
Total liabilities & stockholders' equity	$ 29,943	$ 13,324

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,		
	2012	**2011**	**2010**
Grant Revenue	$ 195	$ 582	$ –
Expenses:			
Research & development	21,570	17,230	17,136
Selling, general & administrative	16,444	7,864	8,392
Total expenses	38,014	25,094	25,528
Operating loss	(37,819)	(24,512)	(25,528)
Change in fair value of common stock warrant liability	555	3,560	6,422
Other income / (expense):			
Interest and other income	6	13	288
Interest and other expense	(57)	(26)	(357)
Other income / (expense), net	(51)	(13)	(69)
Net loss	$ (37,315)	$ (20,965)	$ (19,175)
Net loss per common share - basic and diluted	$ (0.95)	$ (0.93)	$ (1.65)
Weighted average number of common shares outstanding - basic and diluted	39,396	22,660	11,602

See notes to consolidated financial statements

Consolidated Statements of Changes in Stockholders' Equity

(In thousands)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance – January 1, 2010	**8,446**	**$ 8**	**$ 361,622**	**$ (357,280)**	**(21)**	**$ (3,054)**	**$ 1,296**
Net loss	–	–	–	(19,175)	–	–	(19,175)
Issuance of common stock, restricted stock awards	155	–	–	–	–	–	–
Issuance of common stock, 401(k) Plan 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**
Net loss	–	–	–	(20,965)	–	–	(20,965)
Issuance of common stock, restricted stock awards	1	–	–	–	–	–	–
Issuance of common stock, 401(k) Plan 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**
Net loss	–	–	–	(37,315)	–	–	(37,315)
Issuance of common stock, March 2012 financing	16,072	16	42,074	–	–	–	42,090
Issuance of common stock, ATM financing	350	1	1,460	–	–	–	1,461
Issuance of common stock, 401(k) Plan employer match	317	–	763	–	–	–	763
Exercise of common stock warrants	2,289	2	6,875	–	–	–	6,877
Exercise of stock options for cash	3	–	6	–	–	–	6
Issuance of common stock, consultants	40	–	96	–	–	–	96
Stock-based compensation expense	–	–	2,411	–	–	–	2,411
Balance – December 31, 2012	**43,674**	**$ 44**	**$ 455,398**	**$ (434,735)**	**(21)**	**$ (3,054)**	**$ 17,653**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net loss	$ (37,315)	$ (20,965)	$ (19,175)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,150	1,234	1,549
Stock–based compensation and 401(k) Plan employer match	3,270	1,364	1,634
Fair value adjustment of common stock warrants	(555)	(3,560)	(6,422)
Loss / (gain) on disposal of equipment	42	45	(16)
Changes in:			
Inventory	(195)	–	–
Prepaid expenses and other current assets	(277)	(157)	(52)
Accounts payable	55	(574)	391
Accrued expenses	1,187	(314)	(166)
Other assets	–	174	4
Other liabilities and accrued interest on loan payable	(246)	55	(2,017)
Net cash used in operating activities	(32,884)	(22,698)	(24,270)
Cash flows from investing activities:			
Purchase of property and equipment	(636)	(106)	(101)
Net cash used in investing activities	(636)	(106)	(101)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	43,551	22,927	27,977
Proceeds from exercise of common stock warrants	6,741	–	–
Proceeds from exercise of stock options	6	–	–
Principal payments of loan payable	–	–	(8,500)
Principal payments under equipment loan and capital lease obligations	(75)	(145)	(636)
Net cash provided by financing activities	50,223	22,782	18,841
Net increase (decrease) in cash and cash equivalents	16,703	(22)	(5,530)
Cash and cash equivalents as of beginning of year	10,189	10,211	15,741
Cash and cash equivalents as of end of year	$ 26,892	$ 10,189	$ 10,211
Supplementary disclosure of cash flows information:			
Interest paid	$ 13	$ 20	$ 2,123
Equipment acquired through capitalized lease	$ –	$ –	$ 48

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a 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 aerosolized drugs, including our aerosolized KL_4 surfactant and other inhaled therapies. 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.

Our initial strategy is to develop our KL_4 surfactant and drug delivery technologies to improve the management of respiratory distress syndrome (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 have the potential to greatly improve the management of RDS and, collectively over time, to become a new standard of care for premature infants with RDS.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of 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.

In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we determined that one of our analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. We proactively communicated these findings to the FDA, improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result of these efforts, we delayed the commercial availability of SURFAXIN drug product. Although there can be no assurances, if we are able to successfully conclude our planned activities and receive confirmation of our updated product specifications from the FDA within our anticipated timeline in the second quarter of 2013, we believe that we remain on track to manufacture SURFAXIN drug product for commercial use in the second quarter of 2013. This delay in availability of SURFAXIN drug product from the fourth quarter 2012 to the second quarter of 2013 is not expected to have a material adverse effect on our business or financial position, in part because our commercial launch plans for SURFAXIN during this period have always been to focus initially on hospital formulary acceptance.

AEROSURF® is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF for premature infants with or at risk for developing 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. Consequently, neonatologists generally will not treat infants who could benefit from surfactant therapy unless they determine that 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."

We are developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and resuspended to liquid form prior to use 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 engaged in a

technology transfer of our lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect will manufacture drug product for use in our preclinical and clinical development activities. Our development plan is intended initially to support the use of our lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the United States (U.S) and potentially other major markets.

AFECTAIR® devices are our novel disposable aerosol-conducting airway connectors that simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. Our initial device is AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units (NICUs and PICUs, respectively). We are initiating a user experience program that is being conducted in select U.S. critical care centers that represent approximately ten percent (10%) of our target institutions. This initial phase, which is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, is expected to be conducted in the first half of 2013. Following the initial phase, we expect to initiate a broader introduction of the AFECTAIR device for infants in a national phase. We believe that AFECTAIR aerosol-conducting airway connectors have the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to infants receiving aerosolized medication in the NICU and PICU. We believe that revenues from the AFECTAIR device for infants in the fourth full selling year could potentially be $10 million in the U.S. and $20 million globally.

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS and the AFECTAIR device for infants to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in PICUs and intensive care units (ICUs). However, we are delaying these development efforts in the near term in order to focus our resources and expertise on meeting our 2013 goals to advance our development program for AEROSURF to Phase 2 clinical trials and execute the commercial introduction of SURFAXIN and the AFECTAIR device for infants. If we are able to achieve our 2013 objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and aerosol-conductor airway connector technologies to address the critical care needs of patients in the PICU and ICU.

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in and will focus on neonatal indications. These organizations will be primarily responsible to effect the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations to effectively introduce the AFECTAIR device for infants in the U.S. We also expect that, in the future, these teams will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN and the AFECTAIR device for infants to efficiently support the introductions of AEROSURF and SURFAXIN LS, if approved.

An important priority is to secure strategic resources to support the continued development and commercial introduction of our RDS products. While we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our efforts, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the EU. In our discussions to date, the primary focus of our discussions has been on AEROSURF. We also would consider various financing alternatives or collaboration arrangements that would provide infusions of capital and other resources needed to advance our KL4 surfactant development programs. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA.

There can be no assurance that we will be successful in concluding any strategic alliance, collaboration or other similar transaction. *See,* Note 2 – Liquidity Risks and Management's Plans.

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) and a previous at-the-market Program that we entered in December 2011 with Lazard Capital Markets (Lazard ATM Program), capital equipment and debt facilities, and strategic alliances.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. Before additional financing activities, including the second disbursement under the Deerfield Facility and under the ATM Program, as discussed below, we anticipate that we have sufficient cash available to support our operations and debt service obligations through the third quarter of 2013. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and/or strategic and collaborative arrangements with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our December 31, 2012 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

To execute our business strategy and fund our operations over time, we will require additional infusions of capital until such time as the net revenues from SURFAXIN and AFECTAIR, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset cash flow requirements. Given the time required to secure formulary acceptance at our target hospitals and acceptance of a new product, we expect our revenues from SURFAXIN and AFECTAIR will not increase immediately but rather slowly over a period of years. As a result, our investments in our operations are expected to outpace the rate at which we generate revenues in the near term. Even if we are successful in executing the commercial introduction of these products within our planned timeframe, we will require significant additional capital to support our operations. We expect that we may potentially secure additional capital under our Deerfield Facility (discussed below) as well as equity public offerings and other financing transactions, including but not limited to our June 2010 CEFF with Kingsbridge Capital Ltd. (Kingsbridge), pursuant to which, through June 11, 2013, we may sell to Kingsbridge up to approximately 1.1 million shares of our common stock. Based on the closing market price of our common stock on March 1, 2013 ($2.44) we could realize proceeds from the sale of shares under our CEFF of approximately $2.5 million. *See,* "Committed Equity Financing Facility." In addition, under our February 2013 ATM Program with Stifel (discussed below), we have the ability to sell up to $25,000,000 of common stock over a period of three years, at such times and in such amounts that we deem appropriate. However, the ATM Program can be cancelled at any time by either us or Stifel. *See,* Note 17 – Subsequent Events, to our Consolidated Financial Statements. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. To fund our long-term development programs, we would prefer to enter into strategic alliances or collaboration agreements that 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) and, if approved, the introduction of our approved products in various markets outside the U.S.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S. as planned; (ii) advance the AEROSURF development program to initiation of the planned Phase 2 clinical program in the fourth quarter of 2012, and the SURFAXIN LS development program towards potential clinical trials; and (iii) secure one or more strategic alliances or other collaboration arrangements to (a) support the further development and, if approved, commercialization of AEROSURF, and (b) to support the commercial introduction of SURFAXIN and AFECTAIR and , if approved, AEROSURF and SURFAXIN LS, in markets outside the U.S. We believe that our ability to successfully enter into meaningful strategic alliances has likely improved with receipt of marketing approval in the U.S. for SURFAXIN and will further improve if we are able to initiate our AEROSURF Phase 2 clinical program in the fourth quarter of 2013 and advance our SURFAXIN LS program towards initiation of clinical trials. There can be no assurance, however, that our efforts 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.

During the year ended December 31, 2012, we completed the following financing transactions:

- On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock, resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million.
- In March 2012, we initiated an offering under our Lazard ATM Program and issued 350,374 shares of our common stock at an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to the sales agent.
- Holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012.
- Holders of the five-year warrants that we issued in February 2011 (February 2011 five-year warrants) exercised warrants to purchase 51,250 shares of our common stock at an exercise price ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000.

As of December 31, 2012, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 40.3 million shares of common stock were available for issuance and not otherwise reserved.

As of December 31, 2012, we had cash and cash equivalents of $26.9 million. In February 2013, we entered into a Facility Agreement (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield agreed to loan to us up to $30 million on a secured basis. Deerfield advanced $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, following the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. At the time of each disbursement, we agreed to pay Deerfield a transaction fee equal to 1.5% of the amount disbursed. Interest will accrue on the outstanding principal amount of the loan at a rate of 8.75% per annum, payable quarterly in cash. We have the right to prepay the loan at any time without penalty. *See,* "Item 1A – Risk Factors – Our existing and future debt obligations could impair our liquidity and financial condition, and in the event we are unable to meet our debt obligations, the lenders could foreclose on our assets," and "– Even after completing our Deerfield Facility, we will need to obtain additional capital to successfully commercialize our approved products and develop our products under development, including AEROSURF and SURFAXIN LS, and continue our other research and development programs." In connection with the first disbursement, we issued to Deerfield a warrant to purchase approximately 2.3 million shares at an exercise price of $2.81, and in connection with the second disbursement, we have agreed to issue to Deerfield a warrant to purchase approximately 4.7 million shares at an exercise price of $2.81 (individually and collectively, the Deerfield Warrants). Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement (Stifel Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25,000,000 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. We will pay Stifel a commission for each transaction equal to 3% of the gross proceeds.

In addition, as of December 31, 2012, we had outstanding warrants to purchase approximately 8.0 million shares of our common stock at various prices, exercisable on different dates into 2016. Of these warrants, approximately 4.9 million are February 2011 five-year warrants that were issued at an exercise price of $3.20 per share. These

warrants contain anti-dilution 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 warrants. Accordingly, the exercise price of these warrants was adjusted downward to $2.80 per share following a public offering in March 2012 that we conducted at an offering price of $2.80 per share. As of December 31, 2012, 4,948,750 of the February 2011 five-year warrants were outstanding. If the market price of our common stock should exceed $2.80 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these 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. The holders of the Deerfield Warrants may exercise the warrants either for cash or on a cashless basis. In addition, in lieu of paying cash, the holders may elect to reduce the principal amount of the related loan to satisfy the exercise price of the warrants upon exercise. If we issue the second Deerfield warrant and if the holders determine in their discretion to exercise the Deerfield Warrants in a cash exercise instead of a cashless exercise, we potentially could raise up to an additional $19.7 million. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, there can be no assurance that the market price of our common stock will equal or exceed price 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. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Although we currently believe that we will be able to meet our strategic planning goals, there can be no assurance that we will be successful. We require additional capital, either through strategic alliances or other financing transactions, to satisfy debt obligations and sustain operations, and to complete the development and support the commercial introduction of our products, including SURFAXIN, AFECTAIR, and, if approved, AEROSURF and potentially SURFAXIN LS. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

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.

Inventory

Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. In connection with the FDA approval of SURFAXIN and the registration of our initial AFECTAIR device in the U.S., we assessed the potential capitalization of inventory and the timing of when the related costs are expected to be recoverable through the commercialization of our products.

Costs incurred prior to receipt of marketing authorization have been recorded in our statement of operations as research and development expense. As a result, inventory balances and cost of revenue may reflect a lower average per-unit cost of materials for several quarters after we launch our products. As of December 31, 2012, inventories were valued at $0.2 million and consisted of raw materials used in the production of SURFAXIN.

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, 2012 and 2011, respectively. 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 the undiscounted cash flows of an asset are less than its carrying value, an impairment is recorded and the asset is written down to estimated value. No impairment was recorded during the years ended December 31, 2012, 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, 2012, we recognized $195,093 of grant revenue for funds received and expended under a Small Business Innovation Research (SBIR) Phase I award to Discovery Labs from National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) Center for Medical Counter Measures Against Radiation and Nuclear Threats to assess the ability of KL4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury. The total amount of the award is $600,000 and the remainder of the award is expected to be received and expended in 2013.

For the year ended December 31, 2011, grant revenue represents funds received and expended under a $581,839 Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL4 surfactant for RDS.

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 KL4 surfactant program for the prevention of neonatal RDS.

Research and development

We track research and development expense by activity, as follows: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development expense includes personnel, facilities, manufacturing and quality 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 (ASC) 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. The fair value of stock option grants is recognized evenly over the vesting period of the options or over the period between the grant date and the time the option becomes non-forfeitable by the employee, whichever is shorter. Stock option expense is generally included in research and development and selling, general and administrative expenses in the accompanying Consolidated Statements of Operations.

Warrant accounting

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 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.

Income taxes

We account for income taxes in accordance with 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 share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. For the years ended December 31, 2012, 2011 and 2010, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 11.9 million, 15.4 million and 5.3 million shares, respectively. As a result of the Company's net losses for all periods presented, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

Concentration of Suppliers

We currently obtain the active pharmaceutical ingredients (APIs) of our KL4 surfactant drug products from single-source suppliers. In addition, we rely on a number of third-party institutions and laboratories that perform various studies as well as quality control release and stability testing and other activities related to our KL4 surfactant development and manufacturing activities. Among these, our fetal rabbit biological activity test (BAT, an important quality control release and stability test for SURFAXIN) 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. The loss of one or

more of our single-source suppliers or testing laboratories 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, and the manufacture and commercial sales of approved products. 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 issued Accounting Standards Update (ASU) 2011-04, 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 did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, for 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 did not have a material impact on our consolidated financial statements because we do not have any material components of other comprehensive income (loss).

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, 2012 and 2011:

(in thousands)	Fair Value December 31, 2012	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money markets	$ 23,377	$ 23,377	$ –	$ –
Certificate of deposit	400	400	–	–
Total Assets	$ 23,777	$ 23,777	$ –	$ –
Liabilities:				
Common stock warrants	$ 6,305	$ –	$ –	$ 6,305

(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 warrants	$ 6,996	$ –	$ –	$ 6,996

The following table summarizes changes in the fair value of the common stock warrants measured on a recurring basis using Level 3 inputs for 2011 and 2012:

(in thousands)	
Balance at January 1, 2011	**$ 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**
Exercise of warrants [(1)]	(136)
Change in fair value of common stock warrant liability	(555)
Balance at December 31, 2012	**$ 6,305**

[(1)] *See,* Note 8 – Common Stock Warrant Liability.

The significant unobservable inputs used in the fair value measurement of the May 2009 and February 2010 common stock warrants are the historical volatility of our common stock market price, expected term of the applicable warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. In addition to the significant unobservable inputs noted above, the fair value measurement of the February 2011 five-year warrants also takes into account an assumption of the likelihood and timing of the occurrence of an event that would result in an adjustment to the exercise price in accordance with the anti-dilutive pricing provisions in the warrant. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would result in significantly higher or lower fair value measurements.

Significant Unobservable Input Assumptions of Level 3 Valuations	December 31, 2012	2011
Historical Volatility	56% -80 %	98% - 117%
Expected Term (in years)	1.4 – 3.2	2.4 - 4.2
Risk-free interest rate	0.16% - 0.36%	0.31% - 0.60%

Note 5 – Restricted Cash

Restricted cash consists of a certificate of 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 was $400,000 for all periods presented.

Note 6 – Property and Equipment

Property and equipment is comprised of the following:

(in thousands)	December 31, 2012	2011
Equipment	$ 7,775	$ 7,428
Furniture	816	815
Leasehold improvements	2,711	2,875
Subtotal	11,302	11,118
Accumulated depreciation and amortization	(9,565)	(8,825)
Property and equipment, net	$ 1,737	$ 2,293

Equipment primarily consists of: (i) manufacturing equipment to produce our KL4 surfactant products, including SURFAXIN and our lyophilized KL4 surfactant for AEROSURF and SURFAXIN LS, 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. 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 December 2014.

Depreciation expense on property and equipment for the years ended December 31, 2012, 2011 and 2010 was $0.9 million, $1.3 million and $1.4 million, respectively.

Note 7 – Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	December 31, 2012	2011
Accrued compensation	$ 1,206	$ 957
Accrued manufacturing	926	917
Accrued research and development	734	461
Accrued accounting and legal fees	428	315
Accrued sales and marketing	279	-
All other accrued expenses	586	322
Total accrued expenses	$ 4,159	$ 2,972

Accrued compensation primarily consists of employees' unused earned vacation and, in 2012, tax withholding obligations related to severance paid to our former Chief Executive Officer and Chairman of the Board of Directors and, in 2011, 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, generally accepted accounting principles (GAAP) provide that these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under federal securities laws, providing freely-tradable shares upon exercise of the warrants may not be within our control in all circumstances, and (ii) the warrant agreements do not expressly provide that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The accounting guidance expressly precludes an evaluation of the likelihood that cash settlement could occur. 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 form of warrant agreement for the registered five-year warrants that we issued in the February 2011 public offering (February 2011 five-year warrants) expressly provides 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.

Selected terms and estimated fair value of warrants accounted for as derivative are as follows:

Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Value at Issuance Date	Fair Value of Warrants (in thousands) December 31 2012	2011
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ –	$ 82
2/23/2010	916,667	12.75	2/23/2015	5,701	104	554
2/22/2011	4,948,750	2.80	2/22/2016	8,004	6,201	6,360
					$ 6,305	$ 6,996

During the year-ended December 31, 2012, holders of the February 2011 five-year warrants exercised warrants to purchase 51,250 shares of common stock for total proceeds of $162,000. In addition, these warrants contain anti-dilution 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 warrants. Accordingly, the exercise price of these warrants was adjusted downward to $2.80 per share at the time of the March 2012 public offering, which was conducted at an offering price of $2.80 per share.

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

Debt is comprised of the following:

(in thousands)	December 31, 2012	2011
Pennsylvania Machinery and Equipment Loan		
Short-term	$ 69	$ 66
Long-term	148	224
Total	217	290
Capitalized Leases		
Short-term	–	2
Long-term	–	–
Total	–	2
Total Short-term	69	68
Total Long-term	148	224
Total	$ 217	$ 292

For the years ended December 31, 2012, 2011 and 2010, we incurred interest expense of $13,000, $20,000 and $357,000, respectively, on our outstanding debt obligations. Interest expense for 2010 included interest expense of $0.3 million associated with a loan from PharmaBio Development Inc (Pharma Bio), the former strategic investment subsidiary of Quintiles Transnational Corp., of which $0.2 million was related to amortization of deferred financing costs for warrants issued to PharmaBio in 2006 in consideration for restructuring the loan. All of our obligations related to the loan with PharmaBio were paid in full in 2010.

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 October 31, 2013 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

See also, Note 17 – Subsequent Events.

Note 10 – Stockholders' Equity

Registered Public Offerings

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 proceeds). We also granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of common stock at an offering price of $2.80 per share, which expired unexercised in April 2012.

On February 22, 2011, we completed a registered public offering of 10,000,000 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 had an exercise price per share of $2.94 and expired in May 2012. 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 in March 2012, the exercise price of the five-year warrants was adjusted 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.

The March 21, 2012 offering was issued pursuant to our 2011 Universal Shelf, and all other stated offerings were issued pursuant to our 2008 Universal Shelf. (*See,* this Note – Common Shares Reserved for Future Issuance – Universal Shelf Registration Statements – 2011 Universal Shelf and 2008 Universal Shelf.) With respect to the warrants issued in connection with the foregoing offerings, the exercise price and number of shares of common stock issuable upon exercise are subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants are also subject to adjustment if we engage in a "Fundamental Transaction" (such as consolidation or merger, sale or disposal of substantially all of our assets, and among others as defined in the form of the warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not otherwise available for the resale of the warrant shares, the holder may exercise on a cashless basis.

Committed Equity Financing 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, 2012, 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 Stock Purchase Agreement originally provided for the lesser of up to 2.1 million shares or a maximum of $35 million, and expires in June 2013. As of December 31, 2012, there were 1.1 million shares remaining under 2010 CEFF, subject to a maximum of $32.3 million. The remaining shares issuable under the 2010 CEFF will be issued pursuant to 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.

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.

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 through their expiration dates.

Lazard 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, could, at our discretion and at such times that we 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 (Lazard ATM Program).

We 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 provided Lazard with customary representations and warranties, and indemnification rights. The Shares issuable under the

ATM Program were registered pursuant to a prospectus supplement dated December 14, 2011 to our 2011 Universal Shelf. *See,* this Note – Universal Shelf Registration Statements – 2011 Universal Shelf.

We understand that under the U.S. securities regulations, analysts affiliated with brokers and dealers are not permitted to initiate coverage of an issuer's securities while a securities offering is underway. Also under the securities laws, ATM Programs are deemed to be continuous securities offerings at all times, including when no sales are taking place. As a result, an analyst affiliated with Lazard would be prohibited from initiating coverage of our stock so long as we maintain the Lazard ATM Program. Therefore, in connection with initiation of coverage of our stock by an analyst affiliated with Lazard, we agreed with Lazard to terminate the Lazard ATM Program effective August 6, 2012. This decision was based on a number of factors, including, among others, that we did not intend the Lazard ATM Program to be the primary source of the capital that we will need to execute our business plan, and that we believe that coverage of our stock by well-regarded stock analysts may enhance our market exposure and may improve the trading support that our stock receives in the future. We also were not precluded from initiating another at-the-market program with another institution. (*See,* Note 17 – Subsequent Events)

Lazard 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 $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to Lazard under the Sales Agency Agreement.

401(k) Plan Employer Match

We have a voluntary 401(k) savings plan (401(k) 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 currently provide for the company match in the form of newly-issued shares of common stock, which are registered pursuant to a registration statement on Form S-8 filed with the U.S. Securities and Exchange Commission (SEC). For the years ended December 31, 2012, 2011 and 2010, the match resulted in the issuance of 316,543, 265,185 and 61,158, shares of common stock, respectively. Expenses associated with the 401(k) match for the years ended December 31, 2012, 2011 and 2010 were $0.8 million, $0.5 million and $0.2 million, 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, 2012	December 31, 2011	Exercise Price	Expiration Date
Former Employee Warrant	30	30	$ 3.20	3/18/2016
Investor Warrants – February 2011 Financing	4,949	5,000	$ 2.80	2/22/2016
Investor Warrants – February 2011 Financing	-	5,000	$ 2.94	5/22/2012
PharmaBio – October 2010 Financing	79	79	$ 4.10	10/13/201
Investor Warrants – June 2010 Financing	1,190	1,190	$ 6.00	6/22/2015
Kingsbridge – June 2010 CEFF	83	83	$ 6.69	12/11/201
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	11/22/201
Total	7,950	13,001		

Holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012. Holders of the five-year warrants that we issued in February 2011 exercised warrants to purchase 51,250 shares of our common stock at an exercise price ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000.

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 replaced 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 The Nasdaq Capital Market® rules regarding equity compensation, other regulatory changes and market and corporate governance developments. Awards outstanding under the 2007 and our previous, expired plan (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. Shares returnable to the 1998 Plan as a result of cancellations, expirations and forfeitures will not be for issuance under the 1998 Plan or the 2011 Plan

Stock options and awards outstanding and available for future issuance as of December 31, 2012 and 2011 are as follows:

	As of December 31,	
	2012	**2011**
2011 Plan[(1)]		
Outstanding	3,365	1,709
Available for Future Grants	2,966	2,106
Total	6,331	3,815
2007 Plan		
Outstanding	277	297
Available for Future Grants	–	–
Total	277	297
1998 Plan		
Outstanding	355	432
Available for Future Grants	–	–
Total	355	432
Total Outstanding	3,997	2,438
Total Available for Future Grants	2,966	2,106
Total	6,963	4,544

(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, and replaced the 2008 Universal Shelf. As of December 31, 2012, approximately $71.0 million was available under the 2011 Universal Shelf. In addition, as of December 31, 2012, we had reserves for future issuance of warrants and shares under the 2010 CEFF of approximately $75.4 million. Of the amount reserved for future issuance, approximately $32.3 million is reserved for potential issuance under the 2010 CEFF. Since the 2010 CEFF has available for issuance approximately 1.1 million shares and the facility expires in June 2013, we do not expect that the full reserve under the 2011 Universal Shelf will be exhausted.

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. The 2008 Universal Shelf ceased to be available upon effectiveness of the 2011 Universal Shelf.

Common shares reserved for potential future issuance under CEFF arrangements

As of December 31, 2012 and 2011, we had 1,074,114 shares reserved for potential future issuance under the 2010 CEFF.

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

As of December 31, 2012 and 2011, we had 26,290 and 342,833, 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 2011 Plan continues many of the features of the 2007 Plan, but is updated to reflect changes to The Nasdaq Capital Market 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 those plans and the applicable award agreements.

Under the 2011 Plan, we may grant awards for up to 6.2 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. Awards under the Plan may include stock options, stock appreciation rights (SARs), restricted stock (RSAs), restricted stock units, other performance and stock-based awards, and dividend equivalents.

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.

As of December 31, 2012, under the 2011 Plan, there were 3,365,166 stock options outstanding and 2,965,887 shares available for grant. No SARs, RSAs, restricted stock units, other performance and stock-based awards, and dividend equivalents have been granted under the 2011 Plan. 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.

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 with the FDA marketing approval for SURFAXIN. There were no unvested RSAs outstanding as of December 31, 2012. As of December 31, 2011, there were 128,334 unvested RSAs outstanding.

A summary of activity under our long-term incentive plans is presented below:

(in thousands, except for weighted-average data) Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at December 31, 2009	1,065	$ 56.46	
Granted	20	3.19	
Exercised	–	–	
Forfeited or expired	(142)	51.93	
Outstanding at December 31, 2010	943	$ 56.06	
Granted	1,771	1.84	
Exercised	–	–	
Forfeited or expired	(276)	44.95	
Outstanding at December 31, 2011	2,438	$ 17.97	
Granted	1,724	2.63	
Exercised	(3)	1.83	
Forfeited or expired	(162)	24.39	
Outstanding at December 31, 2012	3,997	$ 11.11	7.9
Exercisable at December 31, 2012	1,654	$ 23.53	6.9

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, 2012, 2011 and 2010 was $2.02, $1.45 and $2.48, respectively. For the year ended December 31, 2012, there were 3,334 options exercised, resulting in approximately $6,000 in proceeds. There were no options exercised during the years ended December 31, 2011 and 2010. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2012 is $0.5 million, $0.2 million and $0.2 million, respectively.

A summary of nonvested shares issuable upon exercise of outstanding options and changes during 2012 is presented below:

(shares in thousands)	Option Shares	Weighted-Average Grant-Date Fair Value
Non-vested at December 31, 2011	1,771	$ 1.85
Granted	1,724	2.63
Vested	(1,087)	2.04
Forfeited	(65)	2.37
Non-vested at December 31, 2012	2,343	$ 2.33

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2012:

(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 - $156.45	3,997	$ 11.11	7.9 Years	1,654	$ 23.53	6.9 Years

Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2012, 2011 and 2010, of $2.4 million, $0.9 million and $1.4 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2012	2011	2010
Research and development	$ 487	$ 289	$ 479
Selling, General and administrative	1,924	578	931
Total	$ 2,411	$ 867	$ 1,410

On December 31, 2012, W. Thomas Amick, our former Chief Executive Officer, resigned from his position and as a member of our Board. Under the terms of a separation agreement between Mr. Amick and the company, all of Mr. Amick's outstanding options vested immediately and all such options shall remain exercisable to the end of their stated terms. The company recognized $0.8 million in stock option modification costs related to these items.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the historical volatility of our common stock and other factors. We also use historical data and other factors to estimate option exercises, employee terminations and forfeiture rates within the valuation model. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

	December 31, 2012	2011	2010
Weighted average expected volatility	111%	113%	112%
Weighted average expected term	4.6 years	4.8 years	4.9 years
Weighted average risk-free interest rate	0.74%	1.08%	1.47%
Expected dividends	–	–	–

The total fair value of the underlying shares of the options vested during 2012, 2011 and 2010, equals $2.2 million, $0.6 million and $1.5 million, respectively. As of December 31, 2012, there was $3.4 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 2.1 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. Antonio Esteve, Ph.D., a member of our Board of Directors from May 2002 until his resignation on January 3, 2013, is principal of Esteve. 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 that included a Esteve returning certain rights to us in certain territories (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 U.S. 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. We generally 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 in the license agreements) 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 to pay minimum royalties in the future, 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 J&J proprietary KL4 surfactant technology. 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. We have paid $950,000 to date for milestones that have been achieved including a $500,000 milestone payment in 2012 that became due as a result of the FDA's approval of SURFAXIN. 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.

Note 13 – Commitments

Future payments due under contractual obligations at December 31, 2012 are as follows:

(in thousands)	2013	2014	2015	2016	2017	There-after	Total
Operating lease obligations	$ 1,074	$ 1,087	$ 949	$ 934	$ 935	$ 158	$ 5,137
Equipment loan obligations [1]	69	79	69	–	–	–	217
Total	$ 1,143	$ 1,166	$ 1,018	$ 934	$ 935	$ 158	$ 5,354

[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 January 2013, the lease was extended an additional five years through February 2018. *See,* Note 17 – Subsequent Events. The total aggregate base rental payments under the Lease prior to the extension were approximately $7.2 million and the total aggregate base rental payments under the extended portion of the Lease are approximately $4.9 million.

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. 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, 2013. 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 was $1.0 million for each the years ended December 31, 2012, 2011 and 2010, respectively.

Severance Arrangements

On December 31, 2012, we entered into a Separation of Employment Agreement and Plenary Release Agreement (CEO Separation Agreement) with Mr. W. Thomas Amick, our former Chief Executive Officer and Chairman of the Board of Directors. Pursuant to the CEO Agreement, Mr. Amick resigned his positions with us effective December 31, 2012, and was entitled to (i) on December 31, 2012, a cash payment equal to the sum of (a) all unpaid compensation accrued through December 31, 2012, less any applicable withholding any unreimbursed employee business expenses (subject to submission of appropriate documentation), and a severance payment in the amount of $1,250,000, less any applicable withholding; (ii) the accelerated vesting of all outstanding stock options which shall remain exercisable to the end of their respective stated terms; and (iii) through July 31, 2013, reimbursement of $2,000 per month, plus a tax-gross up adjustment, for temporary living expenses related to an apartment leased by Mr. Amick. We also agreed to pay Mr. Amick's attorneys' fees incurred in connection with negotiating the CEO Agreement.

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement (EVP Separation Agreement) with a former executive who served as Executive Vice President, General Counsel and Corporate Secretary. Pursuant to the EVP 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, in 2012, severance in the amount of $400,000, which amount was reduced by any outstanding amount due under a promissory note that the former execute had issued to us in 2001. The EVP Separation Agreement also contains a general release of claims by the parties and a 12-month non-competition covenant by the former executive.

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, 2012, 2011 and 2010 is as follows:

(in thousands)	December 31,		
	2012	2011	2010
Income tax benefit, statutory rates	$ 12,687	$ 7,128	$ 6,519
State taxes on income, net of Federal benefit	2,288	1,633	1,206
Research and development tax credit	332	662	656
Employee Related	(988)	(1,758)	(4,746)
Warrant Valuation Related	189	1,210	2,184
Other	–	–	18
Income tax benefit	14,508	8,875	5,837
Valuation allowance	(14,508)	(8,875)	(5,837)
Income tax benefit	$ –	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2012 and 2011, are as follows:

(in thousands)	December 31,	
	2012	2011
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 160,522	$ 147,045
Research and development tax credits	9,412	9,080
Compensation expense on stock	3,154	3,535
Charitable contribution carryforward	7	7
Other accrued	524	608
Depreciation	2,665	2,682
Capitalized research and development	1,516	1,740
Total long-term deferred tax assets	177,800	164,697

Long-term deferred tax liabilities	–	–
Net deferred tax assets	177,800	164,697
Less: valuation allowance	(177,800)	(164,697)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2012 and 2011 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. It is the Company's policy to classify interest and penalties recognized on uncertain tax positions as a component of income tax expense. There was no interest or penalties accrued as of December 31, 2012 or 2011, nor were any incurred in 2012, 2011 or 2010.

At December 31, 2012 and 2011, we had available carryforward net operating losses for Federal tax purposes of $396.7 million and $363.3 million, respectively, and a research and development tax credit carryforward of $9.4 million and $9.1 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2032. Approximately $6.2 million of the $396.7 net operating loss carryforwards expire prior to 2014.

At December 31, 2012, 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, 2012 and 2011, we had available carryforward losses of approximately $392.6 million and $360.1 million, respectively, for state tax purposes. Of the $392.6 million state tax carryforward losses, $358.0 million is associated with the state of Pennsylvania, with the remainder associated with the other 9 states that we have established tax nexus within.

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

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

Note 16 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2012 and 2011. The operating results for any quarter are not necessarily indicative of results for any future period.

2012 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Grant Revenues	$ –	$ –	$ –	$ 195	$ 195
Expenses:					
Research and development	4,533	5,206	5,743	6,088	21,570
Selling, General and administrative	2,047	3,610	4,255	6,532	16,444
Total expenses	6,580	8,816	9,998	12,620	38,014
Operating loss	(6,580)	(8,816)	(9,998)	(12,425)	(37,819)
Change in fair value of common stock warrant liability	(3,434)	1,680	(3,309)	5,618	555
Other expense, net	(2)	(2)	(39)	(8)	(51)
Net loss	$ (10,016)	$ (7,138)	$ (13,346)	$ (6,815)	$ (37,315)
Net loss per common share - basic and diluted	$ (0.37)	$ (0.16)	$ (0.31)	$ (0.16)	$ (0.95)
Weighted average number of common shares outstanding	27,162	43,369	43,444	43,521	39,396

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

Note 17 – Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2012 up through the date we issued these financial statements. During this period we noted one recognized subsequent event and two nonrecognized subsequent events as described below:

Loan Facility

On February 13, 2013, the Company entered into a secured loan facility with Deerfield Management Company, L.P. (Deerfield) for up to $30.0 million in financing in 2013 (Deerfield Facility). Under terms of the Deerfield Facility, Deerfield advanced to us $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN (lucinactant) for the prevention of RDS in premature infants at high risk for RDS, provided that the first sale occurs on a date that is not later than December 31, 2013. The loan matures on February13, 2019 and may be prepaid in whole or in part without penalty at any time. The principal amount of the loan is payable in three equal annual installments on the

fourth, fifth and sixth anniversaries of the facility agreement, except that, if the Company achieves certain revenue or market capitalization milestones, the principal payments due on the fourth and fifth anniversaries could be deferred for one year. Accordingly, if the milestones are achieved, payment of the principal amount could be deferred until the maturity date of the loan in 2019. The outstanding principal amount of the loan accrues interest at a rate of 8.75% and is payable quarterly. The facility agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, Deerfield will receive a transaction fee equal to 1.5% of the amount disbursed. In connection with the initial advance on February 13, 2013, Deerfield received warrants to purchase 2.3 million shares of common stock at an exercise price of $2.81 per share. Upon disbursement of the $20 million advance, Deerfield will receive warrants to purchase an additional 4.7 million shares of common stock at an exercise price of $2.81 per share. All of the warrants will expire on the sixth anniversary date of the facility agreement. Pursuant to the Agreement, the Company has granted Deerfield a security interest in substantially all of its assets.

In connection with a Major Transaction, as defined in the warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the warrant or that portion of the warrant for cash in an amount equal to the Black-Scholes value (as defined in the warrant) of the warrant or that portion of the warrant redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the warrant and receive that number of shares of common stock that equals the Black Scholes value of the warrant or that portion of the warrant exercised. Prior to the holder exercising the Warrant for shares in such transactions, we may elect to terminate the warrant or that portion of the warrant and pay the holder cash in an amount equal to the Black Scholes value of the Warrant.

ATM Program

On February 11, 2013, we entered into the Stifel Agreement with Stifel, Nicolaus & Company, Incorporated, under which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell over a three-year period up to a maximum of $25,000,000 of shares of our common stock (Shares) through an 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 Stifel, we may designate the minimum price per share at which Shares may be sold and the maximum number of Shares that Stifel 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. Stifel 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 Stifel and us. Either party may suspend the Offering under the Agreement by notice to the other party.

The ATM Agreement will terminate upon the earliest of: (1) the sale of all Shares of the Company's common stock subject to the Agreement, (2) February 11, 2016 or (3) the termination of the Agreement in accordance with its terms. Either party may terminate the Agreement at any time upon written notification to the other party in accordance with the Agreement, and upon such termination, the Offering will terminate.
The Company will pay Stifel a commission equal to 3.0% of the gross sales price of the Shares for amounts of Shares sold pursuant to the Agreement. With the exception of expenses related to the Shares, Stifel will be responsible for all of its own costs and expenses incurred in connection with the Offering.

Lease Amendment

On January 3, 2013, the Company entered into a Second Amendment to the lease agreement (Amendment) with respect to its headquarters located Warrington, PA. The Amendment provides for a five-year extension of the term of the lease to February 2018; a reduction to the base rent effective as of October 1, 2012; a reduction in the security deposit, over a two year period beginning in 2013, from $400,000 to $225,000; the elimination of the Company's obligation to remove certain improvements and restore the premises; and the Company's option to extend the lease was adjusted to an additional period of five years through February 2023. The total aggregate base rental payments under the lease prior to the extension were approximately $7.2 million and the total aggregate base rental payments under the Amendment are approximately $4.9 million.

The Company has recognized, in 2012, the reduction in base rent and the elimination of its obligation to restore the premises.

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. 333-156237, and Form S-3 No. 333-174786) of Discovery Laboratories, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-180497 and Form S-8 No. 333-184277) pertaining to the Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan

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

(5) 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.

(6) 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.

(7) 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.

(8) 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, Form S-8 No. 333-173259 and Form S-8 No.333-180497) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our reports dated March 15, 2013, with respect to the consolidated financial statements of Discovery Laboratories, Inc. and subsidiary and the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc., included in this Annual Report (Form 10-K) of Discovery Laboratories, Inc. and subsidiary for the year ended December 31, 2012.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 15, 2013

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. I am 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. I have disclosed, based on my 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 15, 2013

/s/ John G. Cooper
John G. Cooper
President and Chief Executive Officer 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, 2012 (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 15, 2013

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

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